WaveLight® EX500

Patient Information Booklet

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

Please read this entire booklet. If you have any questions about it, discuss them with your doctor before you agree to the 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 the 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,
- Topography-Guided LASIK surgery for the **Topography-Guided** reduction or elimination of lower order corneal aberration up to - 8.00 diopters of sphere and up to - 3.00 diopters of astigmatism at the spectacle plane, with a maximum manifest refraction spherical equivalent of - 9.00 diopters,
- 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.

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1. GLOSSARY

Aberrometer	Wavefront Analyzer
Ablation, Ablate	Removal of tissue with an excimer laser.
Ametropic Eye	An eye abnormality, such as nearsightedness, farsightedness, or astigmatism, resulting from faulty refractive ability of the eye.
Analgesic Medication	Pain relieving medication.
Anesthetic Eye Drops	Medication used to numb the eye.
Antibiotic Eye Drops	Medication used to prevent or treat infections of the eye.
Anti-inflammatory Eye Drops	Medication used to prevent or treat inflammation of the eye.
Astigmatism	A type of refractive error occurring when the cornea or lens is flatter or steeper in one direction than it is in the other direction (much like the shape of a football), resulting in images that are focused at two different distances from the retina. 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. An example is multiple sclerosis.
Bandage Contact Lens	Soft contact lens temporarily used to cover the cornea after surgery.
Best Corrected Visual Acuity	The best vision that can be obtained with glasses.
BSCVA	Abbreviation of Best spectacle corrected visual acuity. Best visual acuity with glasses.
Cataract	Clouding of the lens inside the eye 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.
Cornea	The clear front surface of the eye, which bends rays of light to focus an image of objects on the retina.
Corneal Epithelium / Tissue	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.
Custom or Customized Surgery	Refractive surgery that is based on more information than just the amount of nearsightedness, farsightedness and astigmatism.
Cylinder	Value that describes the amount of astigmatism.
Diffuse Lamellar Keratitis	Inflammation under the flap.
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. Astigmatism can be measured in either positive or negative diopters.
Epithelial Ingrowth	A condition in which cells from the surface of the cornea (the corneal epithelium) start growing underneath the corneal flap that's produced in the LASIK procedure.
Excimer Laser	A type of laser emitting UV light that is used in PRK or LASIK to remove corneal tissue precisely and without damage to surrounding tissue.
Eyetracker	Device that detects and tracks the position of the eye or pupil. Such a tracker may enable laser systems to follow movements of the eye with the laser beam.
Farsightedness (Hyperopia)	A type of refractive error in which the cornea is too flat and/or the eye is too short, resulting in images that are focused behind the retina. Near objects seem blurry, distant objects may be seen more clearly than near objects, although objects in the distance may also be blurry.

FDA	Food and Drug Administration. This is the governmental agency that approves medical technology for use in the U.S.A.
Femtosecond Laser	Infrared laser that can divide corneal tissue without heat or impact to the surrounding cornea. This can be used to create a corneal flap for LASIK.
Flap	Thin slice of corneal tissue created on the surface of the cornea with a microkeratome or femtosecond laser as part of the LASIK procedure.
Floaters	Cloudy structures in the fluid in the center of the eyeball causing “floating” structures in the image.
Glaucoma	A group of diseases that cause increased pressure in the eye and can result in vision loss by damaging the optic nerve.
Halo	Circular flares of light around bright lights in dim lighting conditions.
Haze	Cloudiness of the cornea.
Herpes Simplex	A virus that can cause cold sores and eye infections.
Herpes Zoster	A virus that can cause an infection with blisters on one side of the body.
Hyperopia	Medical term for farsightedness.
Immunodeficiency Disease	A condition that alters the body’s ability to fight infection. An example is AIDS.
IOL	Artificial lens used to replace the natural lens of the eye.
Iris	The colored part of the eye, between the cornea and the lens that controls the amount of light reaching the retina by changing the size of the pupil.
Interface	Interface layer between the flap and the remaining corneal tissue.
Keratoconus	Condition of the cornea that results in progressive thinning and steepening of the cornea with a reduction in visual acuity.
Keratomileusis	Sculpting of the cornea by removing tissue.
Keratotomy	Cutting the cornea.

Lamellar Keratitis	Inflammation under the flap.
Laser In-situ Keratomileusis (LASIK)	Refractive surgery that changes corneal curvature by removing corneal tissue beneath a flap.
Laser Microkeratome	Precision laser instrument used to create a flap during LASIK surgery. Also referred to as femtosecond laser.
LASIK	Acronym for laser in-situ keratomileusis.
Lens	A clear structure behind the iris that helps focus rays of light, or an image, on the retina.
Mechanical Microkeratome	A precision instrument that is used to create the flap during LASIK surgery.
Micron	1/1000 of a millimeter or 4/10000 inch. The symbol is ”µm”.
Mixed Astigmatism	A type of astigmatism in which the cornea is too flat in one direction and too steep in the other direction, resulting in blurred vision, double images, or ghost images from images that are focused both in front of the retina and behind the retina.
Myopia	Medical term for nearsightedness.
Nearsightedness (Myopia)	A type of refractive error in which the cornea is too steep and/or the eye is too long, resulting in images that are focused in front of the retina. Distant objects are blurry but near objects are clear. The amount of nearsightedness is measured in diopters.
Optic Nerve	A bundle of more than 1 million nerve fibers in the back of the eye that carry visual messages from the retina to the brain.
Optical	Of or pertaining to sight; applying optics or the principles of optics to assist sight or correct vision. Optics is the branch of science that deals with light and vision.
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 (PRK)	Refractive surgery that changes corneal curvature by removing corneal tissue after the top layer of cells (corneal epithelium) is removed without making a flap.

Presbyopia	A condition where, with age, the lens loses its ability to change shape and the eye exhibits a progressively diminished ability to focus on near objects.
PRK	Acronym for photorefractive keratectomy.
Placido Imaging	Placido Topography is the classical form of mapping the surface of the cornea.
Ptosis	Drooping of the upper eye lid.
Pupil	The opening in the center of the iris. The iris changes the size of the pupil and controls how much light enters the eye.
Radial Keratotomy (RK)	Refractive surgery that changes corneal curvature by using a knife to make pie-shaped cuts in the cornea.
Refractive Error	A condition of the eye that occurs when light does not focus perfectly on the retina and distant images become blurry.
Refractive Surgery	Eye surgery that aims to change the shape of the cornea permanently to correct refractive errors. This change in eye shape restores the focusing power of the eye by allowing the light rays to focus precisely on the retina for improved vision.
Retina	The light-sensitive and color-sensitive membrane inside the eye that transforms light images into nerve signals.
RK	Acronym for radial keratotomy.
Standard LASIK	Wavefront Optimized LASIK refractive surgery that uses only the amount of nearsightedness, farsightedness, and/or astigmatism (refractive error) to calculate the LASIK treatment plan.
Steroids	Medications 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	The part of the microkeratome that attaches it to the eye and holds the eye in position as the corneal flap is made.
Topography	A method of computer-assisted examination of the cornea. It creates a detailed map of the cornea and any variations in the smoothness of the cornea.
Topography-Guided LASIK	LASIK treatment based on topographic acquired data.

Topographic system	Device designed to analyze optical errors by means of topographic data.
Treatment Zone	Area on the cornea where tissue is removed during laser treatment.
Traditional LASIK	Wavefront Optimized LASIK refractive surgery that uses only the amount of nearsightedness, farsightedness, and/or astigmatism (refractive error) to calculate the LASIK treatment plan.
Vitreous, Vitreous body	Gel-like fluid that fills the inside of the eye.
Wavefront	Image of light waves. Can be used to determine errors of an eye.
Wavefront-Guided LASIK	LASIK treatment based on wavefront acquired data.
Wavefront Analyzer	Device designed to analyze optical errors by means of wavefront data.
Wavefront Optimized LASIK	The trade name for LASIK that is performed with the WaveLight® EX500 excimer laser system. This procedure uses the amount of nearsightedness, farsightedness and/or astigmatism and some corneal shape information to calculate the LASIK treatment plan.
WaveLight® Analyzer II	Trade name for a modern wavefront analyzing device, manufactured by WaveLight GmbH in Germany.
WaveLight® EX500 Laser System	Trade name for modern high speed excimer laser system with eyetracker for treatment of refractive errors, manufactured by WaveLight GmbH in Germany.
ALLEGRO Topolyzer / ALLEGRO Topolyzer VARIO	Device for analyzing topographic errors in human eyes.

Table 1: Glossary

2. INTRODUCTION

This booklet has important information about **LASIK, Wavefront-Guided LASIK** and **Topography-Guided LASIK** surgery with the **WaveLight® EX500 laser system**.

Please read this entire booklet before you decide to have this surgery. Your doctor can help you decide if a LASIK treatment is suitable for you. Make sure your doctor answers all your questions to your satisfaction before you agree to have a LASIK treatment. 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.

Discuss the content of this booklet and any questions you may have with your doctor. Your doctor can help you decide if a **LASIK, Wavefront-Guided LASIK** or a **Topography-Guided LASIK** treatment is right for you. Contraindications, warnings and precautions of the procedure are listed in this booklet. Check with your doctor possible contraindications, precautions and warnings that may apply to you. Make sure your doctor answers all your questions to your satisfaction before you agree to have LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK treatment.

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.

3. COMMON VISION PROBLEMS

The human eye (see figure 1 below) is very much like a camera (see figure 2 below). 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**.

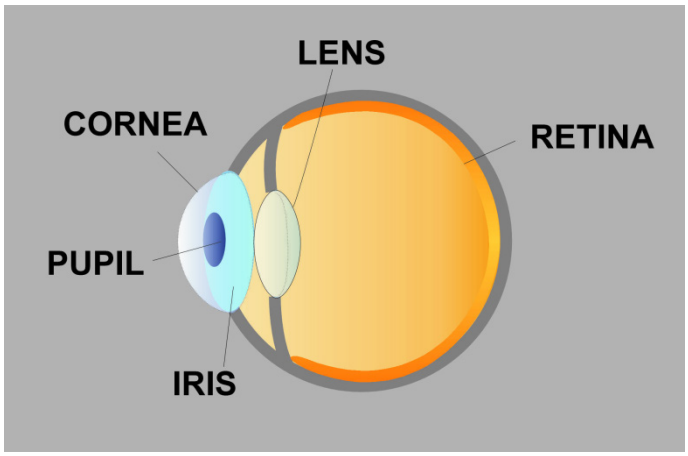

Figure 1: The Human Eye

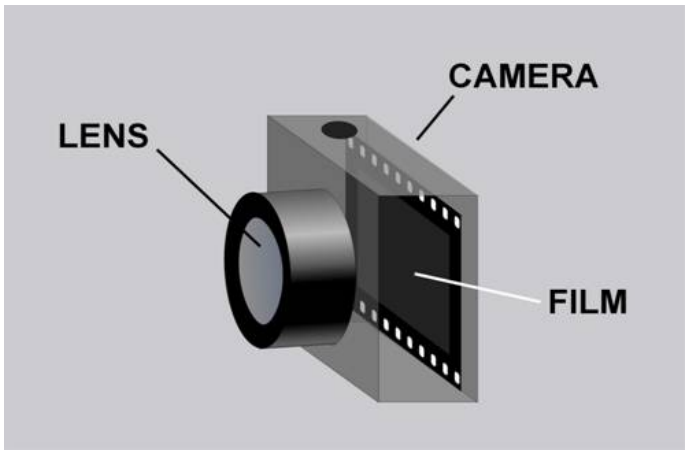

Figure 2: Camera

However, in some people this focusing of light does not occur perfectly. People encounter three types of refractive 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 (**Myopia**) 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.

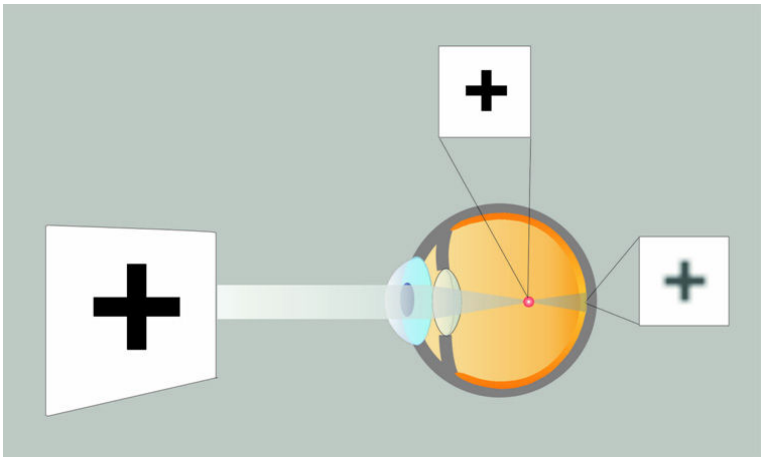

Figure 3: Nearsighted Eye Looking At A Black Cross

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 (**Hyperopia**) 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 as shown in figure 4 below. 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 lose this ability.

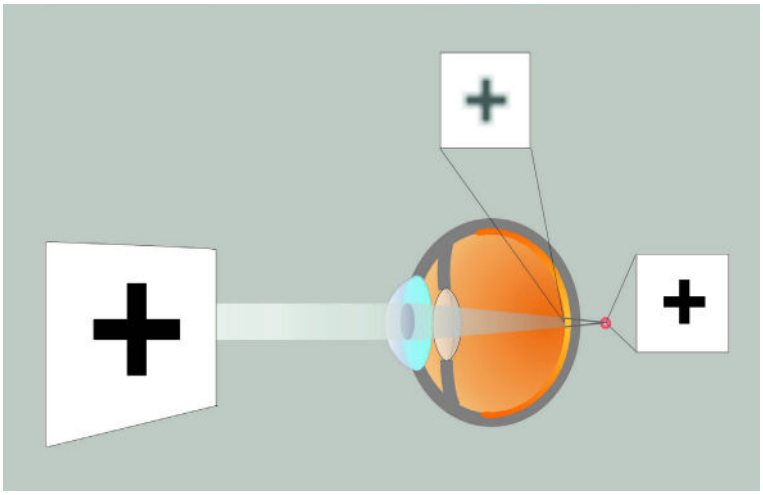

Figure 4: Farsighted Eye Looking At A Black Cross

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 as shown in the figures below. Light from a distant object is focused twice and not perfectly in each focal point. The image on the **retina** is blurry and distorted.

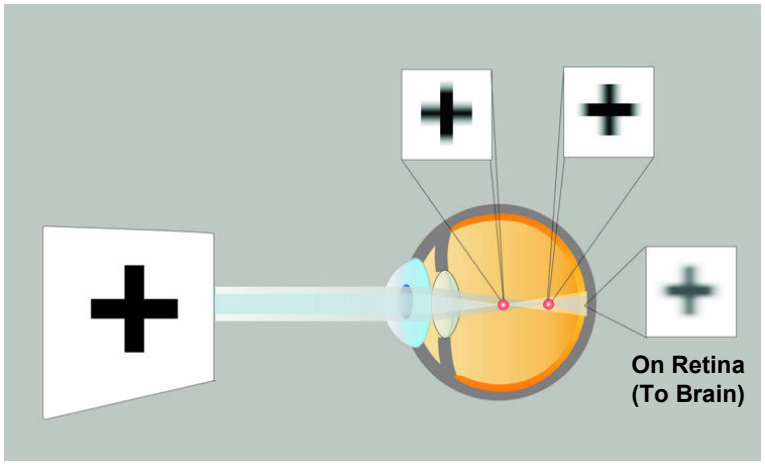

Figure 5: Nearsighted Eye With Astigmatism Looking At A Black Cross

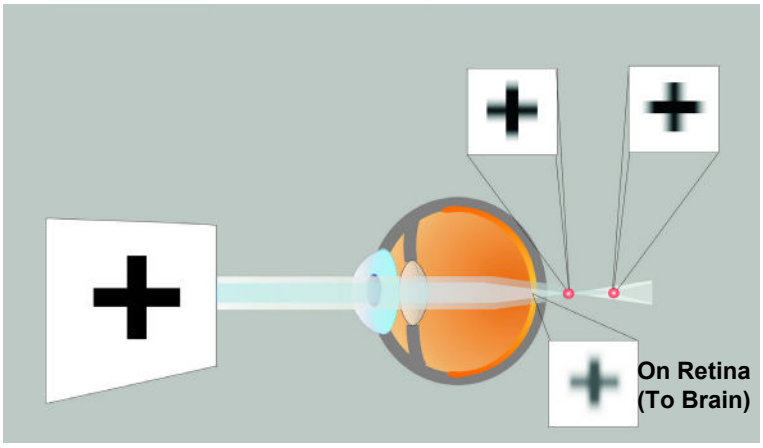

Figure 6: Farsighted Eye With Astigmatism Looking At A Black Cross

Presbyopia is a common type of vision problem that occurs as you age. As people age, the lens becomes stiff, so its focusing power will no longer change. When this occurs, the lens is no longer able to focus light rays on the retina and the light rays become focused behind the retina (similar to farsightedness in figure 6 above). Near objects are blurred, even for eyes with perfect distance vision, and reading glasses may be required to see objects that are close.

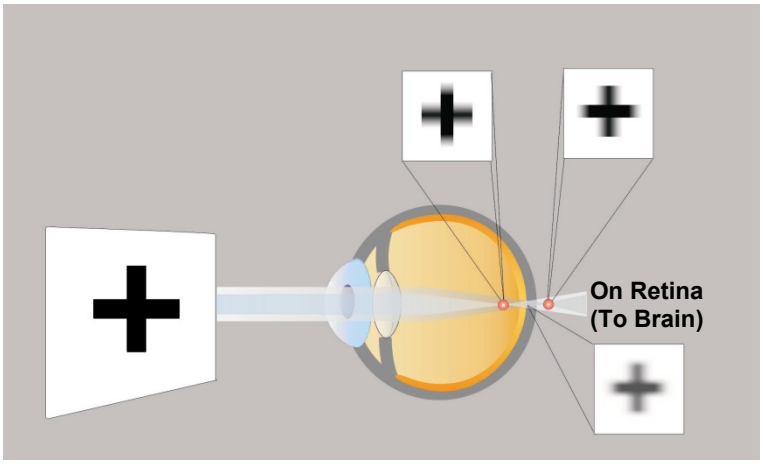

Figure 7: Eye With Mixed Astigmatism Looking At A Black Cross

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

4. WHAT IS THE WAVELIGHT EX500 LASER SYSTEM?

The WaveLight® EX500 laser system (see figure 8 on page 17) consists of the laser console, which includes the laser and all control systems necessary for the surgeon to perform LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK** or **Topography-Guided LASIK**, you will lie down on a bed. This bed is then moved under the laser and the LASIK, Wavefront-Guided LASIK or Topography-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.
- **Topography-Guided** treatments of patients who have up to - 8.0 diopters of nearsightedness with or without astigmatism of up to - 3.0 diopters, with a maximum manifest refraction spherical equivalent of - 9.00 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.

Figure 8: Example WaveLight® EX500 Device

5. WHAT IS WAVEFRONT-GUIDED LASIK?

Glasses and contact lenses correct the main refractive errors nearsightedness, farsightedness and astigmatism. They help your eye to focus the incoming light properly 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 analyze such errors in addition to nearsightedness, farsightedness and astigmatism.

The WaveLight® EX500 uses the acquired information for custom surgery. The WaveLight® EX500 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 data.

Wavefront Analysis:

Wavefront analysis of an eye is a different way to analyze 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 detecting devices are called **wavefront analyzers** or **aberrometers**. Such devices are able to provide highly detailed information for a custom Wavefront-Guided LASIK treatment.

Wavefront data 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 typical eyes nearsightedness, farsightedness and astigmatism are usually much more than the complex individual errors.

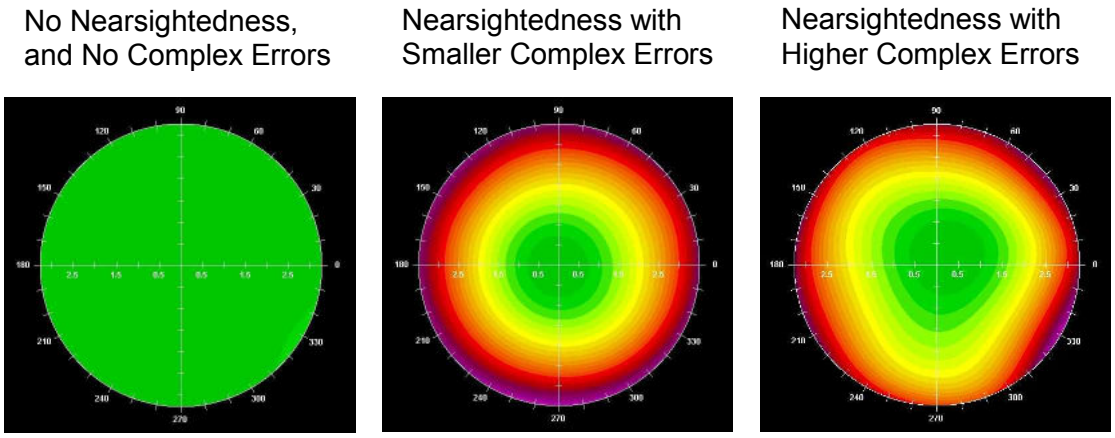

Figure 9: Examples For Wavefront Error Maps Without Nearsightedness And No Complex Errors

An ideal eye has no wavefront error, the wavefront map would be flat (see figure 9 “Examples For Wavefront Error Maps Without Nearsightedness And No Complex Errors” on page 19).

The higher the errors, the higher are the “elevations” of the wavefront map. Different colors represent different elevations.

6. WHAT IS THE WAVELIGHT ANALYZER?

The WaveLight® Analyzer II is a wavefront device for analyzing 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 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 WaveLight® Analyzer II 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 analyzed errors.

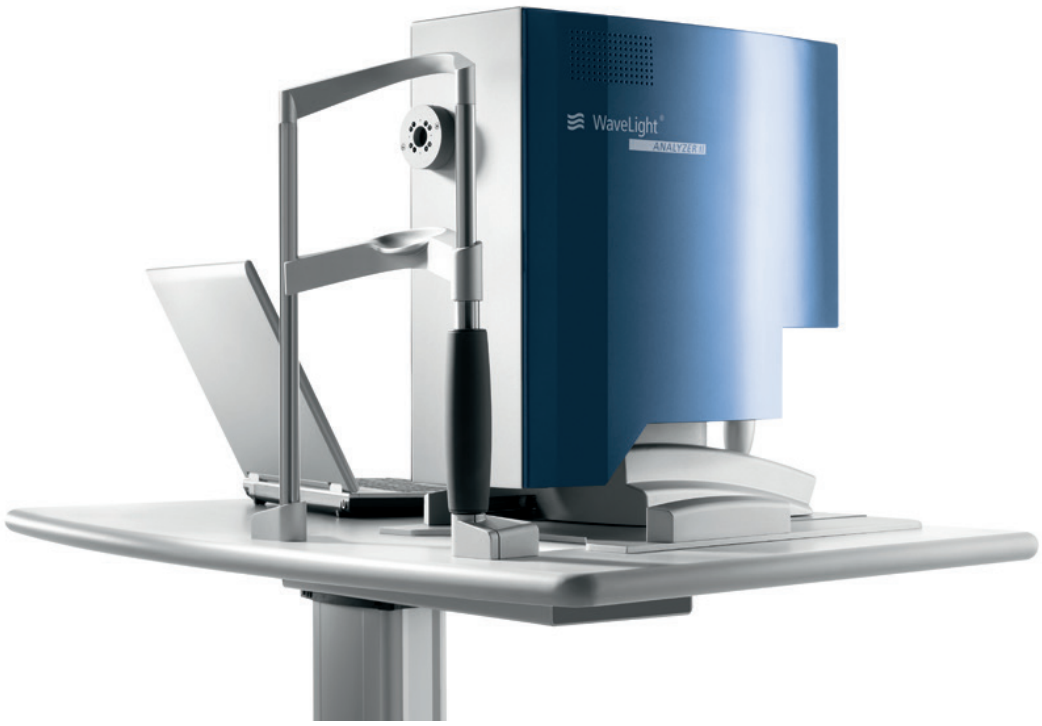

Figure 10: Example WaveLight® Analyzer II Device

7. WHAT IS TOPOGRAPHY-GUIDED LASIK?

Glasses and contact lenses correct the main refractive errors nearsightedness, farsightedness and astigmatism. They help your eye to focus the incoming light properly on the retina.

Topography-Guided LASIK (also called TOPO-G LASIK) is a surgical procedure that corrects nearsightedness and astigmatism by reshaping the front surface of the eye, which enables light to focus properly on the retina.

With **Topographic technology** the optical surface of the eye can be analyzed. As this surface has a very high refractive power compared to the rest of the visual path in the eye, it is possible to reshape the cornea to get back a regular surface by **Topography-Guided LASIK**.

The WaveLight® EX500 uses the acquired information (topography map(s) of the cornea) for planning and performing custom surgery. The WaveLight® EX500 will remove tiny amounts of tissue from the cornea. It does not change any other parts of the eye.

Topography-Guided LASIK is a highly **customized surgery** compared to **standard** (Wavefront Optimized) **LASIK o**r t**raditional LASIK**, which do not use individual topography measurements to help plan the standard LASIK treatment.

Topography-Guided LASIK treatment is permanent because a small portion of your cornea was removed by the laser.

The change in your ability to see after you have Topography-Guided LASIK may or may not be permanent because LASIK does not prevent future changes in the focusing power of your eye that can sometimes occur, such as the development of presbyopia that occurs naturally due to aging. You may need to wear reading glasses after the surgery, even though you did not need to wear reading glasses before Topography-Guided LASIK.

Topographic Analysis:

Topographic analysis of an eye is a way to analyze the anterior optical surface of the eye. Topography may be understood as images of curvatures on the corneal surface of the eye.

Topography can be used to determine the errors of an eye.

Topographic detecting devices are called **corneal topographers**. The WaveLight® EX500 accepts data derived from Placido based (ALLEGRO Topolyzer / ALLEGRO Topolyzer VARIO) anterior topography. Such a device is able to provide highly detailed information for a custom Topography-Guided LASIK treatment.

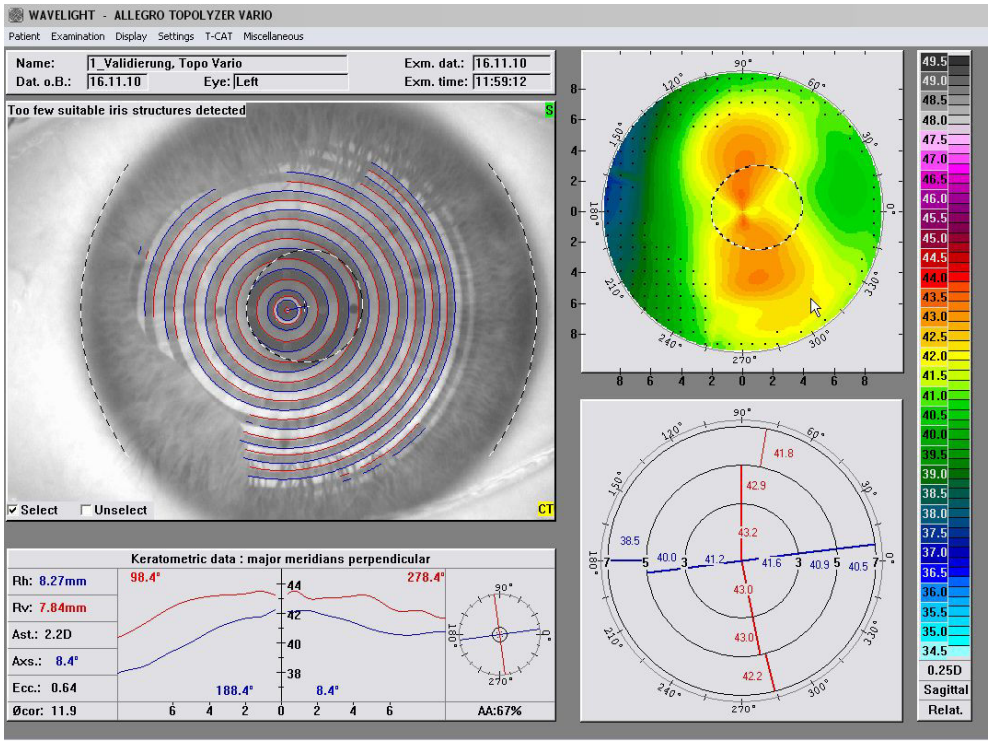

Figure 11: Example **Topolyzer** Image Of Analyzed Cornea

8. WHAT IS THE WAVELIGHT TOPOLYZER?

The **ALLEGRO Topolyzer** / **ALLEGRO Topolyzer VARIO** analyzes the very first optical surface (tear film on the cornea) of the human eye.

A corneal topography system (also known as **photokeratoscopy** or **videokeratography**) projects light onto the surface of the eye and then captures the reflected light to create a map of the cornea's curvature as well as any irregularities.

The map is used for evaluations related to refractive surgery, contact lens fitting and corneal disease management. It is especially useful for analyzing astigmatism. The color map uses blue and green to represent flatter areas of the cornea, while red and orange represent steeper areas. This information is unique to each eye and is used to help plan the custom Topography-Guided LASIK treatment.

Figure 12: Example ALLEGRO Topolyzer Device

Figure 13: Example ALLEGRO Topolyzer VARIO Device

9. 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 beside the **ablation** for nearsightedness or farsightedness, additional tissue is removed on the indicated area to correct the higher order errors.

For **Topography-Guided** correction beside the ablation for nearsightedness or farsightedness, additional tissue is removed on the indicated area to correct the higher order errors.

Surgical procedure:

- Analgesic **eye drops** are given before surgery.
- The **WaveLight® EX500 laser system** does not require a dilated **pupil** for treatment.
- As shown in figure 14, 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.

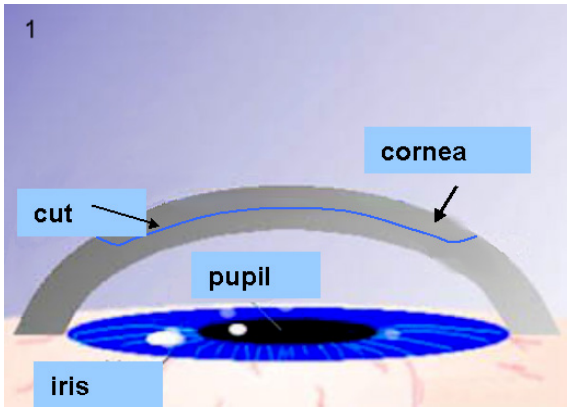

Figure 14: Cross Section Of A Cornea

- Your doctor will fold the **flap** back to expose the inner layers of your cornea (see figure 15).

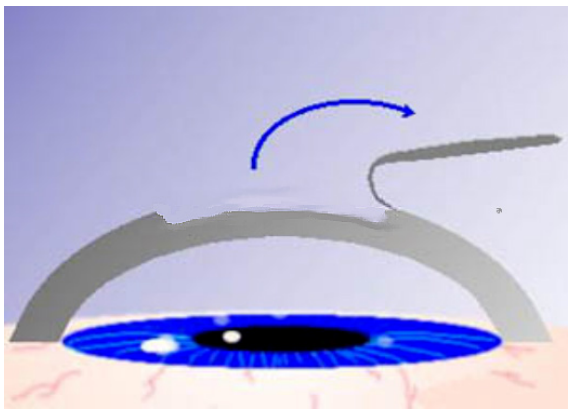

Figure 15: Flap Being Opened

- 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.

  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 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 **(treatment zone)** (see figure 16).

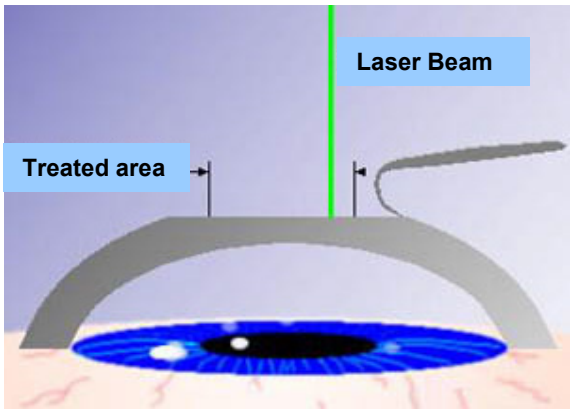

Figure 16: Cornea Being Shaped By Laser

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 the correct position (see figure 17). Your vision will improve immediately, but it will be blurry or cloudy.

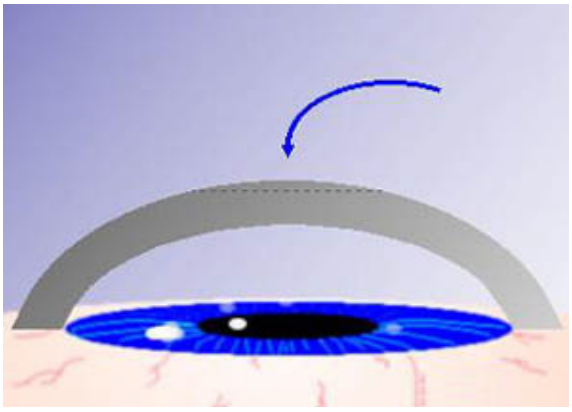

Figure 17: Flap Being Folded Back Into Position

The complete 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 for PRK the upper tissue layer (epithelium) is mechanically removed prior to laser surgery unlike creating a flap when LASIK is applied to you.

10. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications - When Can't You Have LASIK, Wavefront-Guided LASIK or Topography-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 show symptoms of **severe 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.
- you have **diabetes** and depend on insulin, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- your corneas are too thin. If your corneas will be too thin after your doctor has cut a flap and performed the LASIK treatment, you cannot have LASIK.
- you have degenerations of structure of the cornea. This condition can lead to serious corneal problems during and after LASIK.
- you have a weakened immune system. This condition can lead to serious corneal problems during and after LASIK.
- you have recurrent corneal erosion. This condition can lead to serious corneal problems during and after Topography-Guided LASIK surgery.
- you have an advanced glaucoma. It is unknown whether Topography-Guided LASIK is safe and effective for you.

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

Discuss with your doctor if you have any of the following conditions, you may have LASIK, Wavefront-Guided LASIK or Topography-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.

- 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.

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

- 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.

- Taking **medications** with ocular side effects, e.g. Isotretinoin (Accutane®[1]) for acne treatment, because this 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.*

Precautions:

It is unknown whether LASIK, Wavefront-Guided LASIK or Topography-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.

- You take **medicines** that might make it harder for wounds to heal, such as Sumatriptan succinate (Imitrex®[2]) used for **migraine** headaches, because it is unknown whether LASIK is safe and effective for this condition.

- You take medications with ocular side effects, e.g. Amiodarone hydrochloride (Cordarone®[3]) for normalizing heart rhythm, because this may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

- 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.

[2] *Imitrex® is a registered trademark of GlaxoSmithKline Inc.*
[3] *Cordarone® is a registered trademark of Wyeth Inc.*

- Physician Adjustments. Your doctor may modify the wavefront-or topographic-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 patients 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 analyze 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.

- **FDA**-approved treatment range. LASIK treatments provided outside the FDA-approved treatment range may be risky. Please ask your doctor, if your treatment range is approved.

- Medical Conditions. Your doctor should know your medical conditions.

- History of crossed eyes (strabismus). If your eyes are squint-eyed, it is unknown whether LASIK is safe and effective under this condition.

- If you have a decreased vision in one eye, it is unknown whether LASIK is safe and effective under this condition.

- 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.

11. 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 36
- "Clinical Study for Mixed Astigmatism" on page 39
- "Clinical Study for Wavefront-Guided LASIK" on page 41
- "Clinical Study for Topography-Guided LASIK" on page 44

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 14 "Frequently Asked Questions" on page 74.

Study Patient Demographics for Nearsightedness:

Most patients were Caucasian. No patients were over 69 years old. **Table 2** shows the age, race, gender and contact lens history of patients in the study.

Table 2
Demographics of 901 Eyes of 459 Patients

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[4]	8.3%
Range:	Caucasian	92.6%			PMMA[5]	1.0%
18 to 67 years	Hispanic	2.9%			Glasses[6]	34.8%
	Other	1.2%				

Table 2: Demographics Of 901 Eyes Of 459 Patients

* *For the Topography-Guided Study the ALLEGRETTO WAVE Eye-Q excimer laser system with 400 Hz was used.*
[4] *Rigid Gas Permeable*
[5] *Polymethylmethacrylate*
[6] *These patients wore glasses or no method of correction.*

Visual Acuity *without* Glasses After Surgery for Nearsightedness:

Visual Acuity analyzes the sharpness of vision using a letter chart. **Table 3** 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 3
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 3: 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 4 shows that at 3 months after surgery, 75.6% saw as well or better without glasses as they did with glasses before surgery.

Table 4
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[7]	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[8]	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 4: Comparison Of Vision After Surgery With Vision Before Surgery

[7] *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*

[8] *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 14 “Frequently Asked Questions” on page 74.

Study Patient Demographics for Farsightedness:

Most patients were Caucasian. No patients were over 69 years old. **Table 5** shows the age, race, gender and contact lens history of patients in the study.

Table 5
Demographics of 290 Eyes of 151 Patients

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[9]	3.4%
Range:	Caucasian	91.4%			PMMA[10]	0.3%
25 to 69 years	Hispanic	7.2%			Glasses[11]	65.5%
	Other	1.4%				

Table 5: Demographics Of 290 Eyes Of 151 Patients

[9] *Rigid Gas Permeable*
[10] *Polymethylmethacrylate*
[11] *These patients wore glasses or no method of correction.*

Visual Acuity *without* Glasses After Surgery for Farsightedness:

Visual Acuity analyzes the sharpness of vision using a letter chart. **Table 6** 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 6
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 6: 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 7 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 7
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[12]	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[13]	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 7: Comparison Of Vision After Surgery With Vision Before Surgery

[12] *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*

[13] *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 14 “Frequently Asked Questions” on page 74.

Study Patient Demographics for Mixed Astigmatism:

Most patients were Caucasian. No patients were over 70 years old. **Table 8** shows the age, race, gender and contact lens history of patients in the study.

Table 8
Demographics of 162 Eyes of 96 Patients

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[14]	2.5%
Range:	Caucasian	85.8%			PMMA[15]	0.0%
22 to 70 years	Hispanic	8.0%			Glasses[16]	74.1%
	Other	2.4%				

Table 8: Demographics Of 162 Eyes Of 96 Patients

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

Visual Acuity analyzes the sharpness of vision using a letter chart. **Table 9** 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 9
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 9: Visual Acuity Without Glasses After Surgery For Mixed Astigmatism

[14] *Rigid Gas Permeable*
[15] *Polymethylmethacrylate*
[16] *These patients wore glasses or no method of correction.*

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

Table 10 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 10
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[17]	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[18]	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 10: Comparison Of Vision After Surgery With Vision Before Surgery

[17] *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*

[18] *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 14 “Frequently Asked Questions” on page 74.

Study Patient Demographics for Wavefront-Guided LASIK:

Most patients were Caucasian. No patients were over 52 years old. **Table 11** shows the age, race, gender and contact lens history of patients in the study.

Table 11
Demographics of 188 Eyes of 94 Patients

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[19]	5.3%
Range:	Caucasian	93.6%			PMMA[20]	0.0%
21 to 52 years	Hispanic	1.1%			Glasses[21]	28.7%
	Other	0.0%				

Table 11: Demographics Of 188 Eyes Of 94 Patients

[19] *Rigid Gas Permeable*
[20] *Polymethylmethacrylate*
[21] *These patients wore glasses or no method of correction.*

Visual Acuity *without* Glasses After Surgery for Nearsightedness:

Visual Acuity analyzes the sharpness of vision using a letter chart. **Table 12** 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 12
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 12: 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 13 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 13
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[22]	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[23]	13.2%	17.2%	9.0%
Loss of 2 lines[2]	1.7%	0.6%[24]	3.6%
Loss of more than 2 lines[2]	0.6%	1.1%[3]	1.2%

Table 13: Comparison Of Vision After Surgery With Vision Before Surgery

[22] *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*

[23] *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*

[24] *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*

Clinical Study for Topography-Guided LASIK

A clinical study was done to evaluate the benefits and risks of the ALLEGRETTO WAVE Eye-Q Excimer laser system for Topography-Guided LASIK. The study included 249 eyes of 212 patients treated with Topography-Guided LASIK for nearsightedness with or without astigmatism. At the time the Topography-Guided LASIK treatment was performed, the youngest patients in the study were 18 years old; and the oldest patients were 65 years old.

The study results are shown below and in chapter 14 “Frequently Asked Questions” on page 74.

Visual Acuity *without* Glasses Before And After Topography-Guided LASIK For Nearsightedness

The doctors in the clinical study measured visual acuity without glasses (uncorrected visual acuity; UCVA) before the Topography-Guided LASIK treatment and at 1, 3, 6, 9, and 12 months after the procedure.

Three months after the Topography-Guided LASIK treatment for nearsightedness, vision without correction (UCVA) improved with:

- Nearly one-third (31.6%) of the eyes achieved a UCVA of 20/12.5 or better.
- Over two-thirds (68.9%) of the eyes had an UCVA of 20/16 or better.
- A total of 92.7% of the Topography-Guided LASIK eyes had an UCVA of 20/20 or better.
- 99.2% of the eyes in the study were seeing 20/40 or better at 3 months after the Topography-Guided LASIK surgery, which is good enough to drive without glasses or contact lenses in all states.

Vision without glasses tended to continue to improve slightly between 3 and 12 months after Topography-Guided LASIK.

Vision *without* Glasses After Surgery Compared To Vision *With* Glasses Before Surgery

How well eyes treated with Topography-Guided LASIK were able to see without glasses after surgery compared to their vision with glasses before having surgery is presented below. At 3 months after Topography-Guided LASIK:

- Nearly one-third (29.6%) of the eyes saw 1, 2, or more than 2 lines of vision better *without* correction after surgery compared to their vision *with* glasses before treatment.
- Nearly two-thirds (60.3%) of the eyes had vision *without* glasses after Topography-Guided LASIK that was equal to their vision *with* glasses before treatment.
- In total, 9 out of every 10 eyes (90%) treated with Topography-Guided LASIK saw as well, or better, *without* glasses after surgery as *with* glasses before surgery.

12. 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 49
- "Clinical Study for Mixed Astigmatism" on page 54
- "Clinical Study for Wavefront-Guided LASIK" on page 58
- "Clinical Study for Topography-Guided LASIK" on page 63

Clinical Study for Nearsightedness with or without Astigmatism

Visual Acuity *with* Glasses After Surgery for Nearsightedness:

Best vision with glasses was analyzed 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 achieved 20/20 or better and 20/40 or better visual acuity after LASIK surgery while wearing glasses.

Table 14
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 14: Visual Acuity With Glasses After Surgery

* *For the Topography-Guided Study the ALLEGRETTO WAVE Eye-Q excimer laser system with 400 Hz was used.*

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

Best vision with glasses was analyzed before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 15** shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses.

Table 15
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[25]	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[26]	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 15: Change in Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Nearsightedness

[25] *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*

[26] *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 swelling 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 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 swelling and need for lifting and/or reseating the flap/cap.

Subjective Results for Nearsightedness:

Patients were asked to complete a 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 patients reporting “none” or “mild” of these symptoms improved after treatment The results can be found in **Table 16**.

Table 16
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 16: 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 analyzed before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 17** 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 17
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 17: Visual Acuity With Glasses After Surgery

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

Table 18 shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses. Table 7 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 analyses.

Table 18
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[27]	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[28]	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 18: Change in Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Farsightedness

[27] *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*

[28] *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 swelling 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 swelling, foreign body sensation, pain, ghosting or double images, and need for lifting and/or reseating of the flap/cap.

Patients were asked to complete a questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively. **Table 19** details cases in which the patient's response to the survey question indicated a worsening in a symptom.

Table 19
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 19: Change In Patient Symptoms For Patients With Worsening Of Symptoms

Subjective Results for Farsightedness:

Patients were asked to complete a 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 patients reporting “none” or “mild” of these symptoms improved after treatment. The results can be found in **Table 20**.

Table 20
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 20: Patient Symptoms For Farsightedness

Table 21 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 21
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 21: Change In Patient Symptoms At 6 Months

Clinical Study for Mixed Astigmatism

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

Table 22 shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses. Table 10 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 analyses.

Table 22
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[29]	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[30]	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 22: Change In Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Mixed Astigmatism

[29] *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*

[30] *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 swelling 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 swelling, 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.

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

Subjective Results for Mixed Astigmatism:

Patients 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 patients reporting "none" or "mild" of these symptoms improved after treatment. The results can be found in **Table 23**.

Table 23
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 23: Patient Symptoms For Mixed Astigmatism

Table 24 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 24
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 24: 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 analyzed before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 25** 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 25
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 25: Visual Acuity With Glasses After Surgery For Nearsightedness

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

Table 26 shows the percent of patient's eyes that changed visual acuity after Wavefront-Guided LASIK surgery while wearing glasses. Table 13 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 analyses.

Table 26
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[31]	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[32]	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 26: Change In Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Nearsightedness

[31] *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*

[32] *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 swelling 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 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 swelling, any epithelium in the interface, ghosting or double images, and need for lifting and/or reseating of the flap/cap.

Subjective Results for Nearsightedness:

Patients 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 27**, also shows that patient reports of **glare** from **bright lights** and **night driving glare** improved after Wavefront-Guided LASIK. The percent of patients 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 27
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 27: Patient Symptoms

Table 28 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 28
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 28: Change In Patient Symptoms At 3 Months

Clinical Study for Topography-Guided LASIK

Visual Acuity *with* Glasses After Topography-Guided LASIK For Nearsightedness

The doctors in the clinical study measured visual acuity with glasses before the Topography-Guided LASIK treatment and at 1, 3, 6, 9, and 12 months after the procedure.

Three months after the Topography-Guided LASIK treatment:

- None of the eyes (0.0%) had vision with glasses that was worse than 20/40.
- None of the eyes (0%) that had 20/20 or better vision with glasses *before* the surgery, had 20/25 or worse vision with glasses *after* the Topography-Guided LASIK treatment.

How well the eyes treated with Topography-Guided LASIK were able to see *with* glasses after surgery compared to their vision *with* glasses before having surgery is provided below.

At 3 months after Topography-Guided LASIK:

- 11.0% of the eyes gained 2 or more lines of vision with glasses after Topography-Guided LASIK.
- Nearly one-third (29.2%) of the eyes saw 1 line of vision better with glasses compared to their vision with glasses before treatment.
- Almost two-thirds (59.1%) of the eyes saw the same with glasses before and after the Topography-Guided treatment.
- None of the eyes lost 2 or more lines of vision with glasses.

Three eyes had a 2 or more line loss of best vision with glasses at a visit other than the month 3 visit. Each of these occurrences of visual acuity loss was observed at only a single visit, and each eye had another event going on at the same time that affected visual acuity. At 1 month, one of the eyes had inflammation of the LASIK flap area that affected visual acuity; at 6 months, one eye had significant eye dryness that affected visual acuity; and, at 12 months, the patient was taking allergy medicine that affected visual acuity. Each of these occurrences of visual acuity loss was temporary and resolved with treatment for the concomitant event.

Adverse Events

Adverse events that occurred during the study for all eyes treated with Topography-Guided LASIK were as follows:

- Decrease of 2 or more lines of vision with glasses at 3 months or after the Topography-Guided LASIK treatment
  - 1 eye (0.4%) at 6 months
  - 1 eye (0.4%) at 12 months
  - 2 eyes at unscheduled visits

- Retinal detachment
  - 2 eyes (0.8%) at 6 months, both of which occurred in the same patient

Complications

Complications that occurred during the study for all eyes treated were as follows:[33]

- Corneal edema between 1 week and 1 month after the procedure
  - 1 eye (0.4%) at 1 week
- Foreign body sensation at 1 month or later
  - 7 eyes (2.8%) at 1 month
  - 5 eyes (2.0%) at 3 months
  - 3 eyes (1.2%) at 6 months
- Pain at 1 month or later
  - 2 eyes (0.8%) at 1 month
  - 2 eyes (0.8%) at 9 months
- Double images
  - 2 eyes (0.8%) at 1 month
  - 1 eye (0.4%) at 3 months
  - 1 eye (0.4%) at 6 months
  - 2 eyes (0.8%) at 9 months
  - 1 eye at an unscheduled visit
- Ghost images
  - 1 eye (0.4%) at 1 week
  - 2 eyes (0.8%) at 1 months
  - 2 eyes (0.8%) at 3 months
  - 2 eyes at unscheduled visits
- Misaligned LASIK flap
  - 2 eyes (0.8%) at 1 day
- Corneal inflammation
  - 5 eyes (2.0%) at 1 day
  - 2 eyes (0.8%) at 1 week
  - 1 eye (0.4%) at 1 month
  - 4 eyes at unscheduled visits

[33] *Includes eyes that had new reports, plus eyes with ongoing or recurring events reported at the visit.*

- Dry eyes requiring prescribed use of artificial tears eye drops or punctal plugs at 3 months or later
  - 10 eyes (4.0%) at 3 months
  - 8 eyes (3.3%) at 6 months
  - 6 eyes (2.5%) at 9 months
  - 3 eyes (1.3%) at 12 months
  - 6 eyes at unscheduled visits

Other Safety Observations

Other observations occurring with a 1% or greater incidence 3 and 12 months after Topography-Guided LASIK are as follows:

- Blurred vision
  - 5 eyes (2.0%) at 3 months
  - 6 eyes (2.6%) at 12 months
- Dry eye, requiring no treatment or eye drops as needed
  - 25 eyes (10.1%) at 3 months
  - 20 eyes (8.7%) at 12 months
- Fluctuation in vision
  - 0 eyes (0.0%) at 3 months
  - 3 eyes (1.3%) at 12 months
- Halo
  - 3 eyes (1.2%) at 3 months
  - 0 eyes (0.0%) at 12 months
- Irritation
  - 0 eyes (0.0%) at 3 months
  - 4 eyes (1.7%) at 12 months
- Night driving difficulty
  - 3 eyes (1.2%) at 3 months
  - 1 eyes (0.4%) at 12 months
- Photophobia
  - 5 eyes (2.0%) at 3 months
  - 0 eyes (0.0% at 12 months
- Mild corneal inflammation associated with eye dryness
  - 2 eyes (0.8%) at 3 months
  - 4 eyes (1.7%) at 12 months

- Starburst
  - 1 eye (0.4%) at 3 months
  - 3 eyes (1.3%) at 12 months

Contrast Sensitivity

Contrast sensitivity measures the ability to see conditions with decreased contrast with or without bright lights. Contrast vision is important for seeing in dusk, rain, fog, snow fall, and at night; when performing tasks involving similar colors, such as pouring coffee into a dark cup; or, seeing low contrast forms, such as sidewalk curbs or stairs. A person with poor contrast sensitivity may see well in normal lighting conditions but can become visually impaired in low contrast lighting conditions or in situations involving bright lights, such as the glare from headlights of oncoming cars when driving in low contrast conditions.

Best vision with glasses was measured before surgery and at 3 and 6 months after Topography-Guided LASIK using special eye charts that compared changes in contrast sensitivity. Contrast sensitivity was measured in daylight and dim lighting conditions, without glare and with a glare light source. At 3 and 6 months after Topography-Guided LASIK surgery, on average:

- The eyes had better contrast vision, in both daylight and dim light without and with glare conditions, *after* the Topography-Guided LASIK treatment than *before* the surgery.

Patient Self-Evaluation Before And After Topography-Guided LASIK

Study patients were given a questionnaire to fill out to rate whether they had any of the eleven commonly reported visual symptoms in their Topography-Guided LASIK treated eye before the Topography-Guided LASIK treatment and at each visit from 1 to 12 months after the surgery. The absence of a visual complaint was rated as "*none*", and the presence of a visual complaint was rated as "*mild*", "*moderate*", "*marked*" or "*severe*".

Study patients were also given the Refractive Status and Vision Profile (RSVP) questionnaire to evaluate the quality of their vision. The RSVP is a validated questionnaire that measures a patient's self-evaluation of his or her vision-related health status as it relates to refractive surgery. The scales are designed such that higher scores indicate greater dissatisfaction or a greater negative outcome, except expectations, where a lower score represents an improvement. The clinical outcomes measured by the RSVP are a range of visual, functional, and psychological impacts of **refractive error** that are likely to be important to patients. Published literature indicates that a difference of 6 points or more on the total RSVP score is a clinically significant change.[34]

The self-evaluation of visual symptoms and the RSVP questionnaires were completed by each study patient before the Topography-Guided LASIK treatment and at each study visit, beginning at 1 month after the treatment.

[34] *Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery: The refractive status and vision profile. J Cataract Refract Surg. 2001 May;27(5):665-73.*

Moderate To Severe Visual Symptoms

Changes in the degree of severity of the visual symptoms reported via the self-administered visual symptoms questionnaire at 3 months compared to baseline are summarized below. All categories of complaints showed a reduction in severity of complaints after the Topography-Guided LASIK procedure compared to baseline, except double vision and foreign body sensation.

Symptoms commonly associated with LASIK that improved in severity at 3 months after Topography-Guided LASIK treatment were as follows:

- 6.4% decrease in severity of reading difficulty
- 4.4% decrease in severity of complaints of difficulty driving at night
- 4.0% decrease in severity of glare complaints
- 3.6% decrease in severity of light sensitivity
- 2.4% decrease in severity of halos
- 2.0% decrease in severity of starbursts
- 1.6% decrease in severity of dryness
- 1.2% decrease in severity of fluctuation of vision
- 0.4% decrease in severity of pain

Symptoms that had a minimal increase in severity after Topography-Guided LASIK were:

- 0.8% increase in severity of double vision
- 0.4% increase in severity of foreign body sensation

Quality Of Vision

As shown below, the differences between the scores before Topography-Guided LASIK and at 3 months after the treatment demonstrate:

- There is an overall improvement in quality of vision.
- The average improvement in total RSVP score (-15.97 points) is nearly three times the minimum threshold (6 points) for clinically significant and meaningful improvement.
- The study of Topography-Guided LASIK treatment showed improvement in physical/social functioning, driving, visual symptoms, optical problems, and problems with corrective lenses compared to the patient's normal method of vision correction (glasses or contact lenses) before surgery.

Satisfaction With Topography-Guided LASIK

A question to evaluate the study patients self-reported satisfaction with the Topography-Guided LASIK procedure was added during the course of the study. Of the 124 patients who were polled:

- Nearly all of the study patients (98.4%) were satisfied with their outcomes and would have the Topography-Guided LASIK treatment again.

13. 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, Wavefront-Guided LASIK or Topography-Guided LASIK surgery can be performed on one eye at a time or on both eyes during the same surgical session if you and your doctor agree.

Before Surgery:

If you are interested in having LASIK, Wavefront-Guided LASIK or Topography-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. For evaluation and Topography-Guided LASIK treatment your eyes will get topographic examination with a topography system.

CAUTION

- Stop wearing your contact lenses several days before your LASIK, Wavefront-Guided LASIK or Topography-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 1 week 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.

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

- 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.

CAUTION

- Do not 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.
- 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 eye drops**) 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, green 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.

CAUTION

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

Figure 18: Examples Of Patients View Under The Laser (Crisp And Blurred)

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.

The LASIK, Wavefront-Guided LASIK or Topography-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 laser microkeratome is also called "**femtosecond laser**". 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 the plume evacuation, 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, Wavefront-Guided LASIK or Topography-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. The numbing effect will fade 45 to 60 minutes after the surgery. The eye may hurt for 1 to 3 days. Your doctor may prescribe pain medication to make you feel more comfortable during this time.

First Days after Surgery:

CAUTION

- Do NOT rub your eye during the first 3 to 5 days after surgery even if it feels itchy. Rubbing the eye could damage the flap or move it out of place 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.
- 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.
- 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.
- Contact your doctor immediately if you notice any pain, sudden change, or loss of vision in your eye. Eye pain or sudden loss of vision can be a sign of a serious problem.

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, Wavefront-Guided LASIK or Topography-Guided LASIK.

14. FREQUENTLY ASKED QUESTIONS

Is LASIK, Wavefront-Guided LASIK or Topography-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** and **myopic 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 patient 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.

In the clinical study of the ALLEGRETTO WAVE device for nearsightedness with **Topography-Guided LASIK**, there were various defects in patient corrections:

- The visual acuity with glasses was worse than 20/40 in none of the eyes (0.0%). 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 Topography-Guided LASIK.
- None of the eyes (0%) that had 20/20 or better vision with glasses *before* the surgery, had 20/25 or worse vision with glasses *after* the Topography-Guided LASIK treatment.
- Three eyes had a 2 or more line loss of best vision with glasses at a visit other than the month 3 visit. Each of these occurrences of visual acuity loss was observed at only a single visit, and each eye had another event going on at the same time that affected visual acuity.
- 0.4% (1 eye) lost 2 or more lines of vision with glasses after 6 months.

Will I need reading glasses after LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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 the normal aging process 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 to 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 (e.g. pacemaker, insulin pump).

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, Wavefront-Guided LASIK or Topography-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.
- Ingrowth of the **corneal epithelium** 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 Astigmatism):

- 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.

15. WHAT SHOULD YOU ASK YOUR DOCTOR?

You may want to ask your doctor the following questions to help you decide if LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-Guided LASIK?
- Should I have LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK in both eyes?
- How long will I have to wait till I get LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK on the second eye?
- What vision problems may I experience, if I have LASIK, Wavefront-Guided LASIK or Topography-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.

16. SUMMARY OF IMPORTANT INFORMATION

- LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK is a permanent operation to the cornea and cannot be reversed.

- LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-Guided LASIK surgery.

- You are not a good candidate for LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK surgery if you have a collagen vascular disease or autoimmune disease or have a condition that makes wound healing difficult.

- LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-Guided LASIK is not a laser version of RK, these surgeries are completely different from each other.

- Alternatives to LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK include, but are not limited to glasses, contact lenses, PRK and RK.

- Some professions prohibit refractive surgery including LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK.

- Before considering LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-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.

17. 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, Wavefront-Guided LASIK or Topography-Guided LASIK is a permanent procedure.	☐	☐
b) LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK is free of risks.	☐	☐
c) LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK is the same as RK.	☐	☐
d) It does not matter if I wear my contact lenses when my doctor told me not to wear them.	☐	☐
e) I may need reading glasses after LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK.	☐	☐
f) There is a risk that I may lose some vision after LASIK, Wavefront-Guided LASIK or Topography-Guided LASIK.	☐	☐
g) It's ok to have LASIK, Wavefront-Guided LASIK or Topography-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, Wavefront-Guided LASIK or Topography-Guided LASIK.	☐	☐
l) Wavefront-Guided LASIK or Topography-Guided LASIK is the same as Wavefront Optimized LASIK	☐	☐

You can find the answers in chapter 19 "Answers To Self-Test Questions" on page 85.

18. 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 South Freeway
Fort Worth, Texas 76134 U.S.A.
Telephone: 800-TO-ALCON
(800-862-5266)
Internet: ALCON.COM

19. ANSWERS TO SELF-TEST QUESTIONS

a) True (see page 74 and page 82)

b) False (see page 28, page 29, pages 45-48, page 77, page 78 and page 82)

c) False (see page 27 and page 82)

d) False (see page 69)

e) True (see page 76, page 76, page 77 and page 82)

f) True (see page 30, pages 45-48, page 76, page 77 and page 78)

g) False (see page 28 and page 82)

h) True (see page 29 and page 30)

i) True (see pages 33-35, page 74 and page 82)

j) False (see page 16, page 26, page 27 and pages 70-72)

k) False (see page 30 and page 82)

l) False (see page 18 and page 9)

20. INDEX

- End -