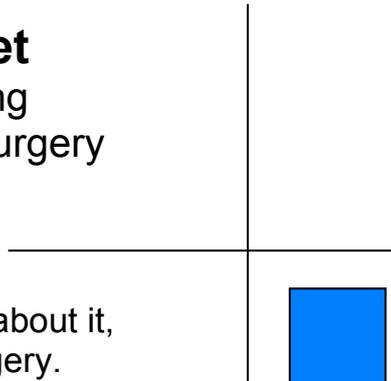


# ALLEGRETTO WAVE EYE-Q

## Patient Information Booklet

Information for patients considering  
Photorefractive Keratectomy (PRK) 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:

- **PRK** surgery for the elimination or reduction of **nearsightedness** of up to - 6.00 diopters (D), of **nearsightedness with astigmatism** of up to - 6.00 diopters (D) and up to - 3.00 diopters of **astigmatism**, and up to - 6.00 diopters (D) MRSE at spectacle plane,
- who are 18 years of age or older; and
- who have documented evidence that their refraction did not change by more than 0.5 diopters during the year before the preoperative examination.



### CAUTION

#### RESTRICTED DEVICE

U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner. U.S. Federal Law restricts this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

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**Alcon**

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## 1. GLOSSARY

<b>Ablation, Ablate</b>	Removal of tissue with an excimer laser.
<b>ALLEGRETTO WAVE® EYE-Q Laser System</b>	Trade name for modern, high speed excimer laser system with eyetracker for treatment of refractive errors, manufactured by WaveLight GmbH in Germany.
<b>Anesthetic Eye Drops</b>	Medication used to numb the eye.
<b>Antibiotic Eye Drops</b>	Medication used to prevent or treat infections of the eye.
<b>Anti-inflammatory Eye Drops</b>	Medication used to prevent or treat inflammation of the eye.
<b>Astigmatism</b>	A common vision condition that causes blurred vision and it occurs 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.
<b>Atopic Disease</b>	Predisposition to developing allergic hypersensitivity reactions. This has both a hereditary and environmental factor components.
<b>Autoimmune Disease</b>	Condition in which the body attacks itself that may lead to inflammation or swelling of parts of the body. An example is multiple sclerosis.
<b>Bandage Contact Lens</b>	Soft contact lens temporarily used to cover the cornea after surgery.
<b>Best Corrected Visual Acuity</b>	The best vision that can be obtained with glasses.
<b>BSCVA</b>	Abbreviation of Best spectacle corrected visual acuity. Best visual acuity with glasses.
<b>Cataract</b>	Clouding of the lens inside the eye that may cause loss of vision.
<b>Cataract Surgery</b>	A procedure where the lens inside your eye that has become cloudy is removed and replaced with an artificial lens (called an intraocular lens, or IOL) to restore clear vision.
<b>Chalazion</b>	A chronic bump on the eyelid.

<b>Collagen Vascular Disease</b>	Condition that changes the way the body creates or processes connective tissue, like collagen. The cornea is made up of collagen. Examples are lupus or rheumatoid arthritis.
<b>Conjunctivitis</b>	Inflammation of the tissue covering the white part of the eye.
<b>Conjunctival Hyperemia</b>	Redness of the white of the eye.
<b>Cornea</b>	The clear front surface of the eye, which bends rays of light to focus an image of objects on the retina.
<b>Cornea Edema</b>	Swelling of the cornea
<b>Corneal Epithelium / Tissue</b>	Surface cells, forming the top layer of the cornea.
<b>Corneal Erosion</b>	When the outer layer (epithelial cells) of the cornea fail to attach to the underlying layer of the cornea (stromal tissue.)
<b>Episcleritis</b>	Inflammation in the space in front of the white part of the eye.
<b>Excimer Laser</b>	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.
<b>Eyetracker</b>	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.
<b>Farsightedness</b>	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.
<b>FDA</b>	Food and Drug Administration. This is the governmental agency that approves medical technology for use in the U.S.A.
<b>Femtosecond Laser</b>	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.
<b>Flap</b>	Thin slice of corneal tissue created on the surface of the cornea with a femtosecond laser as part of the LASIK procedure.
<b>Glaucoma</b>	A group of diseases that cause increased pressure in the eye, and can result in vision loss by damaging the optic nerve.

<b>Halo</b>	Circular flares of light around bright lights in dim lighting conditions.
<b>Haze</b>	Cloudiness of the cornea.
<b>Herpes Simplex</b>	A virus that can cause cold sores and eye infections.
<b>Herpes Zoster</b>	A virus that can cause an infection with blisters on one side of the body.
<b>Hordeolum</b>	An infection of the glands at the base of the eyelashes
<b>IOL</b>	Artificial lens used to replace the natural lens of the eye.
<b>Iris</b>	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.
<b>Iritis</b>	An inflammation of the iris.
<b>Keratitis</b>	Inflammation of the cornea.
<b>Keratoconus</b>	An eye disease where the normally round, dome shaped cornea becomes thin and begins to bulge into a cone-like shape.
<b>Keratomileusis</b>	Sculpting of the cornea by removing tissue.
<b>Lens</b>	A clear structure behind the iris that helps focus rays of light, or an image, on the retina.
<b>Mixed Astigmatism</b>	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.
<b>Nearsightedness</b>	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.
<b>Optic Nerve</b>	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.
<b>Optical</b>	A term that means something to do with the ability to see. For example, glasses are an <i>optical aid</i> .
<b>Optical Power</b>	Ability of an object such as the eye to bend light rays as they pass through.

<b>Presbyopia</b>	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.
<b>Ptosis</b>	Drooping of the upper eye lid.
<b>Punctate keratitis</b>	Punctate keratitis is death of small groups of cells on the surface of the cornea (the clear layer in front of the iris and pupil). The eyes become red, watery, and sensitive to light, and vision may decrease somewhat. Most people recover fully. Symptoms can be relieved.
<b>Pupil</b>	The opening in the center of the iris. The iris changes the size of the pupil and controls how much light enters the eye.
<b>Radial Keratotomy (RK)</b>	Refractive surgery that changes corneal curvature by using a knife to make pie-shaped cuts in the cornea.
<b>Refractive Error</b>	A condition of the eye that occurs when light does not focus perfectly on the retina and distant images become blurry.
<b>Refractive Surgery</b>	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.
<b>Retina</b>	The light-sensitive and color-sensitive membrane inside the eye that transforms light images into nerve signals.
<b>Starbursts</b>	The appearance of rays of light coming out from lighted objects, such as car headlights.
<b>Steroids</b>	Medications used to reduce inflammation or the body's healing response after injury or disease.
<b>Treatment Zone</b>	Area on the cornea where tissue is removed during laser treatment.
<b>Visual acuity</b>	Sharpness of vision, assessed using eye charts to measure how well you see in the distance.
<b>Vitreous, Vitreous body</b>	Gel-like fluid that fills the inside of the eye.
<b>Vitreous Floaters</b>	Deposits in the vitreous of the eye, usually moving about that appear to be like spots or fine lines.
<b>Wavefront</b>	Image of light waves. Can be used to determine optical errors of an eye.

Table 1: Glossary

## 2. INTRODUCTION

This booklet contains important information that should help you decide whether to have **photorefractive keratectomy (PRK)** surgery to correct low to moderate **nearsightedness** with or without low **astigmatism**. With this procedure, an **excimer laser** is used to reshape the **cornea**, the clear structure at the front of the eye, by removing small amounts of **tissue** from the cornea. The excimer laser that will be used is the **ALLEGRETTO WAVE EYE-Q** excimer laser system.

Please read this entire booklet and ask your doctor any questions you may have. All terms printed in bold can be found in the glossary at the beginning of the booklet.

### 3. COMMON VISION PROBLEMS

The human eye (see figure 1 below), is very much like a camera. The camera lens focuses light to form clear images onto film. Similarly, the **cornea** and crystalline **lens** of the eye focus light onto the **retina**, the back surface of the eye.

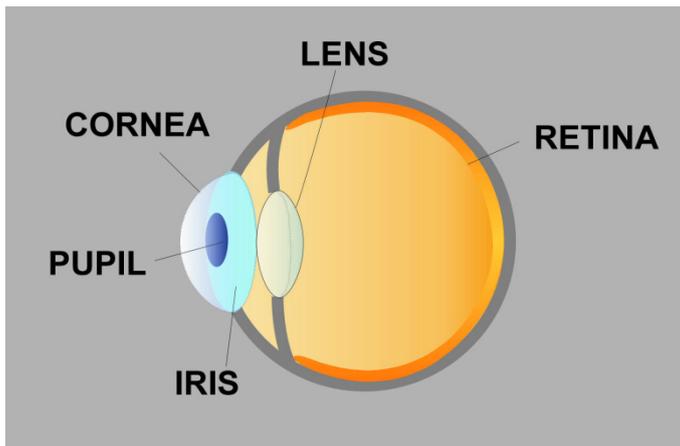


Figure 1: The Human Eye

In some people, the focusing of light doesn't occur perfectly. People encounter **refractive errors** such as nearsightedness and astigmatism.

**Nearsightedness** results in blurry distant vision. Light from a distant object focuses in front of the retina, rather than on the retina. As a result, images of distant objects appear blurry on retina.

Nearsightedness is not a disease but it is a variation of the human eye that tends to be genetic. In the US, half of the people between 20 and 59 years of age are nearsighted<sup>1</sup>. Reasons for the nearsighted condition can be that light rays focus at a point in front of the retina rather than directly on its surface, because your eye is longer than normal. Nearsightedness also can be caused by the cornea and/or the lens inside the eye being too curved for the length of the eyeball. Sometimes the reason for nearsightedness is the combination of the two. This condition starts developing usually during childhood and stabilizes in the late teens or early adulthood.

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<sup>1</sup> Vitale S, Ellwein L, Cotch MF, Ferris FL, Sperduto R. Prevalence of Refractive Error in the United States, 1999-2004. Arch Ophthalmol 2008;126(8):1111-1119.

Figure 2 shows that distant vision is blurry when light focuses incorrectly in nearsighted eyes.

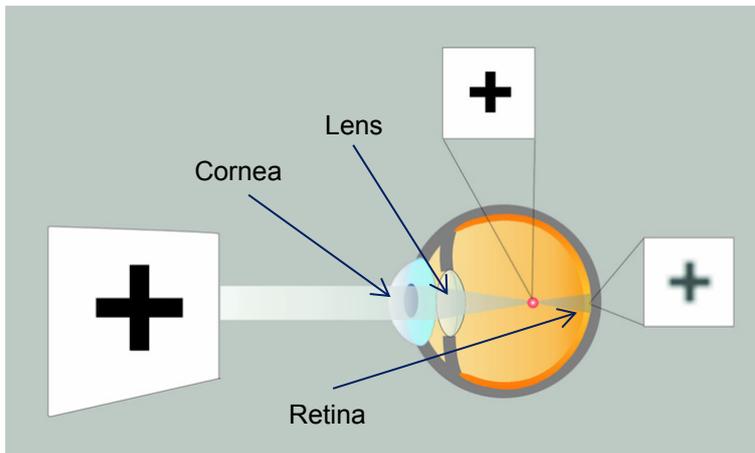


Figure 2: Nearsighted Eye Looking At A Black Cross

Astigmatism may occur alone or along with nearsightedness (myopic astigmatism). It causes an object to have edges that are blurry and others that are not. The reason for this condition is differing **optical powers** of the eye. This leads to different focal points in the eye as shown in figure 3 below. As a result, the image on the retina is blurry and distorted.

In the US, astigmatism of at least - 1.00 **diopter (D)** occur in 23% of people in the age group 20 through 39 years and 27% of people in the age group 40 through 59 years<sup>2</sup>.

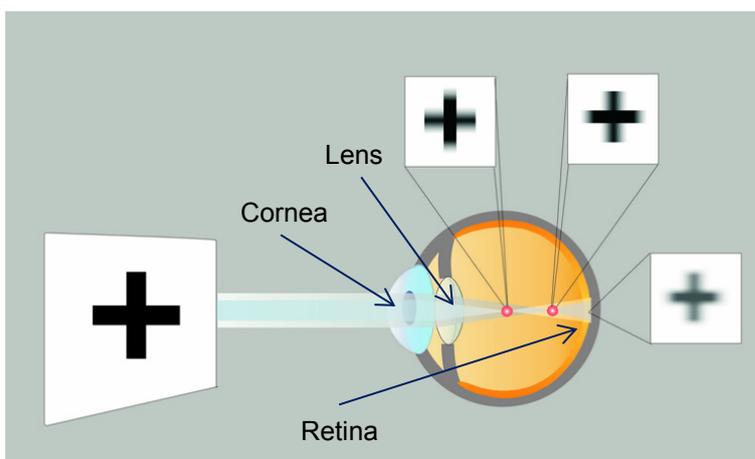


Figure 3: Nearsighted Eye With Astigmatism Looking At A Black Cross, And Sending Images to The Brain.

<sup>2</sup> Vitale S, Ellwein L, Cotch MF, Ferris FL, Sperduto R. Prevalence of Refractive Error in the United States, 1999-2004. Arch Ophthalmol 2008;126(8):1111-1119.

**Presbyopia** is a common type of vision problem that first occurs around the age of 40. It occurs because the crystalline lens becomes stiff and is no longer able to focus light rays on the retina. Instead, the light rays become focused behind the retina. Near objects are blurred, even for eyes with perfect distance vision, and reading glasses may be required for clear near vision.

#### 4. WHAT IS THE ALLEGRETTO WAVE EYE-Q LASER SYSTEM?

The ALLEGRETTO WAVE EYE-Q laser system, shown in Figure 4 below, consists of the laser and all control systems necessary for the surgeon to perform PRK, such as computerized control panels, monitors for the computer systems, and a microscope to view the eye during the surgery. The system is equipped with an **eyetracker** that follows the movement of the eye during surgery. The eyetracker helps assure that the laser pulses are placed in the correct position on the eye, even if the eye moves during treatment. The eyetracker will stop the treatment if the eye moves too much.

The ALLEGRETTO WAVE EYE-Q laser system uses a very small laser beam to shape the cornea precisely to correct irregularities in corneal shape, as well as nearsightedness, farsightedness, and astigmatism.

The ALLEGRETTO WAVE EYE-Q laser system also has a movable bed. When you are prepared for PRK, you will lie down on the bed. This bed is then moved under the laser to properly position your eye for the PRK treatment.



Figure 4: ALLEGRETTO WAVE EYE-Q

### 5. WHAT IS PRK?

PRK is a surgical procedure that is an option for the correction of low to moderate nearsightedness with or without low astigmatism. With this procedure, as a first step the surface of the cornea (i.e. corneal epithelium) will be removed to prepare the eye for the surgery using the surgeons preferred method. This step will allow the ALLEGRETTO WAVE EYE-Q laser system to directly treat the underlying tissue by reshaping the cornea through permanent removal of a small portion of **corneal tissue** as a second step. The amount of corneal tissue that is removed by the laser depends on the amount of nearsightedness and/or astigmatism that is present in the eye to be treated. The greater the error of the eye, the greater the amount of tissue that is removed. The outermost surface which is removed as the first step will heal and grow back over the corneal surface.

### 6. HOW DOES PRK CORRECT NEARSIGHTEDNESS AND FARSIGHTEDNESS?

PRK corrects the error of the eye by enabling the light to focus properly on the retina. In the case of nearsightedness, the focal point of the eye falls in front of the retina. PRK will flatten the cornea so that light is not bent so much and the focal point moves back to the retina, creating a clear image of distant objects. With astigmatism, two focal points exist. To treat astigmatism, the shape of the cornea is changed in a way that both focal points are focused on the retina.

PRK does not prevent future changes in the focusing power of your eye that occurs with presbyopia, a condition that occurs naturally with aging. You may need to wear reading glasses after PRK to correct blurry near vision.

## 7. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

### Contraindications - When Can You Not Have PRK?

If you have any of the following situations or conditions, you should NOT have PRK because the risk is greater than the benefit:

- **Unstable** eyes that have changed by more than 0.5 diopter in nearsightedness or astigmatism in the last 12 months, and your nearsightedness or astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after PRK.
- If you have an active connective tissue disease or autoimmune disease (such as rheumatoid arthritis and lupus) that can cause corneal melting, PRK will increase your risk for severe damage to your cornea and for vision loss. Let your PRK doctor know about any medical conditions you have.
- If you have an active infection or inflammation of the eye (such as inflammation of the cornea or iritis), PRK will likely make your condition worse, resulting in permanent eye damage. Let your PRK doctor know if you are currently being treated, or if you have ever been treated, for such a condition.
- If you have had a herpes (herpes simplex or herpes zoster) eye infection within the past year or you have had corneal damage from prior herpes infections, you are at higher risk for further corneal damage after PRK. Let your PRK doctor know if you have ever had a herpes eye infection.
- You have **thinning of the cornea**. If you have a cone-shaped cornea (*keratoconus*), thinning of the bottom part of the cornea along the edges, or any other condition that may cause a thinning or bulging of your cornea, PRK can worsen these conditions and cause a permanent reduction in your vision. This may result in the need for additional surgery (such as a corneal transplant) after PRK. Your PRK doctor should map the shape of your cornea before PRK surgery to make sure you do not have any thinning.
- Your **cornea is not thick enough**. Your cornea (the clear front part of the eye) must be thick enough to undergo PRK without increasing the risk of causing an abnormal bulging forward of the cornea, which could decrease your vision. Ask your PRK doctor whether the thickness of your cornea puts you at greater risk for this complication.
- You show symptoms of **severe dry eye**. If you have severely dry eyes, PRK may increase dryness. This may or may not go away. This dryness may delay healing of the corneal surface of the eye after surgery.
- You have **uncontrolled diabetes**. If your blood sugar is uncontrolled, your eyeglass prescription can fluctuate and your doctor will not be able to accurately determine what degree of PRK treatment is appropriate. Uncontrolled diabetes can also negatively affect wound healing after PRK. Let your PRK doctor know if you have diabetes.
- You have recurrent **corneal erosion**. This condition can lead to serious corneal problems during and after PRK procedure.
- You have an advanced **glaucoma**. It is unknown whether PRK is safe and effective for you.

### Warnings – What Other Information Do You Need To Know About?

Please inform your doctor if you have ANY of the following conditions that may present a greater risk for poor outcomes or injury related to the PRK procedure. You should discuss your level of risk with your doctor. You and your doctor should determine whether the benefits to you outweigh the risks based on the nature and severity of your condition.

- Systemic diseases likely to affect wound **healing**. If you have a systemic disease such as a connective tissue disease, severe **atopic** disease (e.g., severe eczema, skin inflammation/hypersensitivity, etc.) or are immunocompromised (e.g., AIDS/HIV states, uncontrolled diabetes, patients under anti-graft rejection medications, etc.), PRK may be risky for you because it may affect the ability of your eyes to heal.
- **Controlled autoimmune or connective tissue disease**. Connective tissue diseases or autoimmune diseases (such as rheumatoid arthritis and lupus), even if well controlled and stable, may result in delayed healing and less predictable outcomes after PRK. Depending upon your disease, its severity, and the medication(s) you are taking, there may be additional risks. These may include severe dry eye, infection, inflammation, poor healing, and corneal melting. You should discuss these additional risks with your PRK doctor, after he or she has consulted with the other doctors who are treating you.
- 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, PRK is more risky for you.
- **Uncontrolled or untreated eye allergies**: “If you have uncontrolled or untreated eye allergies, you may be at a higher risk of having corneal clouding (haze) and treatment failure after the PRK procedure. Let your PRK doctor know if you are currently being treated, or if you have ever failed to respond to treatment for such a condition.
- **You have controlled glaucoma**. If you have glaucoma, PRK may make monitoring your eye pressure more difficult. Steroid drops used after the PRK surgery may temporarily raise your eye pressure and potentially cause glaucoma to worsen. Let your PRK doctor know if you have been diagnosed with glaucoma or have a strong family (if undiagnosed).
- **Taking isotretinoin (Accutane®)**. This medication, usually used for acne treatment, increases your risk for dry eye and abnormal wound healing after PRK. If you have taken or plan to take this medication, talk to your PRK doctor, including the doctor prescribing this medication about your risk and the timing of discontinuing temporarily and restarting the medications after the procedure.
- **Significant dry eyes** that have not responded to treatment. If your eyes have not responded to treatment for significant dry eyes, PRK is more risky for you.
- **Controlled diabetes**. Even if your diabetes is well controlled, you may have poor healing of your eye following PRK.



- **Weakened immune system.** If you have a weakened immune system due to medications (such as steroids) or a medical condition (such as AIDS), you may be more prone to infection after surgery. Such conditions and medications may put you at greater risk for other complications as well, such as dry eye or abnormal wound healing. Let your PRK doctor know about any medical conditions you have and all medications you are taking.
- **History of Eye Injury and Eye Pain.** If you have suffered from recurrent corneal surface damage or have any history of shallow eye injury (e.g., scratched the eye with your nail, etc.) and in addition experience recurrent, sudden, unexplained, significant eye pain, light sensitivity, and tearing that comes and goes after the injury, you are not a good PRK candidate as these symptoms may worsen after PRK. Let your PRK doctor know about any of the above history and the accompanying symptoms experienced previously.
- **History of 'crossed eyes' (strabismus).** If you are having PRK and have a history of 'crossed eyes', you may be at an increased risk of having double vision after surgery. Tell your PRK doctor if you have ever had 'crossed eyes' or experienced double vision, including what interventions/treatments were performed.
- **Decreased vision in one eye.** If you have one eye that does not see clearly, even with glasses, you should discuss this with your PRK doctor. This condition can be due to amblyopia, a 'lazy eye,' or damage from an injury or disease. With this type of decreased vision in one eye, complications that might result from PRK in your better seeing eye could more severely impact your functioning.

### Precautions:

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

- **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 PRK treatment or the way your cornea heals after PRK. This may result in poor vision after PRK.
- **Family history of thinning of the cornea.** Eye diseases like a cone-shaped cornea (*keratoconus*), thinning of the inferior part of the cornea, and other conditions that may cause a thinning or bulging of the cornea can run in families. You may not be aware that you have such a condition if it is in its early stages. If you have one of these conditions and it has not been diagnosed, PRK may cause more rapid progression of the disease. You should tell your PRK doctor about any family history of these or any other eye problems. **History of any eye disease (e.g., eye inflammation), abnormality, injury, or surgery.** If you have a history of any of these conditions, you should discuss them with your PRK doctor, as they might increase risks associated with PRK. For example, corneal scars may affect PRK accuracy and vision following the procedure.
- **Taking sumatriptan (e.g., Imitrex<sup>®4</sup>).** This medication, usually used to treat migraine headaches, may cause problems with healing after PRK. Tell your PRK doctor about all medications you are taking.
- **Taking amiodarone hydrochloride (e.g., Cordarone<sup>®5</sup>).** This medication, usually used to treat irregular heartbeats, can cause cloudy areas in the cornea and may cause problems with healing after PRK. Tell your PRK doctor about all the medications that you are taking.
- **Large pupils or very nearsighted.** Many factors affect whether a patient might experience visual symptoms, making it difficult to predict who will have them after surgery. However, very nearsighted patients and patients with large pupils may be at greater risk of experiencing visual symptoms, such as, but not limited to halos and glare, at least temporarily during the recovery/healing period. In addition, patients who are very nearsighted generally may have less accurate correction than those requiring less treatment. Ask your doctor whether you have large pupils or are very nearsighted.
- **Activities under poor lighting conditions.** PRK may decrease your ability to see well in poor lighting conditions, such as in dim lighting, rain, snow, and fog, when contrast (difference in how bright an object is compared to its background) is low, or when there is glare from bright lights, especially at night. You should discuss these potential problems with your PRK doctor. After PRK, you should be careful while driving when you are in poor lighting conditions until you can determine whether you have any difficulties.

- **Future eye health.** PRK will cause difficulties with:
  - **Future assessment of eye pressure.** Thinning of the cornea due to PRK surgery will affect the accuracy of your eye pressure measurements (used as part of the exam for glaucoma), making them more difficult to interpret glaucoma treatment response. This requires your glaucoma specialist to factor in the remaining post PRK corneal thickness to accurately measure your eye pressure. You should inform all eye care (particularly your eye doctor) providers that you have had PRK.
  - **Future cataract surgery.** Almost everyone needs cataract surgery (removal of your natural lens) later in life. PRK surgery may make it more difficult for the surgeon to accurately measure the appropriate artificial lens corrective power. You should ask your PRK doctor for a patient information card (e.g., the “K-Card” found at <http://www.geteyesmart.org/eyesmart/upload/kcard.pdf>) that lists your eye measurements before you have PRK surgery. You should keep this card to help the cataract surgeon accurately calculate the artificial lens power you will need when you have cataract surgery in the future.
- **Severe allergies or eye rubbing.** Some allergy medications cause dry eye symptoms. If you take these medicines, you are at greater risk for severe dry eye after PRK. Let your PRK doctor know about all your allergies and medications (even over-the-counter medications) and if you tend to rub your eyes frequently.
- **Elevated eye pressure or being followed for possible glaucoma.** If you have either of these conditions related to eye pressure, there are several ways PRK can cause problems for you. It is more difficult to accurately monitor your eye pressure after PRK, which may delay the detection of glaucoma. Additionally, steroid drops used after the PRK surgery may raise the eye pressure and cause glaucoma to worsen. Let your PRK doctor know if you have any of these conditions.
- Younger than **18 years of age**, because it is unknown whether PRK is safe and effective for you.
- Over the **long term** (more than 12 months), because it is unknown whether PRK is safe and effective for you.
- You should discuss the risks in depth with your doctor for any PRK 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 PRK 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 PRK may not be safe and 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.

- Treatment zones larger than 6.5 millimeters in diameter were not investigated in the clinical trial. It is unknown whether PRK with ALLEGRETTO WAVE EYE-Q using treatment zones larger than 6.5 millimeters is safe and effective.
- Your **nearsightedness** is worse than - 6 diopters for PRK or your astigmatism is worse than - 3 diopters, because it is unknown whether PRK is safe and effective for you.
- Your **astigmatism** is worse than - 3 diopters, because it is unknown whether PRK is safe and effective for you.
- If you have **mixed astigmatism**, it is unknown whether PRK procedure is safe and effective for you.
- **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 PRK surgery even if you did not have dry eyes before surgery.
- **FDA-approved treatment range.** Up to -6.0 diopters (D) of nearsightedness, or nearsightedness with astigmatism, with up to -6.0 D and up to -3.0 D of astigmatic component and up to - 6.00 diopters (D) MRSE at spectacle plane. PRK treatments provided outside the FDA-approved treatment range may be risky. Please ask your doctor if your treatment range is approved.
- Medical Condition. Your doctor should know your medical conditions.
- History of crossed eyes. If your eyes are squint-eyed, it is unknown whether PRK is safe and effective under this condition.
- If you have a decreased vision in one eye, it is unknown whether PRK 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 will be 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 PRK or by wearing glasses or contact lenses that compensate for the difference.
- The safety and effectiveness of the ALLEGRETTO WAVE EYE-Q was not investigated in pregnant and nursing women. It is unknown whether the PRK procedure with the ALLEGRETTO WAVE EYE-Q is safe and effective in pregnant and nursing women. If you are pregnant or nursing, you should discuss the risks and benefits of undergoing PRK with your doctor.

## 8. ARE YOU A GOOD CANDIDATE FOR PRK?

You are a good candidate for PRK if you:

- Are at least 18 years of age and have nearsightedness with or without astigmatism
- Are **nearsighted** up to - 6.00 diopters or nearsightedness with astigmatism is up to - 6.00 diopters up to -3.0 diopters of astigmatism and up to - 6.00 diopters (D) MRSE at spectacle plane.
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g. , scar, infection, etc.; see Contraindications)
- Have documented evidence that our refraction did not change by more than 0.5 diopters during the year before your pre-operative examination
- Are informed of risks and benefits as compared to other available treatments for nearsightedness with or without astigmatism
- Are able to lie flat without difficulty
- Are able to tolerate local or topical anesthesia
- Are willing to sign an informed consent form as provided by your eye care professional
- Are able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

Surgical alternatives to PRK include **Laser Assisted In Situ Keratomileusis (LASIK)**, radial keratotomy, automated lamellar keratoplasty and clear lens exchange. Like PRK, LASIK uses an excimer laser to reshape the cornea, but a **flap** of corneal tissue is first made and lifted prior to applying the laser light to the cornea. Ask your physician whether you might be a better candidate for LASIK than PRK. Non-surgical alternatives to PRK are wearing glasses or contact lenses.

## 9. WHAT ARE THE BENEFITS OF HAVING PRK?

PRK surgery, as performed with the ALLEGRETTO WAVE EYE-Q excimer laser system, is effective in reducing nearsightedness up to -6.00 diopters with or without refractive astigmatism up to -3.00 diopters and up to - 6.00 diopters (D) MRSE at spectacle plane. It may also reduce or eliminate dependency upon contact lenses or glasses.

While it is reasonable for patients to expect to perform distance tasks without glasses following PRK surgery, a significant number of patients will not achieve 20/20 vision without glasses or contacts due to surgical under correction or overcorrection. Furthermore, as you age, your vision will likely change so that you may need glasses to see up close even if you can still see clearly at distance without glasses.

### 10. WHAT ARE THE RISKS OF HAVING PRK?

The risks of PRK include complications that can be observed by the doctor, and those that may be directly experienced by the patient.

The risks of PRK that may be **observed by the doctor** include, but are not limited to, the following:

- **Loss of vision.** This means that vision becomes unclear (blurry or hazy vision) even with glasses or contact lenses. Your doctor may be able to measure this loss using a vision chart. The loss may be mild or, in rare cases, severe. In extremely rare cases, people can experience a total loss of vision. Vision loss is usually temporary, but there are complications of PRK that can cause permanent loss of vision. How clearly you can see may change from day-to-day or even from minute-to-minute (fluctuating vision). Some of the potential causes of vision loss following PRK surgery are discussed below.
- **Corneal complications.** The following corneal complications may lead to permanent vision loss, for example, due to loss of corneal clarity from scarring or swelling, and may require corneal transplant surgery for treatment:
  - **Infection.** The cornea may get infected right after surgery. This can be treated with topical medication, which may or may not successfully control the infection. On rare occasions, an infection may cause a hole in the clear covering of the eye (perforation of the cornea).
  - **Inflammation.** Excessive inflammation is the body's reaction to tissue disruption, for example, from surgery or infection. Inflammation of the cornea can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal clarity) depending on the severity and response to steroid treatment.
  - **Treatment or healing results in irregular corneal shape or loss of corneal clarity.**
    - **Bulging of the cornea** is probably the most extreme irregularity. This complication is uncommon, but can cause permanent and significantly blurry vision, sometimes requiring corneal transplant.
    - **Smaller irregularities the shape of the cornea** can be measured by the doctor using special instruments. These can cause blurry vision or unwanted images.
- **Retinal detachment.** The retina is the light-sensitive tissue that lines the interior back of the eye and captures images transmitted to the brain, much like the film of a camera. If the retina detaches, or comes unglued from its attachments within the eyeball, it will lose its function and need to be reattached through surgery. This may result in permanent loss of vision in some instances even if the retina is successfully reattached. Retinal detachment after PRK is rare, and usually only occurs in people who are very nearsighted and are prone to this type of retinal problem.

- **Desired correction not achieved or doesn't last.** PRK may not result in the desired amount of vision correction, or the level of vision correction may decrease over time. Additional corrective surgery may not always be possible, and when it is possible may again not result in the desired correction. Even if your vision results are generally good, you may still need glasses or contact lenses to perform certain tasks such as reading.
- **Drooping eyelid.** The lid of the eye(s) that had surgery may droop. This can be a temporary, in rare instances permanent complication from an instrument used to hold the lid during surgery. Besides the appearance of unevenness in the height of the eyelids, this may result in a feeling of the eyes getting tired during the course of the day or difficulty seeing, and may require eyelid surgery in extreme cases.

The risks of PRK that are directly related to the **patient's experience and perceptions** include, but are not limited to, the following:

- **Dry eyes.** PRK may cause or increase eye dryness, which may also cause discomfort and visual problems in severe untreated cases. The doctor may see dry spots on the normally moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go away and may require additional treatment/intervention.

If you have dry eye before surgery, PRK may increase dry eye symptoms and related problems after surgery. Your doctor should test you for pre-existing dry eye prior to surgery. However, even if dry eye tests before surgery are normal, there is no test to guarantee that you will not get a dry eye problem after PRK. Lubricating drops are usually necessary immediately after surgery to help with dryness. Symptoms of dry eye may include a scratchy or sandy feeling as if something is in the eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, light sensitivity, and blurred vision. The sensation of dryness can vary from mild to severe, but in most cases the feelings are a minor annoyance. Eye drops such as artificial tears, or other treatments, such as plugs in the tear drainage system of the eye, may reduce these symptoms, but may not completely resolve them. A small number of patients experience extreme discomfort that interferes with their ability to do daily tasks.

- **Visual Symptoms.** PRK may cause or worsen visual symptoms such as glare, halos, starbursts, and ghost images/double images, most commonly experienced in dim lighting conditions, and blurred and fluctuating vision. These problems usually improve within 3 to 6 months after surgery, but in some cases never go away, even when glasses are worn. Visual symptoms can be mild, but can also be severe enough to cause difficulties in performing daily tasks. **A common complaint is difficulty with driving at night.** Specific visual symptoms are described below.
  - **Glare.** Glare is *difficulty seeing well when there are bright lights like headlights or sunlight.*
  - **Halos.** You may see halos. By halos, we mean *seeing a fuzzy cloud of light around lighted objects.*
  - **Starbursts.** You may see *rays of light coming from lighted objects.*

- **Double images.** Double images, which some people call “ghost” or “shadow” images, are *distorted or blurry visual images*. If you experience such images, close one eye and then the other to determine if you only see the double images with both eyes open. If you still have double images with one eye closed, note in which eye you are experiencing the double images. This information is important to report back to your doctor to help him or her determine the cause of the problem.
- **Decreased ability to see under low lighting conditions.** You may have more difficulty seeing in low lighting conditions after surgery than before surgery. For example, some patients describe having more trouble reading the menu in a dimly lit restaurant or climbing down stairs in a theater. Driving during certain periods of the day, such as dusk and dawn, may become difficult, because of trouble reading signs, distinguishing the curb from the road, and being able to see people crossing the street. Some people have reported having so much difficulty seeing under these types of conditions that they avoid doing certain activities they used to enjoy.
- **Permanent difficulty seeing in dim lighting, rain, snow, fog, or bright glare.** Visual impairment under these conditions (seeing in dim lighting, rain, snow, fog, or bright glare) was not studied; hence it is difficult to predict the possibility and severity of visual impairment in these conditions.
- **Discomfort or pain.** It is not unusual for patients to have some discomfort right after PRK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities.
- **Unintentional imbalance between two eyes.** PRK may cause a visual imbalance between the two eyes if the desired correction is not achieved, or one eye is treated with PRK but the other eye cannot undergo treatment. Imbalances between the two eyes may cause headaches, eyestrain, double vision, and reduced depth perception, if both eyes are not able to focus at the same time at the same distance.
- **Need for glasses for close work.** Almost all people in their 40s or older lose their ability to focus from far to near. PRK does not treat this condition (called “presbyopia”). After surgery, patients who are already over 40 years old (or once they reach their 40’s) usually need to wear glasses for close work, such as reading, even if they did not need to wear them before surgery.

Some problems that patients experience commonly occur during the early period following PRK surgery and are usually greatly reduced within 3 to 6 months. However, in some patients these problems can be permanent and, in rare cases, may impact their ability to perform daily tasks.

See the chapter 15 “Summary Of The Clinical Study Results” on page 35, to find out how often specific problems occurred in those treated with the ALLEGRETTO WAVE EYE-Q laser in the study for FDA approval.

## 11. WHAT WILL HAPPEN BEFORE, DURING AND AFTER PRK?

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

PRK 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 PRK surgery, you will have a complete examination of your eyes before surgery. This will determine if your eyes are healthy and suitable for PRK 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.



### **CAUTION**

- If you are wearing contact lenses, it is very important to stop wearing lenses before the pre-operative examination. Patients wearing soft contact lenses must stop wearing them 1 week before the preoperative examination as well as prior to surgery and patients wearing gas permeable or hard contact lenses must stop wearing lenses 3 weeks before the preoperative examination as well as prior to surgery. 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.
- 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 is about to 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 continuously look at the green blinking light in the center of the black opening (See Figure 5).

**CAUTION**

- Do not let the red and white lights distract you during the PRK surgery. 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 5: 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 eyetracker will be started and your doctor will rearrange the position of you (and your eye) 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, as shown in Figure 6 below.

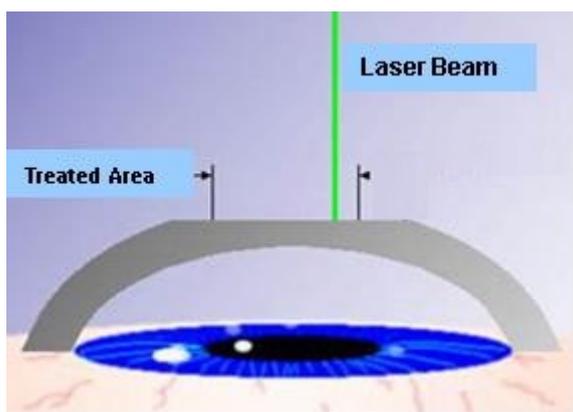


Figure 6: Cornea Being Shaped By Laser

You will hear a buzzing sound when the laser removes tissue from your cornea and you will also hear a suction noise at a close distance. 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 always keep your attention at the blinking green light throughout the treatment. If you move 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.

Your doctor then removes the device holding your eyelid. A bandage contact lens and eye drops will be applied to your eye.

Your entire PRK procedure will take about 5-10 minutes per eye.

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 approximately the first 4 days following the surgery for PRK. 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 eye pressure, 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'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 fixed 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 PRK.

You will need to use eye drops after surgery. The eye drops include **antibiotics**, eye drops or oral medication for pain, ocular **steroids** and lubricant eye drops. Use each medication as directed by your doctor.

You can begin to use lotions, creams, or make-up around the eye area after the surgery as instructed by your doctor. You should wait after the surgery before participating in any sports, depending on how you feel and any instructions from your doctor. You should also avoid swimming or using hot tubs after the surgery to avoid the possibility of infection.

## 12. WHAT SHOULD YOU ASK YOUR DOCTOR?

You may want to ask your doctor the following questions to help you decide if PRK 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 if yes, for how long?
- What are the benefits of PRK for my amount of nearsightedness?
- What vision can I expect the first few months after surgery?
- If PRK does not correct my vision, what is possible that my glasses will be stronger than before? Could my glasses increase over time?
- Will I be able to wear contact lenses after PRK 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 PRK?
- Should I have PRK in both eyes?
- How long will I have to wait until I get PRK on the second eye?
- What vision problems may I experience if I have PRK 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**.

### 13. SUMMARY OF IMPORTANT INFORMATION

- PRK is a permanent operation to the cornea and cannot be reversed.
- PRK involves the use of a laser to permanently remove corneal tissue to correct low to moderate nearsightedness with or without low astigmatism.
- PRK 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 PRK surgery.
- Your vision must be stable at least one year before the pre-operative examination for PRK. You will need written evidence that your nearsightedness and astigmatism have changed only 0.5 diopters or less.
- Pregnant or nursing women do not qualify for PRK surgery.
- You are not a good candidate for PRK surgery if you have a **collagen vascular disease** (such as rheumatoid arthritis) or **autoimmune disease** (such as lupus) or have condition that makes wound healing difficult.
- PRK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery.
- PRK is not a laser version of RK; these surgeries are completely different from each other.
- Some alternatives to PRK include, but are not limited to, glasses, contact lenses, LASIK and RK.
- Before considering PRK surgery, you should
  - a) Have a complete eye exam.
  - b) Talk with one or more eye care professionals about the potential benefits, risks and complications of PRK. You should also discuss the time needed for healing, the discomfort you may experience or problems that may occur during this time.
- A potential benefit of PRK is to have normal vision (20/20 visual acuity) without glasses after surgery. Your nearsightedness with or without astigmatism may not be fully corrected and you may still need to wear glasses or contact lenses. In addition, you may need reading glasses, even if you did not wear them prior to the PRK surgery.
- The risks of PRK include corneal **haze**, dry eye, glare, halos, starbursts, eye pain, burning feeling in eyes, eyes sensitive to light, blurry vision, fluctuation of vision, difficulty focusing in dim or low light, watery eyes and feeling like something is in your eyes. Corneal infiltrates and corneal edema are also possible risks but occur very infrequently.

## 14. FREQUENTLY ASKED QUESTIONS

### Is PRK treatment permanent?

- The portion of your cornea removed by PRK treatment does not regrow at this layer of your cornea.
- The level of vision correction may decrease over time; the effectiveness of PRK with ALLEGRETTO WAVE EYE-Q beyond 12 months has not been investigated

### Will I be able to see sharply at a distance (visual acuity) without glasses after PRK?

The goal of **PRK** in the correction of low to moderate nearsightedness with or without low astigmatism is to reduce or eliminate the need for glasses or contact lenses to see at distance.

- In the clinical study of the ALLEGRETTO WAVE EYE-Q for nearsightedness with or without astigmatism, 93% of eyes had normal vision (visual acuity of 20/20 or better) without glasses. There is a chance that your nearsightedness with or without astigmatism may not be fully eliminated and you maybe need to wear glasses or contact lenses to see sharply at distance

### Will I need reading glasses after PRK?

You may need to wear reading glasses, even though you did not need to before PRK. 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. PRK does not prevent future changes in the focusing power of your eye that occurs with presbyopia, a condition that occurs naturally due to aging.

### Will my vision be perfect after PRK surgery?

As with any surgical procedure there are risks associated with PRK 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 PRK surgery in the same eye for enhancement of the result.
- A special type of astigmatism - known as irregular astigmatism - may occur after PRK surgery that may affect your vision. 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, halos and starbursts at nighttime are not uncommon after PRK. 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 PRK 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.
- Intraocular pressure of the eye may rise in the treated eye(s), possibly due to the prescribed medication to reduce swelling (inflammation) or corneal inflammation. The increased pressure usually does not cause any noticeable symptoms. A severe increase in pressure may cause pain or nausea.
- **Cataracts**, which may affect your vision, could form because of the long term use of steroids after the PRK procedure.

### **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 risks are associated with the surgical procedure?**

- Many patients feel more comfortable with a mild degree of oral sedation before the PRK procedure. If you receive sedation you should not drive or operate machinery for 24 to 48 hours after surgery.
- Patients with very large pupils (larger than 6 mm) are advised of the potential for a poor visual result after PRK surgery including glare, halos, and nighttime driving difficulties.
- The effects of the ALLEGRETTO WAVE EYE-Q laser device on implantable medical devices (such as a heart pacemaker) are unknown.

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

- Do NOT rub your eye, even if it feels itchy.
- You might experience eye irritation related to drying of the corneal surface following PRK surgery. The symptoms may be temporary or, in rare cases permanent, and may require frequent application of artificial tears or instillation of prescription eye drops.
- You might feel moderate pain, discomfort and a feeling of something in the eye for several days after surgery. Pain medication may be necessary.
- You may experience 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. Follow your doctor's instruction regarding when to resume driving activities.
- You may experience 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
- You may experience 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 PRK. Your eyes may remain slightly more sensitive to light than they were before surgery. You may have difficulties with night driving.
- You may experience swelling of the eye or cornea. Swelling usually resolves within 48 hours after surgery.

### **What side effects could follow after having PRK surgery?**

You may experience side effects that are less common after PRK surgery.

- Although visual symptoms, like glare, halos, starbursts, and difficulty driving at night tend to be less frequent and less severe after PRK, some patients may notice an increase in these symptoms after PRK. If you have these visual symptoms, they may be worse under poor lighting conditions than under normal lighting conditions.
- Drooping of the upper eyelid (**ptosis**), has been noted as an uncommon occurrence following PRK. The cause is not yet fully understood. Generally, ptosis after PRK is mild in degree and will resolve by itself over several months.
- Although it is rare, corneal scarring (or **haze**) may occur after PRK surgery. Scarring or haze may cause partial vision loss or cloudiness of vision.
- The development of dry eye symptoms may be a complication of PRK 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 (Nearsightedness):

- 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).
- 0.9% (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).
- 1.4% (3/212) of cases had an increased intraocular pressure of > 5 mmHg.

## 15. SUMMARY OF THE CLINICAL STUDY RESULTS

### **Clinical Study Information:**

A clinical study was conducted at 8 clinical sites in the US to evaluate the benefits and risks of the ALLEGRETTO WAVE EYE-Q excimer laser system used for PRK. A total of 320 eyes from 161 patients with low to moderate nearsightedness, with or without low astigmatism had PRK. Assessments performed during the study included vision testing with and without glasses, measurement of the errors of the eye, evaluation of the health of the eyes. Study visits occurred before and after PRK at scheduled times up to 24 months. The results for up to 12 months are included in this booklet.

Patients who agreed to be involved in the clinical study provided informed consent and completed the required screening procedures to determine study eligibility. Patients had at least one eye with nearsightedness up to - 6.00 diopters with or without astigmatism up to - 3.00 diopters.

The results of the study showed that it takes 6 months for the eye to be stable after PRK for low to moderate nearsightedness with or without low astigmatism. The study results for up to 12 months are described below.

### **Clinical Study Results:**

#### **Vision without Glasses Before And After PRK**

The doctors in the clinical study measured vision without glasses (uncorrected visual acuity [UCVA]) before and after PRK.

Six months after PRK, UCVA was as follows:

- All of the 314 eyes had UCVA of 20/40 or better.
- 292 of the 314 eyes had UCVA of 20/20 or better.

The UCVA results at 6 months were consistent with the results after 6 months.

#### **Vision Without Glasses After PRK Compared To Vision With Glasses Before PRK**

How well eyes were able to see without glasses after PRK compared to their vision with glasses before PRK is presented below. At 6 months after PRK:

- 215 of the 314 of eyes had vision without glasses that was equal to or better than their vision with glasses prior to PRK.

The doctors in the clinical study evaluated the risks of having PRK by measuring vision with glasses (best spectacle corrected visual acuity [**BSCVA**]) and astigmatism before and after PRK for low to moderate nearsightedness with or without low astigmatism. Additionally, adverse events were evaluated. An adverse event is defined as unexpected medical occurrence, unintended disease or injury, or unexpected clinical signs whether or not related to PRK or the ALLEGRETTO WAVE EYE-Q excimer laser system.

### Vision with Glasses after PRK

At 6 months after PRK:

- None of the eyes had vision with glasses that was worse than 20/40.
- None of the eyes lost 2 or more lines of vision with glasses compared to before PRK.
- None of the eyes had induced astigmatism of greater than 2 D as compared to baseline.

The BSCVA results at 6 months were consistent with the results after 6 months.

### **Adverse Events:**

Adverse events were classified as serious and non-serious depending on how they affected the patient's health. No unanticipated adverse events were observed in this study.

The serious adverse events in this study were:

- 1 event of **corneal edema** at approximately 5 months after PRK
- 2 events of corneal infiltrate at 1 day and 4 days after PRK

These 3 events were reported as unrelated to the ALLEGRETTO WAVE EYE-Q excimer laser but related to the PRK procedure.

Some of the non-serious adverse events were collected based on patients' responses to a questionnaire that evaluates symptoms associated with PRK. The questionnaire is called the Visual Symptoms Associated with Refractive Correction (VSARC). The absence of a symptom was rated as "none", and the presence of a symptom was rated as "mild", "moderate" or "severe".

The rates shown below are based on the total number of eyes experiencing an adverse event type up to 12 months.

Adverse events reported based on the patients' responses to the VSARC questionnaire are shown below for 320 eyes that participated:

### Dry eyes

64 eyes with symptoms of dry eye that significantly affected comfort or activities of daily living at 6 months or later.

35 eyes with moderate or severe dry eye at 6 months or later.

### Starbursts

4 eyes with moderate or severe starbursts at 6 months or later.

### Burning feeling in eyes

10 eyes with moderate or severe burning feeling in eyes at 6 months or later.

### Blurry vision

6 eyes with moderate or severe blurry vision at 6 months or later.

### Difficulty focusing in dim or low light

2 eyes with moderate or severe difficulty focusing in dim or low light at 6 months or later.

### Feeling like something is in the eyes.

14 eyes with moderate or severe feeling like there is something in eyes at 6 months or later

**Bolded** words can be found in the glossary

### Glare or **Halos**

14 eyes with glare or halos that significantly affect comfort or activities of daily living at 6 months or later.

2 eyes with moderate or severe glare at 6 months or later.

10 eyes with moderate or severe halos at 6 months or later.

### Eye pain

13 eyes with moderate or severe eye pain at 6 months or later.

### Eyes sensitive to light

19 eyes with moderate or severe eyes sensitive to light at 6 months or later.

### Fluctuation of vision

6 eyes with moderate or severe fluctuation of vision at 6 months or later.

### Watery eyes

5 eyes with moderate or severe watery eyes at 6 months or later.

The symptoms below were also collected by the VSARC questionnaire but these symptoms were reported, for the most part, without the doctor making an evaluation about whether they were an adverse event.

- 23 out of 320 eyes with moderate or severe feeling like something is in the eyes at 1 month or later.
- 30 out of 320 eyes with moderate or severe ghost or double image.
- 22 out of 320 eyes with moderate or severe pain at 1 month or later.

Below is information for the adverse events whereby more events were not resolved versus resolved by 12 months after PRK.

- 33 out of 64 events of any symptom of dry eye that significantly affect comfort or activities of daily living at 6 months or later were not resolved.
- 22 out of 35 events of moderate or severe dry eye at 6 months or later.
- 7 out of 13 events of moderate or severe eye pain at 6 months or later.
- 8 out of 14 events of moderate or severe feeling like there is something in the eyes at 6 months or later.
- 10 out of 19 events of moderate or severe eyes sensitivity to light at 6 months or later.
- 6 out of 10 events of moderate or severe blurry vision at 6 months or later.
- 3 out of 5 events of moderate or severe watery eyes at 6 months or later.

Non-serious adverse events reported by the doctor that were not reported based on the patients' responses to the VSARC questionnaire are shown below for 320 eyes that participated:

1 eye with clinical signs consistent with moderate to severe dry eye at 6 months or later	3 eyes with recurrent <b>corneal erosion</b> at 1 month or later
1 eye with change in visual depth perception (3-dimensional vision)	1 eye with <b>chalazion</b>
1 eye with <b>conjunctival hyperemia</b>	2 eyes with <b>conjunctivitis</b>
5 eyes with allergic conjunctivitis	1 eye with viral conjunctivitis
3 eyes with scratched on the corneal	1 eye with corneal disorder
3 eyes with <b>corneal epithelium</b> defect	3 eyes with <b>corneal erosion</b>
1 eye with swelling of the cornea	18 eyes with corneal opacity (white or cloudy cornea)
4 eyes with dry eye	1 eye with <b>episcleritis</b>
6 eyes with eye allergy	3 eyes with eye pain
1 eye with eyelid inflammation	1 eye with feeling like there is something in the eyes
1 eye with <b>halo</b>	1 eye with <b>hordeolum</b>
1 eye with <b>iritis</b>	3 eyes with <b>keratitis</b>
2 eyes with <b>meibomian gland dysfunction</b>	2 eyes with eyes sensitive to light
1 eye with <b>starbursts</b>	5 eyes with <b>punctate keratitis</b>
3 eyes with vision blurred	1 eye with vision reduced
2 eyes with vision loss or decreased vision	2 eyes with <b>vitreous floaters</b>

**Bolded** words can be found in the glossary

Contrast sensitivity (the ability to see objects that may not be outlined clearly or that do not stand out from their background) is usually tested under various lighting conditions. Below are the results of contrast sensitivity for subjects in the study:

- At 12 months after PRK:
  - 88 out of 311 eyes had significantly better contrast sensitivity in dim light with a glare source
  - 70 of 311 eyes had significantly better contrast sensitivity in dim light without a glare source
  - 42 of 311 eyes had significantly better contrast sensitivity in bright light with a glare source
  - 33 of 311 eyes had significantly better contrast sensitivity in bright light without a glare source
  - 19 out of 311 eyes had significantly worse contrast sensitivity in dim light with a glare source
  - 20 of 311 eyes had significantly worse contrast sensitivity in dim light without a glare source
  - 21 of 311 eyes had significantly worse contrast sensitivity in bright light with a glare source
  - 10 of 311 eyes had significantly worse contrast sensitivity in bright light without a glare source
  - 204 out of 311 eyes had no significant change in contrast sensitivity in dim light with a glare source
  - 221 of 311 eyes had no significant change in contrast sensitivity in dim light without a glare source
  - 248 of 311 eyes had had no significant change in contrast sensitivity in bright light with a glare source
  - 268 of 311 eyes had had no significant change in contrast sensitivity in bright light without a glare source

### **Outcomes Reported By Patients Via Questionnaires**

#### Patient Evaluation of Symptoms Associated with PRK

Results from the VSARC questionnaire were as follows:

- Symptoms that had a higher rate at 6 months or later compared to before PRK were: eye pain, dry eye, burning feeling in eyes, starbursts, eyes sensitive to light, fluctuation in vision and feeling like there is something in the eyes.
- At 6 months after PRK, a small percentage of patients (up to 4.4%) rated the following symptoms as moderate or severe: eye pain, dry eye, burning feeling in eyes, eyes sensitive to light, halos, starbursts, blurry vision, fluctuation in vision, difficulty focusing in dim or low light, and feeling like there is something in their eyes.
- At months 9 to 12 after PRK, the results were consistent with or better than the results at 6 months after PRK.
- Most patients rated the symptoms as none or mild for all visits up to 12 month.

Vision-Related Health Status Patients were given another questionnaire called the Refractive Status and Vision Profile (RSVP). The RSVP was developed in patient's needing corrective lenses to measure a patient's evaluation of his or her vision-related health status. The RSVP questionnaire was completed before and after PRK. At 6 months after PRK, patients did not experience worsening of their vision-related health status on average.

## 16. PATIENTS 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) PRK is a permanent procedure	<input type="checkbox"/>	<input type="checkbox"/>
b) PRK is free of risks	<input type="checkbox"/>	<input type="checkbox"/>
c) PRK is the same as RK	<input type="checkbox"/>	<input type="checkbox"/>
d) It does not matter if I wear my contact lenses when my doctor told me not to wear them	<input type="checkbox"/>	<input type="checkbox"/>
e) I may need reading glasses after PRK	<input type="checkbox"/>	<input type="checkbox"/>
f) There is a risk that I may lose some vision after PRK	<input type="checkbox"/>	<input type="checkbox"/>
g) It's OK to have PRK if I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>
h) It matters if I take medication with ocular or healing side effects, such as Cordarone <sup>®</sup> , Imitrex <sup>®</sup> or Accutane <sup>®</sup>	<input type="checkbox"/>	<input type="checkbox"/>
i) After surgery there is a very good chance that I will be less dependent on eye glasses	<input type="checkbox"/>	<input type="checkbox"/>
j) Since the ALLEGRETTO WAVE EYE-Q uses an eyetracker, I do not have to fixate on the blinking light during laser treatment	<input type="checkbox"/>	<input type="checkbox"/>
k) Even if my refraction was changing a lot over the last year, I am still a good candidate for PRK	<input type="checkbox"/>	<input type="checkbox"/>
l) PRK is the same as LASIK	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers in chapter 18 "Answers To Self-Test Questions" on page 44.

17. WHERE CAN YOU GET MORE INFORMATION?

**Primary Eye Care Professional:**

Name:  
Address:  
Phone:  
Email:

**PRK 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

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**18. ANSWERS TO SELF-TEST QUESTIONS**

- a) True (see page 30)
- b) False (see page 14, page 15 and page 30)
- c) False (see page 30)
- d) False (see page 24)
- e) True (see page 30 and page 31)
- f) True (see page 31 and page 35)
- g) False (see page 30)
- h) True (see page 24)
- i) True (see page 20, page 30 and page 31)
- j) False (see page 25-27)
- k) False (see page 30)
- l) False (see page 13)

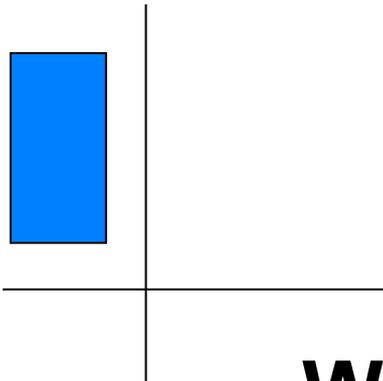
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- End -

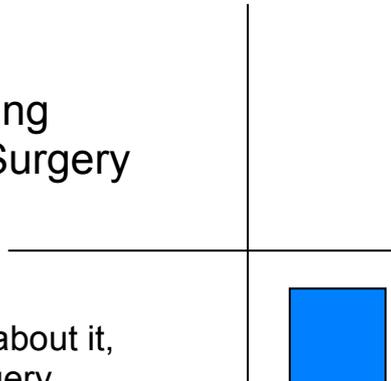




# WaveLight<sup>®</sup> EX500

## Patient Information Booklet

Information for patients considering  
Photorefractive Keratectomy (PRK) 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:

- PRK surgery for the elimination or reduction of nearsightedness of up to - 6.00 diopters (D), of **nearsightedness with astigmatism** of up to - 6.00 diopters (D) and up to - 3.00 diopters of **astigmatism**, and up to - 6.00 diopters (D) MRSE at spectacle plane,
- who are 18 years of age or older, and
- who have documented evidence that their refraction did not change by more than 0.5 diopters during the year before the preoperative examination.



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## 1. GLOSSARY

<b>Aberrometer</b>	Wavefront Analyzer
<b>Ablation, Ablate</b>	Removal of tissue with an excimer laser.
<b>Ametropic Eye</b>	An eye abnormality, such as nearsightedness, farsightedness, or astigmatism, where the eye cannot focus a distant image on the retina.
<b>Analgesic Medication</b>	Pain relieving medication.
<b>Anesthetic Eye Drops</b>	Medication used to numb the eye.
<b>Antibiotic Eye Drops</b>	Medication used to prevent or treat infections of the eye.
<b>Astigmatism</b>	A common vision condition that causes blurred vision and it occurs 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.
<b>Autoimmune Disease</b>	Condition in which the body attacks itself that may lead to inflammation or swelling of parts of the body. An example is multiple sclerosis.
<b>Bandage Contact Lens</b>	Soft contact lens temporarily used to cover the cornea after surgery.
<b>Best Corrected Visual Acuity</b>	The best vision that can be obtained with glasses.
<b>BSCVA</b>	Abbreviation of Best spectacle corrected visual acuity. Best visual acuity with glasses.
<b>Cataract</b>	Clouding of the lens inside the eye that may cause loss of vision.
<b>Cataract Surgery</b>	A procedure where the lens inside your eye that has become cloudy is removed and replaced with an artificial lens (called an intraocular lens, or IOL) to restore clear vision.
<b>Chalazion</b>	A chronic bump on the eyelid.
<b>Collagen Vascular Disease</b>	Condition that changes the way the body creates or processes connective tissue, like collagen. The cornea is made up of collagen. Examples are lupus or rheumatoid arthritis.

<b>Conjunctivitis</b>	Inflammation of the tissue covering the white part of the eye.
<b>Conjunctival Hyperemia</b>	Redness of the white of the eye.
<b>Cornea</b>	The clear front surface of the eye, which bends rays of light to focus an image of objects on the retina.
<b>Corneal Edema</b>	Swelling of the cornea
<b>Corneal Epithelium / Tissue</b>	Surface cells, forming the top layer of the cornea.
<b>Corneal Erosion</b>	When the outer layer (epithelial cells) of the cornea fail to attach to the underlying layer of the cornea (stromal tissue.)
<b>Diopter (D)</b>	Unit of measurement of the amount of nearsightedness, farsightedness and astigmatism of the eye.
<b>Episcleritis</b>	Inflammation in the space in front of the white part of the eye.
<b>Excimer Laser</b>	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.
<b>Eyetracker</b>	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.
<b>Farsightedness</b>	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.
<b>FDA</b>	Food and Drug Administration. This is the governmental agency that approves medical technology for use in the U.S.A.
<b>Femtosecond Laser</b>	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.
<b>Flap</b>	Thin slice of corneal tissue created on the surface of the cornea with femtosecond laser as part of the LASIK procedure.
<b>Floaters</b>	Cloudy structures in the fluid in the center of the eyeball causing “floating” structures in the image.

<b>Glaucoma</b>	A group of diseases that cause increased pressure in the eye and can result in vision loss by damaging the optic nerve.
<b>Halo</b>	Circular flares of light around bright lights in dim lighting conditions.
<b>Haze</b>	Cloudiness of the cornea.
<b>Herpes Simplex</b>	A virus that can cause cold sores and eye infections.
<b>Herpes Zoster</b>	A virus that can cause an infection with blisters on one side of the body.
<b>Hordeolum</b>	An infection of the glands at the base of the eyelashes.
<b>Iris</b>	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.
<b>Iritis</b>	An inflammation of the iris.
<b>Keratitis</b>	Inflammation of the cornea.
<b>Keratoconus</b>	An eye disease where the normally round, dome shaped cornea becomes thin and begins to bulge into a cone-like shape.
<b>Keratotomy</b>	Sculpting of the cornea by removing tissue.
<b>Lens</b>	A clear structure behind the iris that helps focus rays of light, or an image, on the retina.
<b>Meibomian Gland Dysfunction</b>	A condition affecting the glands on the base of the eyelashes.
<b>Mixed Astigmatism</b>	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.
<b>Nearsightedness</b>	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.

<b>Optic Nerve</b>	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.
<b>Optical</b>	A term that means something to do with the ability to see. For example, glasses are an <i>optical aid</i> .
<b>Optical Power</b>	Ability of an object such as the eye to bend light rays as they pass through.
<b>Optical Zone</b>	Part of the treatment area in which the refractive laser treatment shall be effective.
<b>Photorefractive Keratectomy (PRK)</b>	Refractive surgery that changes corneal curvature by removing corneal tissue after the top layer of cells (corneal epithelium) is removed without making a flap.
<b>Presbyopia</b>	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.
<b>Punctate keratitis</b>	Punctate keratitis is death of small groups of cells on the surface of the cornea (the clear layer in front of the iris and pupil). The eyes become red, watery, and sensitive to light, and vision may decrease somewhat. Most people recover fully. Symptoms can be relieved.
<b>Pupil</b>	The opening in the center of the iris. The iris changes the size of the pupil and controls how much light enters the eye.
<b>Radial Keratotomy (RK)</b>	Refractive surgery that changes corneal curvature by using a knife to make pie-shaped cuts in the cornea.
<b>Refractive Error</b>	A condition of the eye that occurs when light does not focus perfectly on the retina and distant images become blurry.
<b>Refractive Surgery</b>	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.
<b>Retina</b>	The light-sensitive and color-sensitive membrane inside the eye that transforms light images into nerve signals.
<b>Starbursts</b>	The appearance of rays of light coming out from lighted objects, such as car headlights
<b>Steroids</b>	Medications used to reduce inflammation or the body's healing response after injury or disease.

<b>Treatment Zone</b>	Area on the cornea where tissue is removed during laser treatment.
<b>Visual acuity</b>	Sharpness of vision, assessed using eye charts to measure how well you see in the distance.
<b>Vitreous, Vitreous body</b>	Gel-like fluid that fills the inside of the eye.
<b>Vitreous Floaters</b>	Deposits in the vitreous of the eye, usually moving about that appear to be like spots or fine lines
<b>Wavefront</b>	Image of light waves. Can be used to determine optical errors of an eye.

Table 1: Glossary

## 2. INTRODUCTION

This booklet contains important information that should help you decide whether to have **photorefractive keratectomy (PRK)** surgery to correct low to moderate **nearsightedness** with or without low **astigmatism**. With this procedure, an **excimer laser** is used to reshape the **cornea**, the clear structure at the front of the eye, by removing small amounts of **tissue** from the cornea. The excimer laser that will be used is the **WaveLight® EX500** excimer laser system.

Please read this entire booklet and ask your doctor any questions you may have. All terms printed in bold can be found in the glossary at the beginning of the booklet.

### 3. COMMON VISION PROBLEMS

The human eye (see figure 1 below) is very much like a camera. The camera lens focuses light to form clear images onto film. Similarly, the **cornea** and crystalline **lens** of the eye focus light onto the **retina**, the back surface of the eye.

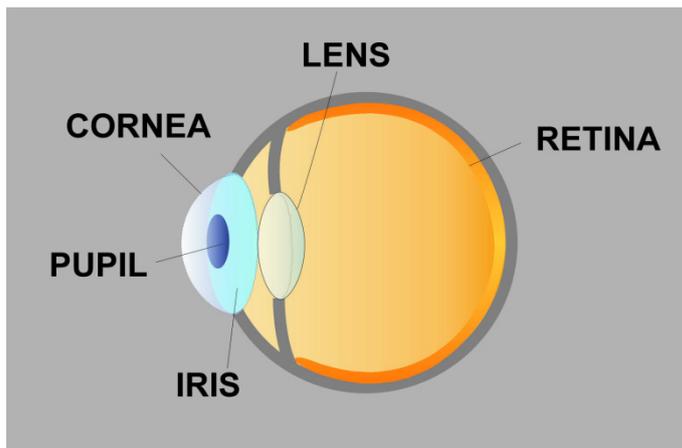


Figure 1: The Human Eye

In some people, the focusing of light doesn't occur perfectly. People encounter **refractive errors** such as nearsightedness and astigmatism.

**Nearsightedness** results in blurry distant vision. Light from a distant object focuses in front of the retina, rather than on the retina. As a result, images of distant objects appear blurry on retina.

Nearsightedness is not a disease but it is a variation of the human eye that tends to be genetic. In the US, half of the people between 20 and 59 years of age are nearsighted<sup>1</sup>. Reasons for the nearsighted condition can be that light rays focus at a point in front of the retina rather than directly on its surface, because your eye is longer than normal. Nearsightedness also can be caused by the cornea and/or the lens inside the eye being too curved for the length of the eyeball. Sometimes the reason for nearsightedness is the combination of the two. This condition starts developing usually during childhood and stabilizes in the late teens or early adulthood.

<sup>1</sup> Vitale S, Ellwein L, Cotch MF, Ferris FL, Sperduto R. Prevalence of Refractive Error in the United States, 1999-2004. Arch Ophthalmol 2008;126(8):1111-1119.

Figure 2 shows that distant vision is blurry when light focuses incorrectly in nearsighted eyes.

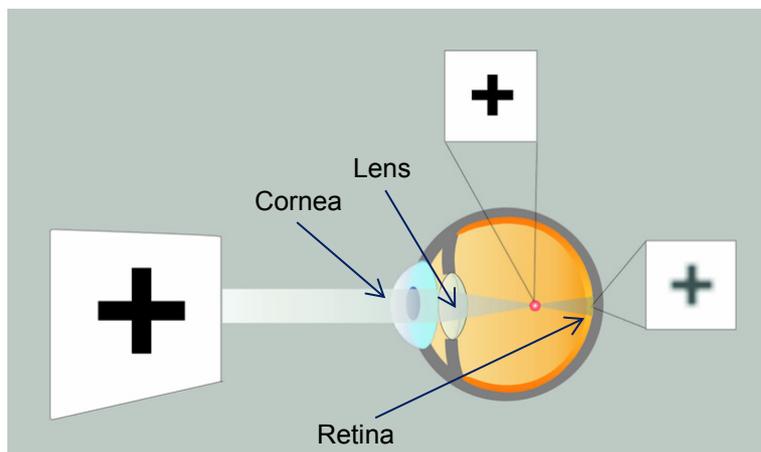


Figure 2: Nearsighted Eye Looking At A Black Cross

Astigmatism may occur alone or along with nearsightedness (myopic astigmatism). It causes an object to have edges that are blurry and others that are not. The reason for this condition is differing **optical powers** of the eye. This leads to different focal points in the eye as shown in figure 3 below. As a result, the image on the retina is blurry and distorted.

In the US, astigmatism of at least - 1.00 **diopter (D)** occur in 23% of people in the age group 20 through 39 years and 27% of people in the age group 40 through 59 years<sup>2</sup>.

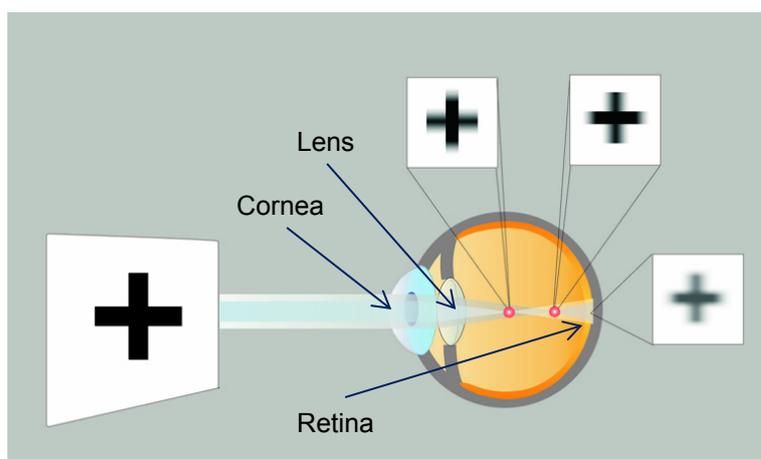


Figure 3: Nearsighted Eye With Astigmatism Looking At A Black Cross And Sending Images to The Brain.

<sup>2</sup> Vitale S, Ellwein L, Cotch MF, Ferris FL, Sperduto R. Prevalence of Refractive Error in the United States, 1999-2004. Arch Ophthalmol 2008;126(8):1111-1119.



**Presbyopia** is a common type of vision problem that first occurs around the age of 40. It occurs because the crystalline lens becomes stiff and is no longer able to focus light rays on the retina. Instead, the light rays become focused behind the retina. Near objects are blurred, even for eyes with perfect distance vision, and reading glasses may be required for clear near vision.

### 4. WHAT IS THE WAVELIGHT EX500 LASER SYSTEM?

The WaveLight® EX500 laser system (see figure 4) consists of the laser console, which includes the laser and control systems, such as control panels, monitors and a microscope. The WaveLight® EX500 laser system uses a specially shaped light beam profile and a small spot diameter to achieve the desired shape of the treated surface. The WaveLight® EX500 laser system applies very short laser light pulses which provide precision in reshaping the cornea and creates a smooth surface. Each pulse removes tissue with a diameter of less than 1 millimeter (0.04 inch). The WaveLight® EX500 laser system delivers 500 pulses per second. This rapid delivery of multiple light pulses makes a buzzing sound when the laser operates. The system is equipped with an **eyetracker** to help ensure 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. When you are prepared for PRK, you will lie down on a bed. This bed is then moved under the laser and the PRK treatment will be started.

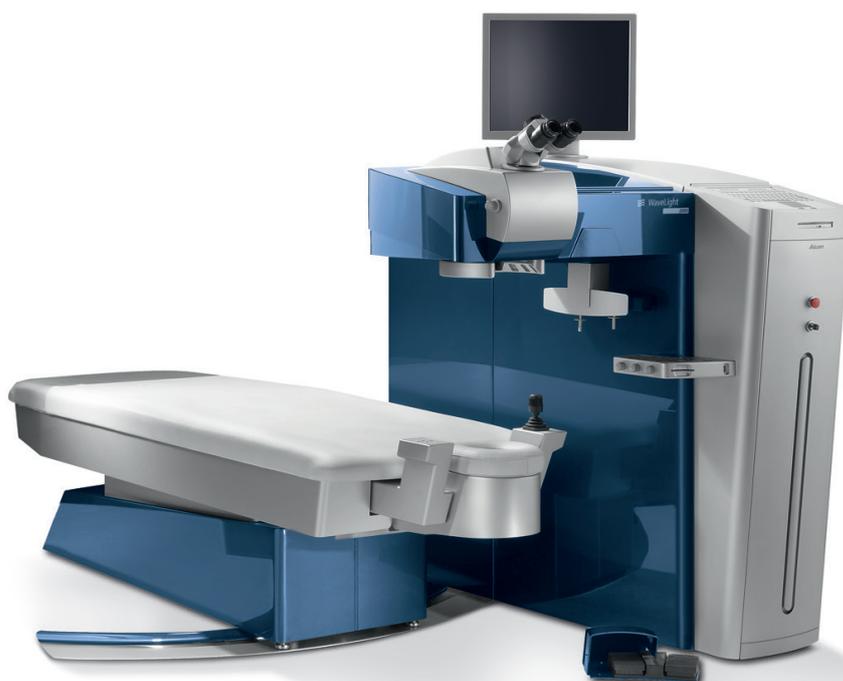


Figure 4: Example WaveLight® EX500 Device

## 5. WHAT IS PRK?

PRK is a surgical procedure that's an option for the correction of low to moderate nearsightedness with or without low astigmatism. With this procedure, as a first step, the outermost surface of the cornea (i.e. corneal epithelium) will be removed to prepare the eye for the surgery using the surgeons preferred method. This step will allow the WaveLight® EX500 laser system to directly treat the underlying tissue by reshaping the cornea through permanent removal of a small portion of **corneal tissue** as a second step. The amount of corneal tissue that is removed by the laser depends on the amount of nearsightedness and/or astigmatism that is present in the eye to be treated. The greater the error of the eye, the greater the amount of tissue, that is removed. The outermost surface which is removed as the first step will heal and grow back over the corneal surface.

## 6. HOW DOES PRK CORRECT NEARSIGHTEDNESS OR FARSIGHTEDNESS?

PRK corrects nearsightedness or farsightedness of the eye by enabling the light to focus properly on the retina. In the case of nearsightedness, the focal point of the eye falls in front of the retina. PRK will flatten the cornea so that light is not bent so much and the focal point moves back to the retina, creating a clear image of distant objects. With astigmatism, two focal points exist. To treat astigmatism, the shape of the cornea is changed in a way that both focal points are focused on the retina, for a clear image.

PRK does not prevent future changes in the focusing power of your eye that occurs with presbyopia, a condition that occurs naturally with aging. You may need to wear reading glasses after PRK to correct blurry near vision.

## 7. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

### Contraindications - When Can't You Have PRK?

If you have any of the following situations or conditions you cannot have a PRK procedure because the risk is greater than the benefit:

- Unstable eyes that have changed by more than 0.5 diopter in nearsightedness or astigmatism in the last 12 months and your nearsightedness or astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after PRK procedure.
- If you have an active connective tissue disease or autoimmune disease (such as rheumatoid arthritis and lupus) that can cause corneal melting, PRK will increase your risk for severe damage to your cornea and for vision loss. Let your PRK doctor know about any medical conditions you have.
- If you have an active infection or inflammation of the eye (such as inflammation of the cornea or iris), PRK will likely make your condition worse, resulting in permanent eye damage. Let your PRK doctor know if you are currently being treated, or if you have ever been treated, for such a condition.
- If you have had a herpes (herpes simplex or herpes zoster) eye infection within the past year or you have had corneal damage from prior herpes infections, you are at higher risk for further corneal damage after PRK. Let your PRK doctor know if you have ever had a herpes eye infection.
- You have **thinning of the cornea**. If you have a cone-shaped cornea (keratoconus), thinning of the bottom part of the cornea along the edges, or any other condition that may cause a thinning or bulging of your cornea, PRK can worsen these conditions and cause a permanent reduction in your vision. This may result in the need for additional surgery (such as a corneal transplant) after PRK. Your PRK doctor should map the shape of your cornea before PRK surgery to make sure you do not have any thinning.
- Your **cornea is not thick enough**. Your cornea (the clear front part of the eye) must be thick enough to undergo PRK without increasing the risk of causing an abnormal bulging forward of the cornea, which could decrease your vision. Ask your PRK doctor whether the thickness of your cornea puts you at greater risk for this complication.
- You show symptoms of severe dry eye. PRK may worsen the dry eye which may or may not go away. This dryness may delay healing of the corneal surface of the eye after surgery.
- You have **uncontrolled diabetes**. If your blood sugar is uncontrolled, your eyeglass prescription can fluctuate and your doctor will not be able to accurately determine what degree of PRK treatment is appropriate. Uncontrolled diabetes can also negatively affect wound healing after PRK. Let your PRK doctor know if you have diabetes.
- You have recurrent corneal erosion. This condition can lead to serious corneal problems during and after PRK procedure.
- You have uncontrolled **glaucoma**. It is unknown whether PRK is safe and effective in eyes with uncontrolled glaucoma.

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

Please inform your doctor if you have ANY of the following conditions that may present a greater risk for poor outcomes or injury related to the PRK procedure. You should discuss your level of risk with your doctor. You and your doctor should determine whether the benefits to you outweigh the risks based on the nature and severity of your condition.

- **Controlled autoimmune or connective tissue disease.** Connective tissue diseases or autoimmune diseases (such as rheumatoid arthritis and lupus), even if well controlled and stable, may result in delayed healing and less predictable outcomes after PRK. Depending upon your disease, its severity, and the medication(s) you are taking, there may be additional risks. These may include severe dry eye, infection, inflammation, poor healing, and corneal melting. You should discuss these additional risks with your PRK doctor, after he or she has consulted with the other doctors who are treating you.
- 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, PRK procedure is more risky for you.
- Significant dry eyes that have not responded to treatment. If your eyes have not responded to treatment for significant dry eyes, PRK procedure is more risky for you.
- **Uncontrolled or untreated eye allergies:** “If you have uncontrolled or untreated eye allergies, you may be at a higher risk of having corneal clouding (haze) and treatment failure after the PRK procedure. Let your PRK doctor know if you are currently being treated, or if you have ever failed to respond to treatment for such a condition.
- **You have controlled glaucoma.** If you have glaucoma, PRK may make monitoring your eye pressure more difficult. Steroid drops used after the PRK surgery may temporarily raise your eye pressure and potentially cause glaucoma to worsen. Let your PRK doctor know if you have been diagnosed with glaucoma or have a strong family history (if undiagnosed).
- **Controlled diabetes.** Even if your diabetes is well controlled, you may have poor healing of your eye following PRK.
- **Weakened immune system.** If you have a weakened immune system due to medications (such as steroids) or a medical condition (such as AIDS), you may be more prone to infection after surgery. Such conditions and medications may put you at greater risk for other complications as well, such as dry eye or abnormal wound healing. Let your PRK doctor know about any medical conditions you have and all medications you are taking.
- **History of Eye Injury and Eye Pain.** If you have suffered from recurrent corneal surface damage or have any history of shallow eye injury (e.g., scratched the eye with your nail, etc) and in addition experience recurrent, sudden, unexplained, significant eye pain, light sensitivity, and tearing that comes and goes after the injury, you are not a good PRK candidate as these symptoms may worsen after PRK. Let your PRK doctor know about any of the above history and the accompanying symptoms experienced previously.

- **History of ‘crossed eyes’ (strabismus).** If you are having PRK and have a history of ‘crossed eyes’, you may be at an increased risk of having double vision after surgery. Tell your PRK doctor if you have ever had ‘crossed eyes’ or experienced double vision, including what interventions/treatments were performed.
- **Decreased vision in one eye.** If you have one eye that does not see clearly, even with glasses, you should discuss this with your PRK doctor. This condition can be due to amblyopia, a ‘lazy eye,’ or damage from an injury or disease. With this type of decreased vision in one eye, complications that might result from PRK in your better seeing eye could more severely impact your functioning.
- **Taking isotretinoin (Accutane®).** This medication, usually used for acne treatment, increases your risk for dry eye and abnormal wound healing after PRK. If you have taken or plan to take this medication, talk to your PRK doctor, including the doctor prescribing this medication about your risk and the timing of discontinuing temporarily and restarting the medications after the procedure.

**Precautions:**

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

- **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 PRK procedure or the way your cornea heals after PRK procedure. This may result in poor vision after PRK procedure.
- **Family history of thinning of the cornea.** Eye diseases like a cone-shaped cornea (*keratoconus*), thinning of the inferior part of the cornea, and other conditions that may cause a thinning or bulging of the cornea can run in families. You may not be aware that you have such a condition if it is in its early stages. If you have one of these conditions and it has not been diagnosed, PRK may cause more rapid progression of the disease. You should tell your PRK doctor about any family history of these or any other eye problems.
- **History of any eye disease (e.g., eye inflammation), abnormality, injury, or surgery.** If you have a history of any of these conditions, you should discuss them with your PRK doctor, as they might increase risks associated with PRK. For example, corneal scars may affect PRK accuracy and vision following the procedure.
- **Taking sumatriptan (e.g., Imitrex®<sup>4</sup>).** This medication, usually used to treat migraine headaches, may cause problems with healing after PRK. Tell your PRK doctor about all medications you are taking.
- **Taking amiodarone hydrochloride (e.g., Cordarone®<sup>5</sup>).** This medication, usually used to treat irregular heartbeats, can cause cloudy areas in the cornea and may cause problems with healing after PRK. Tell your PRK doctor about all the medications that you are taking.
- **Large pupils or very nearsighted.** Many factors affect whether a patient might experience visual symptoms, making it difficult to predict who will have them after surgery. However, very nearsighted patients and patients with large pupils may be at greater risk of experiencing visual symptoms, such as, but not limited to halos and glare, at least temporarily during the recovery/healing period. In addition, patients who are very nearsighted generally may have less accurate correction than those requiring less treatment. Ask your doctor whether you have large pupils or are very nearsighted.
- **Activities under poor lighting conditions.** PRK may decrease your ability to see well in poor lighting conditions, such as in dim lighting, rain, snow, and fog, when contrast (difference in how bright an object is compared to its background) is low, or when there is glare from bright lights, especially at night. You should discuss these potential problems with your PRK doctor. After PRK, you should be careful while driving when you are in poor lighting conditions until you can determine whether you have any difficulties.

- **Future eye health.** PRK will cause difficulties with:
  - **Future assessment of eye pressure.** Thinning of the cornea due to PRK surgery will affect the accuracy of your eye pressure measurements (used as part of the exam for glaucoma), making them more difficult to interpret glaucoma treatment response. This requires your glaucoma specialist to factor in the remaining post PRK corneal thickness to accurately measure your eye pressure. You should inform all eye care (particularly your eye doctor) providers that you have had PRK.
  - **Future cataract surgery.** Almost everyone needs cataract surgery (removal of your natural lens) later in life. PRK surgery may make it more difficult for the surgeon to accurately measure the appropriate artificial lens corrective power. You should ask your PRK doctor for a patient information card (e.g., the “K-Card” found at <http://www.geteyesmart.org/eyesmart/upload/kcard.pdf>) that lists your eye measurements before you have PRK surgery. You should keep this card to help the cataract surgeon accurately calculate the artificial lens power you will need when you have cataract surgery in the future.
- **Severe allergies or eye rubbing.** Some allergy medications cause dry eye symptoms. If you take these medicines, you are at greater risk for severe dry eye after PRK. Let your PRK doctor know about all your allergies and medications (even over-the-counter medications) and if you tend to rub your eyes frequently.
- **Elevated eye pressure or being followed for possible glaucoma.** If you have either of these conditions related to eye pressure, there are several ways PRK can cause problems for you. It is more difficult to accurately monitor your eye pressure after PRK, which may delay the detection of glaucoma. Additionally, steroid drops used after the PRK surgery may raise the eye pressure and cause glaucoma to worsen. Let your PRK doctor know if you have any of these conditions.
- Younger than 18 years of age, because it is unknown whether PRK procedure is safe and effective for you.
- If you have a **cataract** or other problem with the lens or **vitreous** of your eye, it is unknown whether PRK procedure is safe and effective under this condition.
- If you have any conditions of 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 PRK procedure may not be safe effective for you.
- Treatment zones larger than 6.5 millimeters in diameter were not investigated in the clinical trial. It is unknown whether PRK with WaveLight® EX500 Laser System using treatment zones larger than 6.5 millimeters is safe and effective.
- You should discuss the risks with your doctor for any PRK corrections that will not fully correct for distance vision, especially if performed only in one eye.
- If you have **mixed astigmatism**, it is unknown whether PRK procedure is safe and effective for you.

- Your **nearsightedness** is worse than - 6.00 diopters (D) or nearsightedness with astigmatism is worse than - 6.00 diopters (D) with up to - 3.0 diopters (D) of astigmatism and up to - 6.00 diopters (D) MRSE at spectacle plane, because it is unknown whether PRK procedure is safe and effective for you.
- **Large pupils.** Before the procedure your doctor should analyze your pupil size under dim lighting conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to the procedure. 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 the procedure. You may have dry eyes after PRK procedure even if you did not have dry eyes before the procedure.
- **FDA-approved treatment range.** Up to - 6.0 diopters (D) of nearsightedness, or nearsightedness with astigmatism, with up to - 6.0 D and up to - 3.0 D of astigmatic component and up to - 6.00 diopters (D) MRSE at spectacle plane. PRK 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.** If your eyes are squint-eyed, it is unknown whether PRK procedure is safe and effective under this condition.
- If you have a decreased vision in one eye, it is unknown whether PRK procedure is safe and effective under this condition.
- If there is an infection or problem with healing after the procedure, 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 PRK procedure or by wearing glasses or contact lenses that compensate for the difference.
- The effects of the WaveLight® EX500 Laser System on implantable medical devices (such as a heart pacemaker) are unknown.
- The safety and effectiveness of the WaveLight® EX500 Laser System was not investigated in pregnant and nursing women. It is unknown whether the PRK procedure with the WaveLight® EX500 Laser System is safe and effective in pregnant and nursing women. If you are pregnant or nursing, you should discuss the risks and benefits of undergoing PRK with your doctor.

## 8. ARE YOU A GOOD CANDIDATE FOR PRK?

You are a good candidate for PRK if you:

- Are at least 18 years of age and have nearsightedness with or without astigmatism
- Are **nearsighted** up to - 6.00 diopters or nearsightedness with astigmatism is up to - 6.00 diopters up to - 3.0 diopters of astigmatism and up to - 6.00 diopters (D) MRSE at spectacle plane
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g., scar, infection, etc.; see Contraindications)
- Have documented evidence that our refraction did not change by more than 0.5 diopters during the year before your pre-operative examination
- Are informed of risks and benefits as compared to other available treatments for nearsightedness with or without astigmatism
- Are able to lie flat without difficulty
- Are able to tolerate local or topical anesthesia
- Are willing to sign an informed consent form as provided by your eye care professional
- Are able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

Surgical alternatives to PRK include **Laser Assisted In Situ Keratomileusis (LASIK)**, radial keratotomy, automated lamellar keratoplasty and clear lens exchange. Like PRK, LASIK uses an excimer laser to reshape the cornea, but a **flap** of corneal tissue is first made and lifted prior to applying the laser light to the cornea. Ask your physician whether you might be a better candidate for LASIK than PRK. Non-surgical alternatives to PRK are wearing glasses or contact lenses.

## 9. WHAT ARE THE BENEFITS OF HAVING PRK?

PRK surgery, as performed with the WaveLight® EX500 excimer laser system, is effective in reducing nearsightedness up to - 6.00 diopters with or without refractive astigmatism up to - 3.00 diopters and up to - 6.00 diopters (D) MRSE at spectacle plane. It may also reduce or eliminate dependency upon contact lenses or glasses.

While it is reasonable for patients to expect to perform distance tasks without glasses following PRK surgery, a significant number of patients will not achieve 20/20 vision without glasses or contacts due to surgical under correction or overcorrection. Furthermore, as you age, your vision will likely change so that you may need glasses to see up close even if you can still see clearly at distance without glasses.

## 10. WHAT ARE THE RISKS OF HAVING PRK?

The risks of PRK include complications that can be observed by the doctor, and those that may be directly experienced by the patient.

The risks of PRK that may be **observed by the doctor** include, but are not limited to, the following:

- **Loss of vision.** This means that vision becomes unclear (blurry or hazy vision) even with glasses or contact lenses. Your doctor may be able to measure this loss using a vision chart. The loss may be mild or, in rare cases, severe. In extremely rare cases, people can experience a total loss of vision. Vision loss is usually temporary, but there are complications of PRK that can cause permanent loss of vision. How clearly you can see may change from day-to-day or even from minute-to-minute (fluctuating vision). Some of the potential causes of vision loss following PRK surgery are discussed below.
- **Corneal complications.** The following corneal complications may lead to permanent vision loss, for example, due to loss of corneal clarity from scarring or swelling, and may require corneal transplant surgery for treatment:
  - **Infection.** The cornea may get infected right after surgery. This can be treated with topical medication, which may or may not successfully control the infection. On rare occasions, an infection may cause a hole in the clear covering of the eye (perforation of the cornea).
  - **Inflammation.** Excessive inflammation is the body's reaction to tissue disruption, for example, from surgery or infection. Inflammation of the cornea can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal clarity) depending on the severity and response to steroid treatment.
  - **Treatment or healing results in irregular corneal shape or loss of corneal clarity.**
    - **Bulging of the cornea** is probably the most extreme irregularity. This complication is uncommon, but can cause permanent and significantly blurry vision, sometimes requiring corneal transplant.
    - **Smaller irregularities in the shape of the cornea** can be measured by the doctor using special instruments. These can cause blurry vision or unwanted images.
- **Retinal detachment.** The retina is the light-sensitive tissue that lines the interior back of the eye and captures images transmitted to the brain, much like the film of a camera. If the retina detaches, or comes unglued from its attachments within the eyeball, it will lose its function and need to be reattached through surgery. This may result in permanent loss of vision in some instances even if the retina is successfully reattached. Retinal detachment after PRK is rare, and usually only occurs in people who are very nearsighted and are prone to this type of retinal problem.

- **Desired correction not achieved or doesn't last.** PRK may not result in the desired amount of vision correction, or the level of vision correction may decrease over time. Additional corrective surgery may not always be possible, and when it is possible may again not result in the desired correction. Even if your vision results are generally good, you may still need glasses or contact lenses to perform certain tasks, such as reading.
- **Drooping eyelid.** The lid of the eye(s) that had surgery may droop. This can be a temporary, in rare instances permanent complication from an instrument used to hold the lid during surgery. Besides the appearance of unevenness in the height of the eyelids, this may result in a feeling of the eyes getting tired during the course of the day or difficulty seeing, and may require eyelid surgery in extreme cases.

The risks of PRK that are directly related to the **patient's experience and perceptions** include, but are not limited to, the following:

- **Dry eyes.** PRK may cause or increase eye dryness, which may also cause discomfort and visual problems in severe untreated cases. The doctor may see dry spots on the normally moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go away and may require additional treatment/intervention.

If you have dry eye before surgery, PRK may increase dry eye symptoms and related problems after surgery. Your doctor should test you for pre-existing dry eye prior to surgery. However, even if dry eye tests before surgery are normal, there is no test to guarantee that you will not get a dry eye problem after PRK. Lubricating drops are usually necessary immediately after surgery to help with dryness. Symptoms of dry eye may include a scratchy or sandy feeling as if something is in the eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, light sensitivity, and blurred vision. The sensation of dryness can vary from mild to severe, but in most cases the feelings are a minor annoyance. Eye drops such as artificial tears, or other treatments, such as plugs in the tear drainage system of the eye, may reduce these symptoms, but may not completely resolve them. A small number of patients experience extreme discomfort that interferes with their ability to do daily tasks.

- **Visual Symptoms.** PRK may cause or worsen visual symptoms such as glare, halos, starbursts, and ghost images/double images, most commonly experienced in dim lighting conditions, and blurred and fluctuating vision. These problems usually improve within 3 to 6 months after surgery, but in some cases never go away, even when glasses are worn. Visual symptoms can be mild, but can also be severe enough to cause difficulties in performing daily tasks. **A common complaint is difficulty with driving at night.** Specific visual symptoms are described below.
  - **Glare.** Glare is *difficulty seeing well when there are bright lights like headlights or sunlight.*
  - **Halos.** You may see halos. By halos, we mean *seeing a fuzzy cloud of light around lighted objects.*
  - **Starbursts.** You may see *rays of light coming from lighted objects.*

- **Double images.** Double images, which some people call “ghost” or “shadow” images, are distorted or blurry visual images. If you experience such images, close one eye and then the other to determine if you only see the double images with both eyes open. If you still have double images with one eye closed, note in which eye you are experiencing the double images. This information is important to report back to your doctor to help him or her determine the cause of the problem.
- **Decreased ability to see under low lighting conditions.** You may have more difficulty seeing in low lighting conditions after surgery than before surgery. For example, some patients describe having more trouble reading the menu in a dimly lit restaurant or climbing down stairs in a theater. Driving during certain periods of the day, such as dusk and dawn, may become difficult, because of trouble reading signs, distinguishing the curb from the road, and being able to see people crossing the street. Some people have reported having so much difficulty seeing under these types of conditions that they avoid doing certain activities they used to enjoy.
- **Permanent difficulty seeing in dim lighting, rain, snow, fog, or bright glare.** Visual impairment under these conditions (seeing in dim lighting, rain, snow, fog, or bright glare) was not studied; hence it is difficult to predict the possibility and severity of visual impairment in these conditions.
- **Discomfort or pain.** It is not unusual for patients to have some discomfort right after PRK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities.
- **Unintentional imbalance between two eyes.** PRK may cause a visual imbalance between the two eyes if the desired correction is not achieved, or one eye is treated with PRK but the other eye cannot undergo treatment. Imbalances between the two eyes may cause headaches, eyestrain, double vision, and reduced depth perception, if both eyes are not able to focus at the same time at the same distance.
- **Need for glasses for close work.** Almost all people in their 40s or older lose their ability to focus from far to near. PRK does not treat this condition (called “presbyopia”). After surgery, patients who are already over 40 years old (or once they reach their 40’s) usually need to wear glasses for close work, such as reading, even if they did not need to wear them before surgery.

Some problems that patients experience commonly occur during the early period following PRK surgery and are usually greatly reduced within 3 to 6 months. However, in some patients these problems can be permanent and, in rare cases, may impact their ability to perform daily tasks.

See the chapter 15 “Summary Of The Clinical Study Results” on page 33, to find out how often specific problems occurred in those treated with the ALLEGRETTO WAVE EYE-Q laser in the study for FDA approval.

## 11. WHAT WILL HAPPEN BEFORE, DURING AND AFTER PRK?

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

PRK 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 PRK surgery, you will have a complete examination of your eyes before surgery. This will determine if your eyes are healthy and suitable for the surgery.



### **CAUTION**

- 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 those 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 surgery.
- 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**

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

The surface of the cornea will be removed using a surgical tool. You will be moved with the bed under the laser. Look up to the lights (see figure 5). 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 the PRK procedure. Stare at the green blinking light only to ensure that the treatment occurs in the correct location on your eye.
- Do not move your head during the surgery to ensure that the treatment occurs in the correct location on your eye.

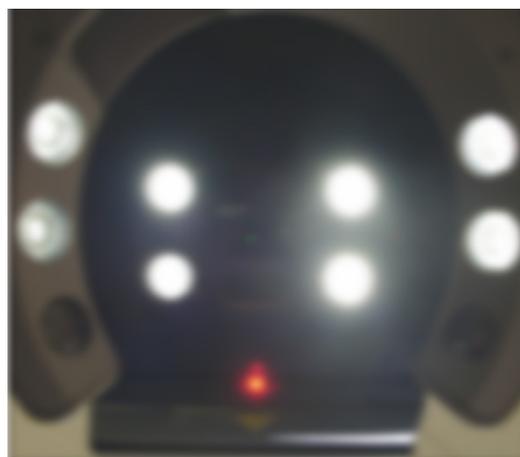


Figure 5: Examples Of Patients View Under The Laser (Crisp And Blurred)

The doctor will place an instrument between your eyelids to hold them open during the procedure. 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 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 a buzzing sound as the laser removes tissue and a suction noise above your head. Although the eyetracker will follow movements of your eye you should stare at the blinking green light throughout the treatment. If you move your eye too far, the tracker will interrupt the 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 PRK procedure will take about 5-10 minutes per eye.

Your doctor then removes the device holding your eyelid. A bandage contact lens and eye drops will be applied to your eye.

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 approximately the first 4 days following the surgery. Your doctor may prescribe pain medication to make you feel more comfortable during this time

**First Days after Surgery:**

You will need to use eye drops after surgery. The eye drops include **antibiotics**, eye drops or oral medication for pain, ocular **steroids** and lubricant eye drops. Use each medication as directed by your doctor.

You can begin to use lotions, creams, or make-up around the eye area after the surgery as instructed by your doctor. You should wait after the surgery before participating in any sports, depending on how you feel and any instructions from your doctor. You should also avoid swimming or using hot tubs after the surgery to avoid the possibility of infection.

**CAUTION**

- Do NOT rub your eye during the first week after surgery even if it feels itchy. Your doctor may provide a plastic shield to protect your eye during this period. If so, you should wear the shield.
- Some possible side effects of ocular steroids are eye pressure, glaucoma or cataract. Read the patient information that comes with your medication to learn more about it.
- Your results depend upon following your doctor's directions for using all medications. Not following your doctor's directions might lead to poor treatment results
- Severe eye pain or sudden loss of vision can be a sign of a serious problem. Contact your doctor immediately if you notice any severe pain, sudden change, or loss of vision in your eye.

If your doctor fixed 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 PRK.

## 12. WHAT SHOULD YOU ASK YOUR DOCTOR?

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

### 13. SUMMARY OF IMPORTANT INFORMATION

- PRK is a permanent operation to the cornea and cannot be reversed
- PRK involves the use of a laser to permanently remove corneal tissue to correct low to moderate nearsightedness with or without low astigmatism.
- PRK 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 PRK surgery.
- Some alternatives to PRK surgery include, but are not limited to glasses, contact lenses and LASIK.
- Your vision must be stable at least one year before the pre-op examination to be eligible for PRK. You will need written evidence that your nearsightedness and astigmatism have changed only 0.5 diopters or less.
- Pregnant or nursing women do not qualify for PRK surgery.
- You are not a good candidate for PRK if you have a **collagen vascular disease** (such as rheumatoid arthritis) or **autoimmune disease** (such as lupus) or have a condition that makes wound healing difficult.
- PRK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery.
- PRK is not a laser version of RK; these surgeries are completely different from each other.
- Before considering PRK surgery, you should
  - a) Have a complete eye exam.
  - b) Talk with one or more eye care professionals about the potential benefits, risks and complications of PRK. You should also discuss the time needed for healing, the discomfort you may experience or problems that may occur during this time.
- A potential benefit of PRK is to have normal vision (20/20 visual acuity) without glasses after surgery. Your nearsightedness with or without astigmatism may not be fully corrected and you may still need to wear glasses or contact lenses. In addition, you may need reading glasses, even if you did not wear them prior to the PRK surgery.
- The risks of PRK include corneal **haze**, dry eye, glare, halos, starbursts, eye pain, burning feeling in eyes, eyes sensitive to light, blurry vision, fluctuation of vision, difficulty focusing in dim or low light, watery eyes and feeling like something is in your eyes. Corneal infiltrates and corneal edema are also possible risks but occur very infrequently.

## 14. FREQUENTLY ASKED QUESTIONS

### **Is PRK treatment permanent?**

- The portion of your cornea removed by PRK treatment does not regrow at this layer of your cornea.
- The level of vision correction may decrease over time; the effectiveness of PRK with WaveLight® EX500 beyond 12 months has not been investigated.

### **Will I be able to see sharply at a distance (visual acuity) without glasses after PRK surgery?**

The goal of PRK in the correction of low to moderate nearsightedness with or without low astigmatism is to reduce or eliminate the need for glasses or contact lenses to see at distance. In the clinical study of the ALLEGRETTO WAVE EYE-Q (which is equivalent to the WaveLight® EX500 Laser System) for nearsightedness with or without astigmatism, 93% of eyes had normal vision (visual acuity of 20/20 or better) without glasses. There is a chance that your nearsightedness with or without astigmatism may not be fully eliminated and you may need to wear glasses or contact lenses to see sharply at distance.

### **Will I need reading glasses after PRK surgery?**

You may need to wear reading glasses after PRK to correct presbyopia even though you did not need to wear reading glasses before PRK. PRK does not prevent future changes in the focusing power of your eye that occurs with presbyopia, a condition that occurs naturally due to aging.

### Will my vision be perfect after PRK surgery?

As with any surgical procedure, there are risks associated with PRK surgery. Below are some conditions that may prevent you from having perfect vision after the PRK:

- 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. If the result of the surgery is not satisfactory, you may need to wear glasses or contact lenses. In the clinical study, no eyes were overcorrected by 1 or 2 diopters and only one eye was undercorrected by more than 1 diopter.
- A special type of astigmatism - known as irregular astigmatism - may occur after PRK surgery that may affect your vision. In this condition, the cornea does not heal smoothly and you may need to wear hard (gas permeable) contact lenses to achieve best vision. Irregular astigmatism may lessen over several weeks or months.
- Glare, halos and starbursts are not uncommon after PRK surgery. As seen in the clinical study, 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**.
- Infection of the eye is a potential complication following PRK surgery that could lead to vision problems. 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.
- **Cataracts**, which may affect your vision, could form because of the long term use of steroids after the PRK procedure.

### What risks are associated with the surgical procedure?

A summary of the risks as observed in the clinical study are described in chapter 10 "What Are The Risks Of Having PRK?" on page 22.

### 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 PRK or by wearing glasses or contact lenses that compensate for the difference.

## 15. SUMMARY OF THE CLINAL STUDY RESULTS

### Clinical Study Information:

A clinical study was conducted at 8 clinical sites in the US to evaluate the benefits and risks of the ALLEGRETTO WAVE EYE-Q excimer laser system used for PRK. A total of 320 eyes from 161 patients with low to moderate nearsightedness, with or without low astigmatism had PRK. Assessments performed during the study included vision testing with and without glasses, measurement of the errors of the eye, evaluation of the health of the eyes patients. Study visits occurred before and after PRK at scheduled times up to 24 months. The results for up to 12 months are included in this booklet.

Patients who agreed to be involved in the clinical study provided informed consent and completed the required screening procedures to determine study eligibility. Patients had at least one eye with nearsightedness up to - 6.00 diopters with or without astigmatism up to - 3.00 diopters.

The study was conducted with the ALLEGRETTO WAVE EYE-Q excimer laser system. This booklet is for the WaveLight® EX500 excimer laser system which is expected to produce similar clinical results as the ALLEGRETTO WAVE EYE-Q excimer laser system because non-clinical data submitted to **FDA** show that the two laser systems are similar.

The results of the study showed that it takes 6 months for the eye to be stable after PRK for low to moderate nearsightedness with or without low astigmatism. The study results for up to 12 months are described below.

### Clinical Study Results:

#### **Vision without Glasses Before And After PRK**

The doctors in the clinical study measured vision without glasses (uncorrected visual acuity [UCVA]) before and after PRK.

Six months after PRK, UCVA was as follows:

- All of the 314 eyes had UCVA of 20/40 or better.
- 292 of the 314 eyes had UCVA of 20/20 or better.

The UCVA results at 6 months were consistent with the results after 6 months.

#### **Vision Without Glasses After PRK Compared To Vision With Glasses Before PRK**

How well eyes were able to see without glasses after PRK compared to their vision with glasses before PRK is presented below. At 6 months after PRK:

- 215 of the 314 of eyes had vision without glasses that was equal to or better than their vision with glasses prior to PRK.

The doctors in the clinical study evaluated the risks of having PRK by measuring vision with glasses (best spectacle corrected visual acuity [**BSCVA**]) and astigmatism before and after PRK for low to moderate nearsightedness with or without low astigmatism. Additionally, adverse events were evaluated. An adverse event is defined as unexpected medical occurrence, unintended disease or injury, or unexpected clinical signs whether or not related to PRK or the ALLEGRETTO WAVE EYE-Q excimer laser system.

### Vision with Glasses after PRK

At 6 months after PRK:

- None of the eyes had vision with glasses that was worse than 20/40.
- None of the eyes lost 2 or more lines of vision with glasses compared to before PRK.
- None of the eyes had induced astigmatism of greater than 2 D as compared to baseline.

The BSCVA results at 6 months were consistent with the results after 6 months.

### **Adverse Events:**

Adverse events were classified as serious and non-serious depending on how they affected the patient's health. No unanticipated adverse events were observed in this study.

The serious adverse events in this study were:

- 1 event of **corneal edema** at approximately 5 months after PRK
- 2 events of corneal infiltrate at 1 day and 4 days after PRK

These 3 events were reported as unrelated to the ALLEGRETTO WAVE EYE-Q excimer laser but related to the PRK procedure.

Some of the non-serious adverse events were collected based on patients' responses to a questionnaire that evaluates symptoms associated with PRK. The questionnaire is called the Visual Symptoms Associated with Refractive Correction (VSARC). The absence of a symptom was rated as "none", and the presence of a symptom was rated as "mild", "moderate" or "severe".

The rates shown below are based on the total number of eyes experiencing an adverse event type up to 12 months.

Adverse events reported based on the patients' responses to the VSARC questionnaire are shown below for 320 eyes that participated:

### Dry eyes

64 eyes with symptoms of dry eye that significantly affected comfort or activities of daily living at 6 months or later.

35 eyes with moderate or severe dry eye at 6 months or later.

### Glare or Halos

14 eyes with glare or halos that significantly affect comfort or activities of daily living at 6 months or later.

2 eyes with moderate or severe glare at 6 months or later.

10 eyes with moderate or severe halos at 6 months or later.

### Starbursts

4 eyes with moderate or severe starbursts at 6 months or later.

### Eye pain

13 eyes with moderate or severe eye pain at 6 months or later.

### Burning feeling in eyes

10 eyes with moderate or severe burning feeling in eyes at 6 months or later.

### Eyes sensitive to light

19 eyes with moderate or severe eyes sensitive to light at 6 months or later.

### Blurry vision

6 eyes with moderate or severe blurry vision at 6 months or later.

### Fluctuation of vision

6 eyes with moderate or severe fluctuation of vision at 6 months or later.

### Difficulty focusing in dim or low light

2 eyes with moderate or severe difficulty focusing in dim or low light at 6 months or later.

### Watery eyes

5 eyes with moderate or severe watery eyes at 6 months or later.

### Feeling like something is in the eyes.

14 eyes with moderate or severe feeling like there is something in eyes at 6 months or later

**Bolded** words can be found in the glossary

The symptoms below were also collected by the VSARC questionnaire but these symptoms were reported, for the most part, without the doctor making an evaluation about whether they were an adverse event.

- 23 out of 320 eyes with moderate or severe feeling like something is in the eyes at 1 month or later.
- 30 out of 320 eyes with moderate or severe ghost or double image.
- 22 out of 320 eyes with moderate or severe pain at 1 month or later.

Below is information for the adverse events whereby more events were not resolved versus resolved by 12 months after PRK.

- 33 out of 64 events of any symptom of dry eye that significantly affect comfort or activities of daily living at 6 months or later were not resolved.
- 22 out of 35 events of moderate or severe dry eye at 6 months or later.
- 7 out of 13 events of moderate or severe eye pain at 6 months or later.
- 8 out of 14 events of moderate or severe feeling like there is something in the eyes at 6 months or later.
- 10 out of 19 events of moderate or severe eyes sensitivity to light at 6 months or later.
- 6 out of 10 events of moderate or severe blurry vision at 6 months or later.
- 3 out of 5 events of moderate or severe watery eyes at 6 months or later.

Non-serious adverse events reported by the doctor that were not reported based on the patients' responses to the VSARC questionnaire are shown below for 320 eyes that participated:

1 eye with clinical signs consistent with moderate to severe dry eye at 6 months or later	3 eyes with recurrent <b>corneal erosion</b> at 1 month or later
1 eye with change in visual depth perception (3-dimensional vision)	1 eye with <b>chalazion</b>
1 eye with <b>conjunctival hyperemia</b>	2 eyes with <b>conjunctivitis</b>
5 eyes with allergic conjunctivitis	1 eye with viral conjunctivitis
3 eyes with scratched on the corneal	1 eye with corneal disorder
3 eyes with <b>corneal epithelium</b> defect	3 eyes with <b>corneal erosion</b>
1 eye with swelling of the cornea	18 eyes with corneal opacity (white or cloudy cornea)
4 eyes with dry eye	1 eye with <b>episcleritis</b>
6 eyes with eye allergy	3 eyes with eye pain
1 eye with eyelid inflammation	1 eye with feeling like there is something in the eyes
1 eye with <b>halo</b>	1 eye with <b>hordeolum</b>
1 eye with <b>iritis</b>	3 eyes with <b>keratitis</b>
2 eyes with <b>meibomian gland dysfunction</b>	2 eyes with eyes sensitive to light
1 eye with <b>starbursts</b>	5 eyes with <b>punctate keratitis</b>
3 eyes with vision blurred	1 eye with vision reduced
2 eyes with vision loss or decreased vision	2 eyes with <b>vitreous floaters</b>

**Bolded** words can be found in the glossary

Contrast sensitivity (the ability to see objects that may not be outlined clearly or that do not stand out from their background) is usually tested under various lighting conditions. Below are the results of contrast sensitivity for subjects in the study:

- At 12 months after PRK:
  - 88 out of 311 eyes had significantly better contrast sensitivity in dim light with a glare source
  - 70 of 311 eyes had significantly better contrast sensitivity in dim light without a glare source
  - 42 of 311 eyes had significantly better contrast sensitivity in bright light with a glare source
  - 33 of 311 eyes had significantly better contrast sensitivity in bright light without a glare source
  - 19 out of 311 eyes had significantly worse contrast sensitivity in dim light with a glare source
  - 20 of 311 eyes had significantly worse contrast sensitivity in dim light without a glare source
  - 21 of 311 eyes had significantly worse contrast sensitivity in bright light with a glare source
  - 10 of 311 eyes had significantly worse contrast sensitivity in bright light without a glare source
  - 204 out of 311 eyes had no significant change in contrast sensitivity in dim light with a glare source
  - 221 of 311 eyes had no significant change in contrast sensitivity in dim light without a glare source
  - 248 of 311 eyes had had no significant change in contrast sensitivity in bright light with a glare source
  - 268 of 311 eyes had had no significant change in contrast sensitivity in bright light without a glare source

### **Outcomes Reported By Patients Via Questionnaires**

#### Patient Evaluation of Symptoms Associated with PRK

Results from the VSARC questionnaire were as follows:

- Symptoms that had a higher rate at 6 months or later compared to before PRK were: eye pain, dry eye, burning feeling in eyes, starbursts, eyes sensitive to light, fluctuation in vision and feeling like there is something in the eyes.
- At 6 months after PRK, a small percentage of patients (up to 4.4%) rated the following symptoms as moderate or severe: eye pain, dry eye, burning feeling in eyes, eyes sensitive to light, halos, starbursts, blurry vision, fluctuation in vision, difficulty focusing in dim or low light, and feeling like there is something in their eyes.
- At months 9 to 12 after PRK, the results were consistent with or better than the results at 6 months after PRK.
- Most patients rated the symptoms as none or mild for all visits up to 12 month.

Vision-Related Health Status Patients were given another questionnaire called the Refractive Status and Vision Profile (RSVP). The RSVP was developed in patients needing corrective lenses to measure a patient's evaluation of his or her vision-related health status. The RSVP questionnaire was completed before and after PRK. At 6 months after PRK, patients did not experience worsening of their vision-related health status on average.

## 16. PATIENTS 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) PRK surgery is a permanent procedure.	<input type="checkbox"/>	<input type="checkbox"/>
b) PRK surgery is free of risks.	<input type="checkbox"/>	<input type="checkbox"/>
c) It doesn't matter if I wear my contact lenses when my doctor told me not to wear them.	<input type="checkbox"/>	<input type="checkbox"/>
d) I may need reading glasses after PRK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
e) There is a risk that I may lose some vision after PRK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
f) It's ok to have PRK surgery if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
g) It matters if I take medication with ocular or healing side effects like Cordarone®, Imitrex® or Accutane®.	<input type="checkbox"/>	<input type="checkbox"/>
h) After surgery there is a very good chance that I am less dependent on eye glasses.	<input type="checkbox"/>	<input type="checkbox"/>
i) Since the WaveLight® EX500 uses an eyetracker, I do not have to fixate the blinking light during laser treatment.	<input type="checkbox"/>	<input type="checkbox"/>
j) Even if my refraction was changing a lot over the last year, I am still a good candidate for PRK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
k) PRK surgery is the same as LASIK	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers in chapter 18 "Answers To Self-Test Questions" on page 42.

**17. WHERE CAN YOU GET MORE INFORMATION?**

**Primary Eye Care Professional:**

Name:  
Address:  
Phone:  
Email:

**PRK 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

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**18. ANSWERS TO SELF-TEST QUESTIONS**

- a) True (see page 30 and page 31)
- b) False (see page 22, page 30 and page 32)
- c) False (see page 25)
- d) True (see page 31 and page 32)
- e) True (see page 32 and page 33)
- f) False (see page 30)
- g) True (see page 25)
- h) True (see page 21, page 30 and page 31)
- i) False (see pages 26-27)
- j) False (see page 30)
- k) False (see page 14)

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