



INFORMED CONSENT FOR

PHOTOREFRACTIVE KERATECTOMY (PRK) VISION CORRECTION

Custom PRK is one type of surgery used to correct the refractive errors, which impair your ability to see without glasses or contact lenses. Your blurry vision is caused by a mismatch between the shape of your cornea and the length of your eye.

The cornea is the part of the eye that helps focus light to create an image on the retina. It works much the same way that the lens of a camera focuses light to create an image on film. The bending and focusing of light is also known as refraction. Usually the shape of the cornea and the eye are not perfect and the image on the retina is out-of-focus (blurred) or distorted. These imperfections in the focusing power of the eye are called refractive errors.

There are four primary types of refractive errors: myopia, hyperopia, astigmatism and presbyopia. Persons with myopia, or nearsightedness, have more difficulty seeing distant objects as clearly as near objects. Astigmatism is a distortion of the image on the retina caused by irregularities in the cornea or lens of the eye. Combinations of myopia and astigmatism or hyperopia and astigmatism are common. Presbyopia is a condition that generally occurs in your 40's. The eye muscles lose their ability to focus on close objects. Glasses or contact lenses are designed to compensate for the eye's imperfections. Surgical procedures aimed at improving the focusing power of the eye are called refractive surgery.

In PRK surgery, an excimer laser reshapes the cornea, changing its focusing power. PRK can correct for nearsightedness, farsightedness or astigmatism.

Custom PRK is a procedure in which the excimer laser is used to reshape the cornea to properly focus light rays on the retina (back of the eye). First, your surgeon will remove the corneal epithelium (protective outer layer of the cornea). Laser pulses will then be applied to the stromal bed (inner corneal layer) to re-shape the cornea. The reshaping portion of the surgery usually takes less than a minute. After the laser is complete, the surgeon may place a medication on the eye to reduce the risk of haze formation. The surgeon will then place a contact lens on the eye, which acts like a bandage. This lens will stay on until the epithelial layer has completely healed. This usually takes a few days to a week. While the contact lens is on the eye, the vision is generally blurry. This will improve over time.

I have read and understand this page. Please Initial _____

RISKS

Custom PRK is able to correct a range of prescriptions, but we do not want you to feel we are making the procedure sound too easy, simple, or that the procedure is perfect or guaranteed. No surgery can be guaranteed to be 100% successful. As with any surgical procedure, there is the risk of complications.

Possible complications include:

(1) Problems during surgery, (2) problems during the first six months after surgery, and/or (3) problems more than six months after surgery.

Possible Problems during Surgery

Laser Reshaping in the Wrong Location: Although Custom PRK is performed with advanced eye tracking systems, it is possible that the laser treatment pattern not be centered correctly on the pupil and visual axis. Such decentration typically results in night glare symptoms and induced astigmatism, often reducing the patient's quality of vision.

Possible Problems during the First Three Months after Surgery

Foreign Body Sensation, Glare, Haziness of Vision and Tearing: During the first few days following PRK, it is very common for patients to experience pain or a foreign body sensation while the epithelium is healing. Some patients may experience increased sensitivity to light, vision fluctuation, or haziness of their vision. These conditions may persist during the normal stabilization period of up to 6 months, but in rare cases, may be permanent.

Infections: Mild or severe infection is possible. Mild infection can usually be treated with topical antibiotics, and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring of the cornea and blurred vision. Very severe cases may result in the need for a corneal transplant, or result in the loss of the eye.

Haze: Corneal healing problems with PRK are more likely to be experienced by patients corrected for higher degrees of nearsightedness, farsightedness and astigmatism. Higher degrees of correction may potentially slow visual recovery and increase the need for enhancement procedures. Healing haze or scar tissue may be produced with PRK. Healing haze consists of collagen proteins, which develop on the surface of the eye during normal PRK healing. Mild haze may not be noticeable by the patient and usually clears over time. However, more severe haze typically presents as a dirty windshield type of appearance to your vision. Haze is not the initial blurriness you will experience post-operatively but may become evident over several weeks or months. If scar tissue develops, it can usually be treated with another laser procedure. In some cases a treatment with medication may be considered to reduce scar tissue. Scarring may be persistent or infrequently, recurrent, requiring multiple surgeries and possibly producing loss of visual sharpness or overcorrection. Dependent on your particular case, the surgeon may elect to use medication on your cornea during the procedure to reduce risk of developing haze.

I have read and understand this page. Please Initial _____

Steroid complications: Post-operative drops are typically used up to 4 months, in some cases, up to 6 months, tapering monthly. Patients must be monitored monthly while using topical steroid drops. For optimal results, patients must use the medication as prescribed. Your doctor may adjust the medication if required based on your healing pattern. It is very important to follow your doctor's instructions regarding the use of eye drops as this can affect your final outcome. During the initial healing process, the purpose of the drops is to reduce redness, swelling and light sensitivity. In the later stages, it is to promote normal healing and to reduce haze. Excessive use can increase eye pressure, produce eyelid drooping, promote farsightedness and rarely, promote cataract formation. Rapid discontinuation can promote regression and can increase haze. Careful monitoring while on topical steroid drops will reduce such risks.

Reading Vision, Vision Aids and Muscle Imbalance: While healing occurs, temporary glasses may be required, either for distance, or near vision. It is possible that dependence on reading glasses may increase, or that reading glasses may be required at an earlier age. If the procedure is performed on one eye only, balance problems between the two eyes may occur. This may cause eyestrain and make judging distance, or depth perception, more difficult. The first eye may take longer to heal than is usual, prolonging the time of balancing difficulties.

Possible Problems More than Six Months after Surgery

Refractive Error Not Treated Completely: Not every patient treated achieves 20/20 vision, primarily due to differences in the way patients heal. Some patients find it necessary to temporarily wear glasses after surgery. While this can be treated with an additional laser application, the ideal time for the second procedure is between 6 and 9 months after the initial procedure.

Irregular Astigmatism: Irregular Astigmatism following PRK is the term used to describe corneal irregularity that is not correctable with glasses. When the cornea has a significant degree of irregular astigmatism, there is a loss of sharpness, crispness and clarity. In these cases, a gas permeable contact lens is needed in order to restore vision.

Corneal Ectasia: One of the most serious complications is the development of corneal ectasia. This occurs when there is a loss of corneal stability or strength, resulting in thinning and bulging of the cornea. This is believed to be caused by a genetic condition known as Keratoconus, that was undetected and accelerated by PRK. If a patient develops Corneal Ectasia, they may need to wear a gas permeable contact lens to correct vision, have collagen cross linking or may even require a corneal transplant.

Dry Eye: Following PRK surgery, is the increased risk of eye irritation related to drying of the corneal surface. This is known as "dry eye". These symptoms may be temporary, lasting 1-6 months, or, on rare occasion be permanent, and may require frequent use of artificial tears, ointment, prescription medication, or other dry eye treatment methods. Although Dry Eye sounds rather innocuous, it can be quite debilitating, affecting both vision and comfort. Patients with significant dry eye symptoms prior to surgery should avoid having PRK.

I have read and understand this page. Please Initial _____

Night Glare and other Night Visual Disturbances: Immediately after refractive surgery, most patients experience night glare around headlights or other similar situations, usually described as "starbursting" or a "halo" effect around lights. Others may simply experience a general reduction in the sharpness of their vision under low-light situations, affecting their general ability to drive at night, or see well in dim light. This is usually a temporary condition that improves over 6 months. Patients with very high prescriptions and pre-operative night vision difficulties are at greatest risk for decreased night vision.

ALTERNATIVE TREATMENTS

Custom PRK is an elective procedure. It is not necessary for you to undergo this procedure in order for you to see. You may continue to wear glasses or contact lenses and forgo surgery altogether. Alternatively, you may be able to have a different surgical procedure such as LASIK or LASEK.

PRESBYOPIA

When we are young, the lens inside our eye is extremely flexible, and allows us to focus easily on close objects. Over time, the lens gradually loses its flexibility, which makes it more difficult to focus on close objects. This condition is called Presbyopia, and is a normal part of the aging process. Presbyopia happens to everyone, even those who have never had a vision problem before. As the condition progresses, most patients begin to hold things farther away, and require brighter light to see clearly. At this stage, most patients will require reading glasses, bifocals or a progressive multifocal, to help focus objects that are close. It is important to note that if you use reading glasses now, you will likely need them after refractive surgery, unless you and your physician discuss other options in advance.

Monovision is another option to aid reading vision and manage presbyopia. Monovision requires leaving one eye slightly nearsighted after surgery. The goal of Monovision treatment is to allow one eye to focus for distance, and the other eye to focus for reading. Patients may feel less balanced unless they have used Monovision contact lenses in the past, and will definitely notice that the monovision eye is blurry for distance.

Monovision will not eliminate the need for reading glasses for all near tasks in all lighting conditions, but may greatly reduce your dependence on them. You may notice with Monovision, an increase in night vision disturbances. The majority of patients do not notice this when using both eyes simultaneously.

I have read and understand this page. Please Initial _____

TREATMENT OF ONE OR BOTH EYES SAME DAY

Today, the vast majority of refractive surgeries are performed on both eyes on the same day. Many patients prefer having both eyes treated at once, as it is more convenient. Operating on both eyes will help you avoid having an imbalance between the corrected eye and the uncorrected eye, making it far easier to drive. Many patients note improved depth perception, and faster resolution of night glare.

Naturally, there are definite risks with having surgery performed on both eyes on the same day. For example, there may be unrecognized surgical or healing complications. Whether you choose to have surgery on both eyes on the same day, or on separate days, visual recovery from laser vision correction may be as brief as one day, or take several weeks or longer, depending on your healing pattern and the development of any unforeseen problems.

I ELECT TO HAVE:

(Please circle the appropriate term)

BOTH EYES TREATED TODAY

ONE EYE TREATED TODAY

I have read and understand this page. Please Initial _____

I CONFIRM THAT EACH OF THE FOLLOWING STATEMENTS IS TRUE AND ACCURATE:

I understand that Custom PRK is an elective procedure. There are alternatives to these surgeries. I could continue wearing contact lenses or glasses and have adequate visual acuity. I could also choose a different type of refractive surgery.

Initial _____

I have not received a guarantee of a successful outcome of my particular surgery. I understand the possible short- and long-term risks associated with Custom PRK and that there may be risks that are unknown at this time.

Initial _____

I understand that the correction I expect to gain from Custom PRK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances for the rest of my life. I understand that I may need glasses to refine my vision for some tasks requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

Initial _____

I understand that if I currently need reading glasses I will still need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery. I understand that if I am over 40 years of age and have both eyes corrected for clear distance vision, I will need reading glasses for many close tasks.

Initial _____

I verify that I am at least 18 years of age, I am not pregnant or nursing and that I must abstain from using any contact lens prior to my PRK procedure, as directed by my eye surgeon.

Initial _____

I confirm that I have disclosed my eye and general health history, including medications and allergies, to my eye doctor and eye surgeon. I confirm that I have told my eye doctor and eye surgeon if I have or have had any of the following eye conditions: glaucoma, cataracts, keratoconus, retinal or optic nerve disease, herpes simplex or herpes zoster (shingles) of the eye, lazy eye, strabismus (muscle imbalance), or prior refractive surgery.

Initial _____

LEGAL RESPONSIBILITIES AND DISCLOSURES:

CONFIDENTIALITY

By initialling below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Clarity Eye Institute, the Excimer laser manufacturer, and the governmental regulatory authorities. The data will be utilized for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Initial _____

GOVERNING LAW/JURISDICTION

By initialling below, you agree that the relationship and resolution of any and all disputes between yourself, the surgeon and Clarity Eye Institute, shall be governed by and construed in accordance with the laws of the Province of Ontario. You also acknowledge with your initials that the procedure was performed in the Province of Ontario and that the courts of the Province of Ontario shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in the Province of Ontario and you irrevocably submit to the exclusive jurisdiction of the Province of Ontario.

Initial _____

Please write in the box below, in your own handwriting the following statement. This will confirm that you understand and accept that laser vision correction is an elective surgical procedure and the result cannot be guaranteed.

"I have read and understand the above. "There are risks and no guarantees and I may still need to wear glasses."

I give the below named surgeon permission to perform Custom PRK in accordance with my instructions above.

PATIENT NAME (Please print): _____

PATIENT SIGNATURE: _____ DATE: _____

WITNESS SIGNATURE: _____ DATE: _____

SURGEON SIGNATURE: _____ DATE: _____