



Laser Vision Correction (Refractive Surgery) Consent Form

Photorefractive Keratectomy (PRK)

1. General information

The following information is intended to help you make an informed decision about having PRK Laser Vision Correction surgery to correct your vision.

It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or commonly known are not discussed. There may be long-term effects not yet known or anticipated at the present time. PRK with the Excimer laser has been approved for over fifteen years.

2. An overview of the Laser Vision Correction procedure

Diagnosis: You have myopia (nearsightedness) or hyperopia (farsightedness), with or without astigmatism.

Laser Vision Correction Surgery Described: Laser Vision Correction permanently changes the shape of the cornea. The surgery is performed with topical anesthetic (drops in the eye). The procedure involves displacing the surface layer of corneal tissue, then removing a thin layer of deeper corneal tissue (stroma) with ultraviolet light from an excimer laser. The cornea is usually protected with a contact lens for 3-7 days. The removal of thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, or steepen in the case of farsightedness, or become more rounded in the case of astigmatism. The focusing power of the cornea is permanently changed.

Limits of Laser Vision Correction: The goal of refractive surgery is to reduce your dependence on corrective lenses. This result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve vision adequate for your needs. Fewer than 10% of patients require additional correction. The accuracy of the correction depends in part on the magnitude of your correction, and on your individual healing.

Laser Vision Correction does not correct the condition known as presbyopia (aging of the eye) which occurs after age 40, and requires the use of reading glasses for near vision. If you presently need reading glasses, you will likely still need reading glasses after this treatment unless monovision is your choice (discussed separately). Even if you do not need reading glasses now, you will need them at a later age.

Refractive surgery will not prevent your developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment; however, it will not interfere in their treatment. Surface (vs lamellar) refractive surgery will not permanently worsen dry eyes. It may improve some surface conditions of the cornea, at least for several years.

3. Risks and contraindications

Risks: the risks of Laser Vision Correction surgery include, but are not limited to:

- *Loss of Vision:* Laser Vision Correction surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection (internal or external), corneal irregularity or scarring, and may require additional treatment, either medical or surgical. These complications are rare, but have been reported. The surgeon will discuss the risks of surgery that may be more likely in your case.
- *Visual Side-Effects:* Other conditions that can occur with Laser Vision Correction surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); hazy vision; fluctuating vision during the day, and from day to day; increased or decreased sensitivity to light that may be incapacitating for some time, and may not completely go away; glare and halos around lights which may not completely go away.
- *Overcorrection or Undercorrection:* It may be that Laser Vision Correction surgery will not give you the result you desired. Some procedures result in the eye being undercorrected. If this occurs, it may be possible to have additional surgery to improve the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by overtreating myopia) or nearsighted (by overtreating hyperopia). It is possible that your initial results could regress over time. In some, but not all cases, retreatment, glasses, or contact lenses could be effective in correcting vision.
- *Other Risks:* Other reported complications include: corneal ulcer formation; ptosis (droopy eyelid); corneal swelling; contact lens intolerance. Complications could also arise requiring further corrective procedures including either a partial or full thickness corneal transplant using donor cornea. There are also potential complications due to anesthesia and medications which may involve other parts of your body. It is also possible that the excimer laser could malfunction and stop the procedure. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.
- *Complications related to flap creation in Lasik:* In the case of Lasik, there could be complications related to the flap such as flap slippage, infection under the flap, inflammation under the flap, flap striae. PRK Laser Vision correction has none of these.
- *Later-discovered complications:* You should be aware that other complications may occur that have not yet been reported. Longer term results may reveal additional risks and complications. After the procedure, you should continue to have routine check-ups to assess the condition of your eyes.
- *Risks of Not Undergoing Laser Vision Correction:* The risks of not having the surgery are limited to those associated with your current visual condition and its correction (i.e., contact lenses). These include, but are not limited to: problems associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, the small risks of trauma to the eye caused by breakage of spectacles or contact lenses.
- *Keratoconus:* Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. This condition can develop at a later time even in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement), which are a routine part of our preoperative evaluation.

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- *Keratoconus may occur without your having the refractive surgery. There is no absolute test that will ensure a patient will not develop keratoconus sometimes years following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.*

Contraindications: those who may not be eligible to have Laser Vision Correction are people:

- with uncontrolled vascular disease
- with autoimmune disease
- who are immune-compromised or on drugs and/or therapy which suppress the immune system
- with signs of keratoconus (steeping of the cornea)
- possibly with a previous history of keloid formation
- who are pregnant, nursing, or expecting to become pregnant within the six months following the Laser Vision Correction procedure
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia, hyperopia or astigmatism in either eye
- with active or residual disease(s) likely to affect wound healing capability, like uncontrolled rosacea, allergy, or dry eye
- with severe nearsightedness, farsightedness or astigmatism that is outside the limits approved by the Food and Drug Administration
- with unstable or uncontrolled diabetes
- with progressive myopia or hyperopia
- with uncontrolled glaucoma

4. Alternatives to Laser Vision Correction

Laser Vision Correction is an elective procedure, and you may decide not to have this operation at all. Among the alternatives are:

- Eyeglasses/spectacles
- Contact lenses
- LASIK
- Radial keratotomy (RK)
- Orthokeratology
- Conductive keratoplasty (CK) (for farsightedness)
- Clear lens extraction (CLE), an intraocular procedure
- Intraocular contact lens (ICL), an intraocular procedure

Loss of best-corrected vision following Laser Vision Correction is rare (less than 0.5%), and most commonly due to an unusual healing response of the cornea (haze), especially when higher levels of correction are planned. This is preventable with the use of mitomycin C in cases where the depth of corneal ablation is over 80 microns. If it occurs, it is treatable in almost all cases.

5. Pre and post-operative care

Before the Laser Vision Correction surgery:

- *Pregnancy:* Pregnancy could adversely affect your treatment result, since your refractive error can fluctuate during pregnancy, may affect your healing process, and some medications may pose a risk to an unborn or nursing child.

- *Medications and allergies:* You should inform your physician your medications and any drug allergies.
- *Contact lens wearers:* Patients who wear gas permeable or hard contact lenses must completely stop wearing such lenses at least one month prior to the initial eligibility examination. (This period may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least two weeks prior to the eligibility examination. Following the examination, if both you and your doctor agree that Laser Vision Correction is the appropriate treatment, you must leave your contact lenses out of the eye(s) to be treated.

Precautions after your Laser Vision Correction surgery:

- *Operating Motor Vehicles:* After surgery, you may experience "fog" starburst-like images or "halos" around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the Laser Vision Correction procedure, you should arrange to be driven home after the procedure.
- *Pain and Discomfort:* The amount of pain and discomfort that can be expected soon after the Laser Vision Correction procedure varies with the individual. You should expect that the eye will be painful and sore to some extent after the surgery. Vision will be blurry and you may experience some redness and/or corneal edema (swelling of the cornea) for several days. Some patients report the temporary sensation of a foreign object in the eye, or dryness. Your comfort improves after the bandage lens is removed and the eye is almost always comfortable by one week.

6. Patient statement

I have read this Informed Consent Form (or it has been read to me). The Laser Vision Correction procedure has been explained to me in terms that I understand.

I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with Laser Vision Correction. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks.

I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.

My decision to undertake the Laser Vision Correction procedure was made without duress of any kind. I understand that Laser Vision Correction is an elective procedure, and my myopia or hyperopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that Laser Vision Correction will reduce or possibly eliminate my dependency on glasses or contact lenses. I understand that the correction obtained may not be completely adequate, and that additional correction with glasses or contact lenses may be needed, at least for some activities.

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I authorize the physicians and other health care personnel involved in performing my refractive surgery procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care.

I CONSENT TO HAVE LASER VISION CORRECTION ON MY RIGHT EYE FOR DISTANCE/ NEAR

I CONSENT TO HAVE LASER VISION CORRECTION ON MY LEFT EYE FOR DISTANCE / NEAR

Patient Name: _____

Patient Signature: _____ Date_____

Witness Name: _____

Witness Signature: _____ Date_____

Physician Name: _____

Physician Signature: _____ Date_____

Please see our website for any additional information:

www.triangleeye.com