

INFORMED CONSENT FOR PRK/LASIK

This information is provided to you so you can make an informed decision regarding refractive surgery to reduce your nearsightedness, farsightedness, or astigmatism. Only you and your doctor can determine if you should have refractive surgery based on your own visual needs and medical considerations. Any questions you have regarding refractive surgery or other alternative therapies for your case should be directed to your doctor.

Refractive surgery for vision correction is a choice. Please be aware that the practice of medicine and surgery is not an exact science and no guarantees can be made as to the results of the operation. There are other methods of obtaining useful vision without surgery.

Alternatives to refractive surgery: Refractive surgery is an elective procedure, and you may decide not to have this procedure at all. Alternative methods for correcting your vision include:

- Eyeglasses/Spectacles/Contact lenses
- Astigmatic Correction with Relaxing Incisions
- Clear Lens Extraction
- Implantable (Intracollamer) lenses (ICL)

Risks: Like all surgical procedures, refractive surgery has risks that should be considered. The risks of refractive surgery include, but are not limited to:

Loss of Vision: Refractive surgery can rarely cause loss of best-corrected vision. This can be due to infection, inflammation, irregular healing, irregular laser treatment, scarring or other complications. These rare complications can often, but not always, be corrected with glasses or contact lenses.

Visual Side Effects: Other visual aberrations that can occur with refractive surgery include; double or “ghosting” of vision, hazy vision, decreased contrast sensitivity, fluctuating vision during the day and from day to day, increased or decreased light sensitivity, glare and halos around lights or starburst from lights. Many of these side effects improve over time, but may not completely go away. In rare instances, some of these could affect your night driving. If your occupation depends on night vision, you should consider this potential risk carefully.

PRK/LASIK does not correct the condition known as PRESBYOPIA (aging of the eye), which occurs in most people around age 40 and requires reading glasses for close-up work. If you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses, you may need them at a later age. In addition, PRK/LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

Over-correction or Under-correction: It may be that refractive surgery will not give you the result you desired. It is possible after the initial procedure you may be over-corrected or under-corrected (still nearsighted or farsighted). Occasionally the initial result regresses over time. In many cases, but not all, additional surgery is needed to fine-tune or enhance the initial result. It is possible, that you may still need eyeglasses after this procedure to obtain the vision you want.

Dry Eye Side Effect: Eyes that have undergone Laser Vision Correction are often bothered by dry eye symptoms following surgery. The dry eye state typically improves over 6 to 12 months following the procedure and most often resolves. Treatment with artificial tears is common and usually sufficient. Other treatments occasionally performed may include punctal plugs placed in the tear drainage system, nutritional supplements, and/or prescription eye drops.

Other Rare Risks: Other reported very rare complications include corneal ulcer formation; recurring corneal abrasion with poor healing; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance; retinal detachment; and progressive corneal thinning (ectasia). In very rare cases, complications could result in loss of vision requiring a partial (lamellar) or full-thickness corneal transplant to restore vision.

For Women Only: I understand that pregnancy could adversely affect my treatment result.

By signing this form, I acknowledge I understand and accept the following:

I have been given the opportunity to ask any questions about my condition, alternative forms of anesthesia and treatment, risks of non-treatment, the procedures to be used and the rights involved. I believe that I have sufficient information to give this informed consent.

- My decision to undergo laser refractive surgery has been my own and has been made without duress of any kind.
- My laser refractive surgery has been explained to me in terms I understand; and I understand and accept the possible risks, side effects, benefits, and alternatives that can result from my eye surgery of laser vision correction.
- I understand that anesthesia involves additional risks, but I request the use of anesthetics for the relief and protection from pain during surgery. I realize that the anesthesia may have to be changed, possibly without explanation to me. I understand that certain complications may result from the use of any anesthetic including respiratory problems, drug reactions, and even death.
- I give permission for data concerning my operation and subsequent treatment to be released to investigators, physicians and responsible authorities demonstrating a need for such information.
- I authorize The Eye Institute of Utah and the attending physician to permit the attendance of observers and to collect, utilize and present data for routine medical studies.

Important Items to Note:

You should be aware that some agencies or organizations that have physical or visual requirements for participation, governmental or otherwise, including the military, FAA, airlines, fire departments, police and possibly others, may at the present or in the future, decide to impose limitations on various physical conditions including having LASIK/PRK or other refractive surgery. We cannot be responsible for keeping current on the legislation of every conceivable organization, either locally or nationally, and if there is a particular group that you are either a member of or anticipate the possibility of joining as a member, you should verify the requirements in writing before having such surgery.

AN OVER VIEW OF THE PRK PROCEDURE

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

PRK Surgery Described: PRK permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops in the eye). The procedure involves removing the surface layer of cells called the epithelium. This is done either mechanically, chemically (alcohol) or with the laser. Once these cells have been removed, a thin layer of the corneal tissue is removed with the Excimer laser. 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 and changes the focusing power of the cornea. After the laser treatment, a bandage contact lens is applied to the surface of the eye to facilitate healing of the epithelium.

Limits of PRK: Discomfort during healing, slower recovery of vision as well as haze. Although the goal of PRK is to improve vision to the point of not being dependent of glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, these results cannot be guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve adequate vision.

AN OVER VIEW OF THE LASIK PROCEDURE

Diagnosis: You may have been diagnosed with myopia (nearsightedness), myopia with astigmatism, hyperopia (farsightedness), hyperopia with astigmatism or mixed astigmatism.

LASIK Surgery Described: LASIK permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops in the eye). The procedure involves creating a corneal flap and folding it back to expose the stroma of the cornea with a laser. A thin layer of corneal tissue is removed from the stromal bed with the light from the Excimer laser. After the laser treatment, the flap is replaced and bonds back into place, usually without the need for stitches. LASIK permits a faster return to normal activities. The corneal flap secures to the cornea, but significant trauma may cause flap irregularities, wrinkling, dislocation or loss. 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 and changes the focusing power of the cornea.

Limits of LASIK: Although the goal of LASIK is to improve vision to the point of not being dependent of glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, these results cannot be guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve adequate vision. Flap risks; in rare instances, there may be problems while cutting the flap, or healing of the flap that may require additional treatment or procedures.

The procedure I have chosen:

_____ **LASIK**

_____ **PRK**

_____ **with Monovision**

Revision

I am making an informed decision in giving my permission to have the above procedure performed on my:

_____ **Right Eye**

Revision

_____ **Left Eye**

Revision

_____ **Both Eyes**

Revision

For women only: I am not pregnant or nursing.

I hereby authorize _____ and whomever he/she may designate as his/her assistants to perform the planned surgical procedure(s) on me: OD OS OU

In the event of an accidental exposure of my blood or bodily fluids to a physician, employee or contractor of the facility, I consent to testing for HIV and Hepatitis.

I permit one or more observers to be present in the operating room and release The Eye Institute of Utah and my surgeon from all or any liability that may result from their presence.

Patient's Signature _____ Date _____

Patient's Name (Print) _____

Witness' Signature _____ Date _____

Pre- and Post- Operative Care (Co-management)

Co-management: In ophthalmology, often pre-operative examination data is gathered by the patient's referring eye doctor. He/she then recommends the patient to an eye surgeon for evaluation for the procedure. In most cases, patients are referred back to their primary eye doctors for care after the procedure of laser vision correction. This system of shared care between two eye care providers is termed co-management. It is important for you to understand that the decision whether or not to be co-managed is yours alone. The most common reasons patients choose co-management are (a) a relationship and trust in their doctor, (b) travel distances and (c) convenience.

Your pre-operative examination and post-operative care may be managed by an Optometrist, a person licensed by the state in the diagnosis and treatment of eye diseases and conditions. Your laser vision correction will be performed by an Ophthalmologist, a person licensed by the state of Utah in the diagnosis, treatment, and surgery of the eye.

Accept co-management with Dr. _____.

Decline co-management.

Patient Signature

Date