

## LASER IN-SITU KERATOMILEUSIS (LASIK) - INFORMED CONSENT

The goal of Laser In-Situ Keratomileusis (LASIK) laser vision surgery with a device known as a femtosecond laser, combined with the use of a device known as an excimer laser, is to reduce or eliminate the dependence upon or need for contact lenses and/or eyeglasses. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness and astigmatism.

Only you and your doctor can determine if you should have LASIK surgery based upon your own visual needs and medical considerations. Any questions you have regarding LASIK or other alternative therapies for your case should be directed to your doctor.

### ADVANTAGES/DISADVANTAGES

#### Advantages of LASIK vs. PRK

- With LASIK, there is a shorter time to reach stable vision and more rapid visual recovery. Typically, vision is about 80% improved within 2 days of surgery.
- LASIK provides Less discomfort than PRK. Mild discomfort, including eye irritation and watering, rarely lasts more than one day following the procedure.
- The LASIK procedure is easier to enhance if another treatment is needed.

#### Disadvantages of LASIK vs. PRK

- With LASIK, more corneal tissue is altered. PRK may be preferable to LASIK in certain patients with thinner corneas or with corneal surface irregularity - PRK disrupts less corneal tissue than a comparable LASIK surgery.
- The LASIK procedure takes longer than PRK. PRK is technically simpler than LASIK and utilizes only one laser.
- Occasionally, patients who undergo LASIK have more dryness after the procedure than patients who have PRK.

### PROCEDURE

The LASIK procedure is done under local anesthesia and takes about 15 minutes to treat both eyes. In LASIK, the femtosecond laser is used to shave the cornea to create a flap. The flap then is opened like the page of a book to expose tissue just below the cornea's surface. Next, the excimer laser is used to remove ultra-thin layers from the cornea to reshape it to reduce nearsightedness. Finally, the flap is returned to its original position, without sutures.

### MEDICATIONS

After surgery, an eye drop regimen which combines an anti-inflammatory and anti-biotic treatment is prescribed to help in the healing process.

### ALTERNATIVES TO LASIK SURGERY

The alternatives to LASIK include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK has been explained to me.

## **RISKS AND COMPLICATIONS**

LASIK is an elective procedure: There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse.

### **VISION THREATENING COMPLICATIONS**

1. I understand that the femtosecond laser or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. I understand that, in using the femtosecond laser, instead of making a flap, an entire portion of the central cornea could be cut off, and very rarely could be lost. If preserved, I understand that my doctor would put this tissue back on the eye after the laser treatment, using sutures, according to the ALK procedure method. It is also possible that the flap incision could result in an incomplete flap, or a flap that is too thin. If this happens, it is likely that the laser part of the procedure will have to be postponed until the cornea has a chance to heal sufficiently to try to create the flap again.
3. I understand that irregular healing of the flap could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing LASIK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
4. I understand that it is possible a perforation of the cornea could occur, causing devastating complications, including loss of some or all of my vision. This could also be caused by an internal or external eye infection that could not be controlled with antibiotics or other means.
5. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.
6. I understand that I could develop keratoconus. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus 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.
7. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of "floaters" and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

### **NON-VISION THREATENING COMPLICATIONS**

1. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.

2. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
3. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
4. After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate.
5. I understand that I may not get a full correction from my LASIK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.
6. I understand that there may be a “balance” problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.
7. I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
8. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
9. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
10. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
11. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
12. I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.
13. I understand that the correction that I can expect to gain from LASIK 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 I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

14. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.
15. I understand that if I currently need reading glasses, I will still likely 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.
16. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. If the enhancement is performed within the first six months following surgery, there generally is no need to make another cut with the femtosecond laser. The original flap can usually be lifted with specialized techniques. After 6 months of healing, a new LASIK incision may be required, incurring greater risk. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
17. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

**By signing below, you agree that:**

- You read this informed consent, or someone read it to you.
- You understand the information, including the risks, benefits and alternatives to surgery.
- Dr. Harvey and/or his staff offered you a copy of this informed consent form.
- Dr. Harvey and/or his staff answered your questions about PRK surgery.
- You give permission for Dr. Harvey and/or his staff to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand PRK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my PRK procedure will be performed.

**My personal reasons for choosing to have LASIK surgery are as follows:** \_\_\_\_\_

**FOR PRESBYOPIC PATIENTS (those requiring a separate prescription for reading):**

The option of monovision has been discussed with my ophthalmologist \_\_\_\_\_ (initial)

**FOR WOMEN ONLY:**

I am not pregnant or nursing.

I understand that pregnancy could adversely affect my treatment result. \_\_\_\_\_ (initial)

**I consent to have LASIK surgery in my:**                      **RIGHT eye**                      **LEFT eye**                      **BOTH eyes.**

Signature \_\_\_\_\_ Date \_\_\_\_\_ Witness \_\_\_\_\_

## PHOTOREFRACTIVE KERATECTOMY (PRK) - INFORMED CONSENT

The goal of Photorefractive Keratectomy (PRK) laser vision surgery with an excimer laser is to reduce or eliminate the dependence upon or need for contact lenses and/or eyeglasses. PRK surgery aims to reduce or eliminate nearsightedness, farsightedness and/or astigmatism.

Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to your doctor.

### ADVANTAGES/DISADVANTAGES

#### Advantages of PRK vs. LASIK

- PRK can accurately correct nearsightedness. Approximately 90% of PRK patients have 20/20 vision without glasses or contact lenses one year after the surgery. Over 95% have 20/40 or better without glasses or contacts.
- PRK may be preferable to LASIK in certain patients with thinner corneas or with corneal surface irregularity. PRK disrupts less corneal tissue than a comparable LASIK surgery.
- PRK is technically simpler than LASIK and utilizes the same modern laser treatment systems. For this reason, some refractive surgeons prefer PRK to LASIK.

#### Disadvantages of PRK vs. LASIK

- Mild discomfort, including eye irritation and watering, that may last several days following the procedure. This is due to the need for the corneal surface cells (epithelium) to regenerate. These cells are removed by the surgeon right before the corrective laser treatment is performed.
- Longer time to reach stable vision. Typically, vision is about 80% improved at 1 month after surgery and about 95% by 3 months after surgery. LASIK, in contrast, provides a more rapid visual recovery.
- The outcome is not completely predictable due to variations in individual wound healing, and a small number of patients may still require glasses or additional surgery to achieve their best vision.

### PROCEDURE

The PRK procedure is done under local anesthesia and takes about 10 minutes to treat both eyes, slightly less time than LASIK. During PRK, an eye surgeon removes the corneal surface cells, then uses a laser to reshape the cornea. A clear contact lens is usually placed at the end of surgery to reduce irritation during the healing process.

### MEDICATIONS

After surgery, an eye drop regimen which combines an anti-inflammatory and anti-biotic treatment is prescribed to help in the healing process.

### RISKS AND COMPLICATIONS

Any laser procedure has risks and the potential for complications. The long-term risks and effects of PRK surgery beyond nine (9) years are unknown. As with all forms of treatment, the results of PRK surgery cannot be guaranteed and there is a remote chance of partial or complete loss of vision in the eye that has had PRK surgery.

#### Possible short-term effects of PRK surgery:

The following have been reported in the short- term post-treatment period and are associated with the normal post-treatment healing process: mild discomfort or pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity, and tearing.

**Possible long-term complications of PRK surgery:**

- Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually but not always resolves over time.
- Glare: Sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance.
- Halo: Hazy rings surrounding bright lights may be seen, particularly at night.
- Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
- IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.

**The following complications have been reported infrequently by those who have had PRK surgery:** itching, dryness of the eye, or foreign body feeling in the eye; double or ghost images; patient discomfort; inflammation of the cornea or iris; persistent corneal surface defect; persistent corneal scarring severe enough to affect vision; ulceration/infection; irregular astigmatism (warped corneal surface which causes distorted images); cataract; drooping of the eyelid; and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

**ALTERNATIVES TO PRK SURGERY**

The alternatives to PRK include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK has been explained to me.

**CONSENT**

1. I understand that PRK surgery is an elective procedure and that PRK surgery is not reversible.
2. I understand that it is not possible to state every complication that may occur as a result of PRK surgery and that complications or a poor outcome may manifest weeks, months, or even years after PRK surgery.
3. I understand that there is no guarantee that I will completely eliminate my reliance on eyeglasses and/or contact lenses with PRK surgery. It is possible that the treatment could result in under-correction, where some degree of nearsightedness or farsightedness or astigmatism may remain, requiring the use of glasses or contact lenses.
4. I understand that the PRK treatment may also result in overcorrection, causing farsightedness, nearsightedness, and/or astigmatism, which may or may not require the use of glasses or contact lenses.
5. I understand that if I currently need reading glasses, I will likely still need reading glasses after this treatment (unless I select a monovision treatment in which one eye is corrected for distance and other for reading). I further understand that it is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have PRK surgery.
6. I understand that further treatment may be necessary, including a variety of eyedrops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK surgery.
7. I understand that my best vision, even with glasses or contacts, may become worse.
8. I understand that there may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.
9. I understand there is a remote chance of partial or complete loss of vision in the eye that has had PRK surgery.

By signing below, you agree that:

- You read this informed consent, or someone read it to you.
- You understand the information, including the risks, benefits and alternatives to surgery.
- Dr. Harvey and/or his staff offered you a copy of this informed consent form.
- Dr. Harvey and/or his staff answered your questions about PRK surgery.
- You give permission for Dr. Harvey and/or his staff to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand PRK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my PRK procedure will be performed.

I consent to have PRK surgery in my:                      **RIGHT eye**                      **LEFT eye**                      **BOTH eyes.**

**My personal reasons for choosing to have PRK surgery are as follows:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**FOR WOMEN ONLY:**

I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result. \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_ Witness \_\_\_\_\_