

Drs. Fine, Hoffman and Packer, LLC

PHYSICIANS AND SURGEONS, EyeMDs
OPHTHALMOLOGY

1550 Oak Street, Suite 5
Eugene, OR 97401-7701
(541) 687-2110
1-800-452-2040
FAX (541) 484-3883

**I. Howard Fine, M.D.
Richard S. Hoffman, M.D.
Mark Packer, M.D.**

www.finemd.com
Email: tpreynolds@finemd.com

**INFORMED CONSENT FOR
LASER IN-SITU KERATOMILEUSIS (LASIK)**

INTRODUCTION

This information is being provided to you so that you can make an informed decision about the use of a device known as a microkeratome, combined with the use of a device known as an excimer laser, to perform LASIK.

AN OVERVIEW OF THE LASIK PROCEDURE

DIAGNOSIS: You have been diagnosed with a refractive error such as myopia (nearsightedness) or hyperopia (farsightedness), with or without 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 folding back a thin layer of corneal tissue (corneal flap) with a microkeratome (a surgical instrument much like a carpenter’s plane). Once the flap has been made, a thin layer of corneal tissue is removed with the light from an excimer laser. After removal, the flap is replaced and bonds back into place, usually without the need for stitches. 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, which 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 on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision. LASIK does not correct the condition known as presbyopia (aging of the eye) which occurs in most people around age 40 and may require them to wear reading glasses for close-up work. LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

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.

ALTERNATIVES TO LASIK

If you decide not to have LASIK, there are other methods of correcting your refractive error. These alternatives include, among others, eyeglasses, contact lenses, radial keratotomy, Automated Lamellar Keratoplasty (ALK), Photorefractive Keratectomy (PRK), intraocular contact lens, clear lens extraction with intraocular lens implantation, and laser thermal keratoplasty.

PATIENT CONSENT

In giving my permission for the use of the microkeratome and a FDA-approved excimer laser for LASIK, I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

VISION THREATENING COMPLICATIONS

1. I understand that the microkeratome 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 microkeratome, 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 glasses or contact lenses might 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 for a perforation of the cornea to 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 cannot 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 other very rare complications can occur threatening vision, including but not limited to, corneal swelling, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

NON-VISION THREATENING SIDE EFFECTS

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 one to three months after surgery, but they may also be permanent.
2. I understand that an overcorrection could occur and be either permanent or treatable. I understand an overcorrection 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.
3. 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 opening in the eyelid.
4. I understand that at night there may be a “starbursting” or halo effect around lights. I understand that this condition usually diminishes with time, but could be 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. I understand that I should not drive until my vision is adequate both during the day and at night.
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, RK or Astigmatic Keratotomy (a technique similar to RK for correcting astigmatism), 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 may 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, 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 LASIK has not been in use long enough to measure long-term effects following the procedures, and that unforeseen complications or side effects could occur.
12. I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially or completely back to the level it was immediately prior to having the procedure.
13. I understand that the correction, which 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, or 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 understand that I must not drive for at least one day following the procedure 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. Typically if -1.00 diopter or greater correction remains or vision is 20/40 or worse, an enhancement may be performed. Enhancement surgeries are generally performed no sooner than 3 months after the first surgery. Generally, at this point there is no need to make another cut with the microkeratome, the original flap can usually be lifted with specialized techniques. After 6 months of healing, a new LASIK incision is usually 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, which 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.
18. I understand that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize my physician, and his assistants or designees to perform such other procedures as are in the exercise of his professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
19. For purposes of advancing medical education I consent to the admittance of observers in the operating room.
20. Cost for post-procedure office visits related to the original LASIK procedure for 1 year are included in the surgical fee.
21. If you are pregnant or nursing, let us know immediately, because a refractive change may occur and therefore change the accuracy of the surgical calculations.
22. Patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks 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 (2) weeks prior to the eligibility examination. Following the examination, if both you and your doctor agree that LASIK is the appropriate treatment, you must leave the contact lens out of the eye to be treated.

23. Post-treatment precautions: Avoid exposing the eye to tap water in bath or shower for the first week after surgery, as such nonsterile water may expose the eye to increased risks of infection. Avoid rubbing the eye. The eye may be more fragile to trauma from impact. Evidence has shown that, as with any other scar the corneal incision will not be as strong after healing as the original cornea was at the site of the incision. Therefore, the eye is somewhat more vulnerable to all varieties of injuries after LASIK, at least for the first year after surgery. It is advisable to wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing objects contacting the eye may be high.

PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as LASIK have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I therefore consent to LASIK surgery.

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. 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 LASIK procedure will be performed.

I have read this Informed Consent (or it has been read to me). The LASIK 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 LASIK. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that because LASIK is a relatively recent procedure, 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 LASIK procedure was made without duress of any kind. I understand that LASIK 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 LASIK 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.

I authorize the physicians and other health care personnel involved in performing my LASIK 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 LASIK procedure that they deem relevant to providing me with care.

I consent to have LASIK performed on my right eye / left eye / both eyes.

I have been offered a copy of this consent form (please initial)_____

Patient Name

Patient Signature

Date

Witness Signature

Date

CONSENT FOR BILATERAL SIMULTANEOUS LASIK

Introduction

LASIK surgery can be performed on one eye at a time on separate days or simultaneously on the same day. This is a choice determined by the patient. Simultaneous bilateral LASIK is more convenient for patients and most patients choose this option. There may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. If you elect to have surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.

THE ADVANTAGES OF HAVING LASIK PERFORMED ON EACH EYE AT A SEPARATE TIME ARE:

Safety: You will not experience the risk of developing an infection in both eyes at the same time, which although very rare, could lead to significant loss of vision in both eyes. Since the pressure in the eye is increased significantly for a short time during the LASIK procedure, there is a very remote possibility of internal bleeding or damage to the retina which could lead to significant loss of vision or even blindness. Should this happen to both eyes, the consequences could of course be devastating.

It is also possible to develop a delayed cloudiness in the cornea or even corneal scarring which is not visible immediately after the procedure. Although this is uncommon and generally clears with time, it can result in significant loss of vision for a prolonged period of time. Should this occur in both eyes at the same time, carrying out normal activities could be difficult.

Accuracy: The doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye, increasing the likelihood of a better outcome in the second eye.

Visual Recovery: Although most LASIK patients experience a rapid recovery in their vision, the recovery can at times be delayed. If the eyes are operated separately, you can function with the fellow eye while the first eye fully recovers. This is especially true if you are able to wear a contact lens in the unoperated eye.

Satisfaction: You will be given the opportunity to determine whether the LASIK procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects such as glare, ghost images, or increased light sensitivity. If you are over age 40, you will have an opportunity to experience the change in your close vision, which results from the correction of your nearsightedness. This could influence your decision of whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

THE DISADVANTAGES OF HAVING LASIK PERFORMED ON EACH EYE AT A SEPARATE TIME ARE:

Convenience: It may be inconvenient for you to have each eye treated at separate visits. This will necessitate two periods of recovery from the laser surgery and may require additional time away from work.

Visual Recovery: There will be a potential period of imbalance in vision between your two eyes. This is especially important if you are unable to wear a contact lens in your unoperated eye. It is not usually possible to use the operated eye without a corrective lens along with a strong corrective lens in the unoperated eye because it produces a strong sense of imbalance, dizziness, and a form of double vision.

THE ADVANTAGES OF HAVING LASIK PERFORMED ON BOTH EYES AT THE SAME TIME ARE:

Convenience: It may be more convenient to have both eyes treated during the same visit.

Visual Recovery: The balance in vision between your two eyes will usually be restored more rapidly. This is especially true if you are unable to wear a contact lens in your unoperated eye.

THE RISKS OF HAVING LASIK PERFORMED ON BOTH EYES AT THE SAME TIME ARE:

Safety: The risks of infection, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these serious but rare complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness.

Accuracy: By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye. Therefore, if there is an overcorrection or undercorrection in one eye, chances are it will happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye will also require a retreatment.

Visual Recovery: LASIK patients generally experience rapid visual recovery. Some patients, however, can experience delayed visual recovery and experience symptoms such as blurred vision, night glare or ghost images. There is no way of predicting how long your eyes will take to heal, and some of these complications can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks in both eyes, which could make driving difficult or dangerous and could interfere with your ability to work. The healing corneal flap is most susceptible to trauma during the first several weeks after surgery. Should both flaps become accidentally displaced, significant visual loss in both eyes may result.

Satisfaction: Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated.

CONSENT STATEMENT:

“I have read and understand the above risks and benefits of bilateral simultaneous LASIK, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous LASIK. My doctor has answered all of my questions about the LASIK procedure. I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.

Patient Signature

Date

Witness

Date