

CONSENT FOR BILATERAL SIMULTANEOUS LASIK

Introduction

Both within and outside the United States, LASIK has become a common procedure for many refractive surgery patients. The FDA does recommend a minimum of three months between the treatment of the first and second eye with PRK, but there is no recommendation made about LASIK. In both PRK and LASIK, the second eye may be treated sooner than three months after the first eye, or even at the same time; however, 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 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 that 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 on 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 the 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 resulting from the correction of your nearsightedness. This could influence your decision whether 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.

Cost: Fees may be greater if the eyes are operated on different days and the additional time off work can be costly.

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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.

Cost: in addition to possibly missing less work by allowing both eyes to recover at the same time, fees may be discounted if you have surgery on both eyes at the same time,

The risks of having LASIK performed on both eyes at the same time are:

Safety: The risk of infection, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage is rare but potentially devastating. If these serious but rare complications occur in one eye, they may also occur in 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 over-correction or under-correction 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 also will require a retreatment.

Visual Recovery: LASIK patients generally experience a rapid visual recovery. Some patients, however, experience delayed visual recovery and symptoms such as blurred vision, night glare or ghost images. There is no way to predict 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. 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.

PATIENT CONSENT

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 _____
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Witness Signature _____ Date _____

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. LASIK is one of a number of alternatives for correcting refractive errors. In LASIK; the microkeratome 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 refractive error. Finally, the flap is returned to its original position, without sutures.

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 (RK), Automated Lamellar Keratoplasty (ALK) , Photorefractive Keratectomy (PRK), Conductive Keratoplasty (CK), Implantable intraocular lens, and refractive lens exchange. There is also **blade-less LASIK** which uses an additional laser, called the **INTRALASE**, to create the flap. This eliminates the use of the microkeratome. The blade-less LASIK method may lower the risk of flap complications and lead to improved visual outcomes.

PATIENT CONSENT

In giving my permission for the use of the microkeratome and an FDA-approved excimer laser for LASIK, I understand the following: LASIK is a relatively new surgery and as such, has not as yet been completely and exhaustively studied by medical researchers in this country. I have received no guarantee as to the success of my particular case. I understand the following known 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. I understand that LASIK thins the cornea and may result in an unstable, thin cornea with irregular astigmatism. 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.

I understand that there are other complications threatening vision including, but not limited to, infection, inflammation, retinal detachment, hemorrhage, cataract formation, venous and arterial blockage, and that any of these could lead to total blindness and even loss of my eye.

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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 from one to three months, but they may also be permanent.
2. I understand that an overcorrection could occur I understand that if I was nearsighted this would cause me to become farsighted, and that this farsightedness could 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 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.
4. 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.
5. I understand that there may be a “balance” problem between my two eyes after LASIK, especially if 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 if I elected to have monovision these same problems may occur
6. 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, especially 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.
7. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
8. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
9. 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.
10. I understand that the follow-up effects of LASIK beyond five years presently are unknown and that LASIK has not been in use long enough to measure long-term effects (those occurring after 10 years or more) following the procedures, and that unforeseen complications or side effects could occur
11. I understand that visual acuity 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.
12. 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, 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

Please initial after reading this page _____

13. I understand that I may be patched after the procedure and may be given medication in conjunction with the procedure and I can not drive after the procedure until the next day when my doctor checks my vision.
14. 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.
15. 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. 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.
16. 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.

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 my satisfaction. I therefore consent to LASIK surgery.

I give my consent and permission for Jeffrey H. Singer, M.D., to perform LASIK surgery on both my right and left eye during the same operation.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

I have been offered a copy of this consent form (patient initials) _____