

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

Please read the following consent form very carefully. Please initial each page where indicated. Do not sign this form unless you have read and understand each page.

PATIENT'S NAME: _____ PROCEDURE DATE: ___/___/___

SURGEON'S NAME: *Michael A. McMann, MD, FAAO*

TREATMENT EYE (CIRCLE): RIGHT Eye LEFT Eye BOTH Eyes Patient Initials _____

MONOVISION (CIRCLE): YES NO SLIGHT Which Eye? _____

COMMENTS: _____

INTRODUCTION:

This information is to help you make an informed decision about having Laser Assisted In-Situ Keratomileusis (LASIK) surgery to treat nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision before signing this form. You are encouraged to ask questions and have them answered to your satisfaction before you give your permission for surgery. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information presented.

LASIK involves the use of a device known as a microkeratome combined with the use of a device known as an excimer laser. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness and astigmatism. In LASIK, a 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 layers of tissue from the cornea to reshape it to reduce your 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 the same visual acuity you now have. LASIK, at best, can only match your best corrected visual acuity that you have with contact lenses or glasses. 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 or requiring more extensive surgery.

You shall understand that LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment.

During pregnancy, your degree of myopia or hyperopia can fluctuate, which could influence your results. If you know you are pregnant, plan to, or become pregnant within the next six months, it is important that you notify Dr. McMann immediately. You also should advise Dr. McMann of any drug therapy you are on or any vascular or auto-immune diseases you may have.

ALTERNATIVES TO LASIK

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures.

PATIENT CONSENT

In giving my permission for LASIK, I understand the following: The long-term risks and effects of LASIK are unknown. 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 Dr. McMann would put this tissue back on the eye using either sutures or a contact lens. I understand that if this were to happen Dr. McMann may or may not do the laser part of the procedure. It is also possible that the flap incision could result in an incomplete flap, a buttonhole, 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 it is possible that a perforation of the cornea could occur, causing devastating complications, including loss of some or all of my vision and my eye. 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 occasionally after LASIK that a condition called Diffuse Lamellar Keratitis (DLK) may occur. DLK is an inflammatory condition that occurs between the underside of the flap and the underlying cornea. It's usually of unknown cause. DLK is usually treated effectively with aggressive use of topical steroids. Topical steroids, however, if used for a number of months in multiple doses per day can cause a condition called glaucoma which can permanently damage the optic nerve. Cataracts also can be the result of using topical steroids for too long. In order to effectively treat the more severe cases, it may require Dr. McMann to lift my flap and irrigate underneath it. I understand that in some cases DLK can result in permanent scarring and visual loss.
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.
8. I understand keratoconus is a degenerative non-inflammatory progressive corneal thinning 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 or an indistinguishable condition called post-LASIK ectasia can develop in patients who have no known pre-operative risk factors. Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus/post-LASIK ectasia following laser vision correction. Keratoconus/post-LASIK ectasia is usually treated with rigid or hard contact lenses, but in severe cases may require a cornea transplant.

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 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 some occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.**

Patient Initials _____

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 that an enhancement or contact lenses or glasses may be needed to correct a possible overcorrection or undercorrection. 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. **I understand that 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. Although there are several possible causes for these difficulties, 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. These risks in relation to my particular pupil size and amount of correction have been discussed with me.**

Patient Initials ____

5. 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.

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.

7. 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 and I will therefore need a driver.
15. I understand that presbyopia is a condition that affects the lens inside the eye and occurs in all individuals as they age into their 40's. With presbyopia, the lens inside the eye loses its ability to change focus planes, thus leaving the eye with one fixed focal plane. When this occurs, most individuals notice that they need bifocals or reading glasses in order to read up close. LASIK reshapes the surface of the eye (cornea) and does not correct presbyopia. 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. I understand that 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 microkeratome. 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 Dr. McMann 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.

Addendum: Consent for Bilateral Simultaneous LASIK

LASIK has become a common procedure for many refractive surgery patients. While many patients choose to have both eyes treated at the same surgical setting, 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.**

Safety: The risks of infection, severe inflammation, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these 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. By choosing to have LASIK performed on separate days, you avoid the risk of having one or more of these complications in both eyes at the same time.

Accuracy: If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, 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. In some patients, this might improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Visual Recovery: Most LASIK patients experience rapid visual recovery, but some may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the fellow eye while the first eye fully recovers. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes will usually be restored more rapidly if they are operated on the same day.

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. By having each eye treated on separate dates, you

will have the opportunity to determine whether the LASIK procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects. If you are over age 40, you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

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

Cost: Professional and facility fees may be greater if the eyes are operated on different days, and the additional time off work that may also be needed can be costly.

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. Dr. McMann 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 Dr. McMann determines that the treatment in the first eye appeared to be technically satisfactory.

The reason(s) I wish to have both eyes treated at the same time are:

- Greater convenience
- Possible faster recovery
- Less time away from work
- Contact lens intolerance and/or difficulty wearing contacts
- Elimination of possible vision imbalance between treated and untreated eyes
- Other: _____

Patient Signature

Date

Witness Signature

Date

Michael A. McMann, MD

Date