

OHIO EYE LASER CENTER

Informed Consent For Laser In-Situ Keratomileusis (LASIK) For the Correction Of Myopia (nearsightedness) and Hyperopia (farsightedness)

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 nearsightedness or farsightedness. 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 nearsightedness and farsightedness. 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 risk, many of which are listed below. You should also understand that there might 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 care, the result might be effected 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 nearsightedness or farsightedness. These alternatives include, among others, eyeglasses, contact lenses, radial keratotomy, Automated Lamellar Keratoplasty (ALK), and Photorefractive Keratectomy (PRK).

PATIENT CONSENT

In giving my permission for the use of the microkeratome and FDA approved excimer laser for LASIK,

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 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 change 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 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 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 other very rare complications threatening vision include, but 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 from one to three months, but they also have be permanent.
2. I understand that an overcorrection could occur, causing me to become farsighted or nearsighted, and that this farsightedness and nearsightedness could be either permanent or treatable. I understand an overcorrection is more likely in people over 40 years and my 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 to a "star bursting" 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 that 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 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 then 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 the site. I understand that the treated eye, therefore, is somewhat more vulnerable to varieties of injuries, at least for the first year following LASIK.
7. I understand that there is a natural tendency of the eyelids to droop with age and that the 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 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.
11. I understand that the correction, which I can expect to gain from LASIK, ay 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.
12. 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 drove for at least one day following the procedure and not until I am certain that my vision is adequate for driving.
13. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. .

- 14 I understand that if 90% clarity of vision is still blurry, enhancement surgeries can be performed when vision is stable, UNLESS it is unwise or unsafe. Typically, if -1.00 or +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 not adequate tissue remaining, 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.
- 15 I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug interactions, 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.

PATIENTS 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 the 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 LASIK. 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.

PATIENT SIGNATURE

DATE

WITNESS SIGNATURE

DATE

PHYSICIAN SIGNATURE

DATE

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

Patient's initials _____

LASIK/PRK CONSENT

#1 You have been informed that for the first few weeks you will notice halos and glare around lights at night.

No ____ Yes ____

#2 You have been informed and understand, that once your nearsightedness or farsightedness has been corrected and if you are in your 40's or older, that you will need bifocals or reading glasses for close-up work. Example: reading, applying make-up.

No ____ Yes ____

#3 We want to hear about any visual changes you may be experiencing after surgery, but we will need you to agree to wait for at least 3 months following surgery before we consider any corrective action. This will allow your brain time to adjust to the new visual operating system in your eyes.

No ____ Yes ____

#4 You have been informed that all advanced directives have been waived while a patient at this facility

No ____ Yes ____

#5 You are aware of the fact that Dr. Stark has a financial interest in this facility.

No ____ Yes ____

#6 I have been informed by Dr. Stark that Custom Cornea Wavefront is a better procedure for me, but I have elected to have a conventional excimer laser treatment.

No ____ Yes ____ N/A ____

Patient Signature _____ Date _____

Witness' Signature _____ Date _____