

The purpose of this consent form is to educate you on the bladeless (Intralase) LASIK procedure. It is not intended to scare you or deter you from surgery, but rather to inform you of the risks and benefits of laser vision correction. It may contain words that you do not understand. Please feel free to ask the doctor or a member of the staff to explain any words or information that you do not clearly understand. The surgeon will review your chart before you come in for your procedure and again when you arrive.

The Bladeless (Intralase) LASIK Procedure

Bladeless (Intralase) LASIK is performed as an outpatient procedure. Anesthetic (numbing) eye drops are placed in the eye immediately prior to surgery in order to minimize pain during the procedure. In some cases, a mild sedative pill may be administered to reduce apprehension prior to surgery. The eyelid is cleansed and held open using a special instrument. A patch generally covers the other eye during the treatment.

The first step of the procedure involves creating the corneal flap. In order to do this accurately, the pressure inside the eye needs to be raised, which makes the eye feel "full" and the vision to dim or go completely dark. Once the pressure inside the eye is sufficiently elevated by the suction ring, the Intralase laser is used to create a corneal flap (generally less than 1/3 of the total corneal thickness) of corneal tissue. After the flap is created, it is folded back, exposing the underlying tissue.

While the underlying tissue is exposed, multiple pulses of excimer light are applied in a computer-controlled pattern in order to remove a precise amount and pattern of tissue. This generally takes 30-60 seconds and varies with your refractive error. During the procedure, the patient may hear a snapping sound and may detect a slight odor (resulting from the interaction of the laser light and the corneal tissue). After the laser ablation, the flap is carefully laid back down. Antibiotic and anti-inflammatory eye drops are placed in the treated eye.

After having LASIK, the patient is examined the next day and if needed, every 24-48 hours following until the corneal surface heals. Subsequent follow-up visits will be determined by the doctor according to your progress, but typically occur within the first 3 months. Additional visits may be scheduled according to your doctor's recommendation.

The post-operative medication regimen is reviewed with the patient both before and after surgery. In the immediate post-operative period, the patient may notice his/her vision is significantly improved compared to before surgery. Best vision, however, may take several days or weeks to achieve. Due to blurry vision, light sensitivity, and because you may have taken a light sedative, you must have a ride home. Surgery will not be performed unless a driver is present (or other arrangements have been made).

A major concern in the early post-operative phase following LASIK involves dislodging the flap. It is generally believed that this is most likely to occur in the first one to two weeks after surgery and can be caused by vigorous eye rubbing, a fingernail or other injuries to the surface of the eye. Patients will be asked to consciously avoid rubbing their eyes and to wear protective eye shields when they go to sleep immediately after surgery.

In order to minimize the risk of infection and post-operative discomfort, as well as maximize the visual results of the LASIK procedure, it is important that the patient complies faithfully with this medication dosage and schedule. Medications are usually necessary for only a few days. We recommend the usage of artificial tears frequently–every 15 minutes--for the first week, then every 30 minutes for the second week to alleviate dry eye symptoms common after LASIK.

Although the vast majority of patients report markedly improved uncorrected vision quite soon after LASIK, an individual patient's best vision may not be realized for several weeks or months after the procedure. Delayed visual recovery following LASIK may be a result of, among other factors, surface defects, dryness, folds in the flap, improper positioning or dislodging of the flap, or haze/scarring in the interface between the flap and the underlying corneal tissue.

Patients who do not experience full correction may opt to wear glasses, contact lenses or could possibly have additional refractive surgery (either LASIK or other procedures). These enhancements (re-operation of LASIK or other procedures) for low-to-moderate nearsightedness occur in less than 10% of patients. Generally, re-operation will not be performed for at least three months following the original procedure.

Presbyopia

If both eyes are corrected for distance, glasses for reading will be needed sometime after the age of forty. This condition, known as "presbyopia", occurs as a result of the natural aging process of the lens inside the eye. Without surgery, presbyopia results in the need for bifocals. After surgery, if the distance vision is good, near vision will be blurry and magnifiers will be needed.

One approach to address the issue of presbyopia is called "monovision", which involves intentionally undercorrecting one eye in order to leave a small amount of nearsightedness. The result is for this eye to have good uncorrected near vision (but somewhat blurred distance vision) while the fully corrected eye will have good distance vision (and somewhat blurred near vision). However, not everyone can successfully adjust to monovision. Even successful monovision LASIK patients may require glasses for specific tasks (e.g., driving at night and reading small print in dim lighting). Also, it is important to note that the need for reading correction progresses as we age; if the need overcomes the degree of residual nearsightedness left in the "reading" eye in a monovision procedure, reading glasses may become necessary. We will demonstrate this for patients over forty during the evaluation. Patients interested in monovision may benefit from a trial with contact lenses prior to surgery.

CONTRAINDICATIONS

LASIK should not be performed on persons:

- 1. who are immune-compromised or on drugs or therapy which suppress the immune system.
- 2. with signs of keratoconus (steepening of the cornea).
- 3. with a previous history of keloid formation.
- 4. who are pregnant, nursing or expecting to become pregnant within 1-3 months.
- 5. with residual, recurrent or active ocular disease(s), or abnormality except for myopia (or hyperopia or astigmatism) in either eye.
- 6. with active or residual disease(s) likely to affect wound healing capability.
- 7. with unstable or uncontrolled diabetes.
- 8. with progressive myopia (or hyperopia).
- 9. with heart disease.
- 10. with drug interactions.

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions which might affect your decision to undertake LASIK surgery, you should discuss them with your physician.

RISKS, COMPLICATIONS AND SIDE EFFECTS OF LASIK:

What follows is a discussion of the most common side effects of LASIK. It is impossible to include all conceivable side effects, risks and complications of the procedure. It is also possible that there are side effects not known to us at this time.

Pain: Although most patients feel little or no discomfort following LASIK, some may feel discomfort or pain for several hours immediately after surgery. Occasionally, analgesics may be necessary. Pain or tenderness of the eyelids resulting from the instrument used to keep the lids open during surgery may occur. If you have post-operative discomfort or if pain increases or extends beyond 48 hours, you should report this immediately to the medical staff.

Light Sensitivity: Light sensitivity following LASIK is quite common. This sensitivity, though mild in degree and usually most intense for the first 48 hours or slightly longer after LASIK, may necessitate the use of sunglasses.

Blurred Vision: Your vision may be somewhat blurred in the early postoperative period, particularly in the first 48-72 hours, and this may interfere with functions such as driving, working and hobbies. The actual level of vision necessary for people to comfortably function is quite individual and varies with individual healing. Therefore it is impossible to precisely predict when your vision will be good enough for you to feel comfortable.

Tearing: Tearing commonly occurs after LASIK, but is usually limited to the first 24 to 48 hours after surgery. In rare cases, tearing may be so profuse as to blur vision and interfere with functions such as driving.

Sedation Related: Many patients feel more comfortable taking a light sedative prior to the LASIK procedure. If you receive sedation, you may not feel sufficiently comfortable to drive or operate machinery for 24 hours after surgery.

Under- and over-healing and Regression: While the introduction of the excimer laser has improved the accuracy of refractive surgery, variations in the individual biology of wound healing (as well as other factors) from patient to patient mean that LASIK is not a 100% accurate procedure. It is not possible to accurately predict how your eyes will respond to the treatment. While our goal is to provide you with the vision we demonstrate in the office, you may be left with a residual refractive error (nearsightedness, farsightedness, astigmatism, or some combination). In fact, mild nearsightedness may be preferable because of the "protection" it may offer against the need to wear glasses or contact lenses. Should you desire an enhancement (or "touch-up procedure"), this cannot be completed until your vision is stable, a fair amount of healing has occurred, and it is medically safe to proceed. These conditions are typically met 3 to 6 months after the initial procedure.

Glare, Halos and Night Vision Problems: Mild glare, halos, shadows or "ghosting images" are not uncommon immediately after surgery. In most patients these will slowly return to normal over time as the dryness improves and the eyes heal. Driving at night is always more difficult than driving in daylight, and some patient request glasses for night driving. In rare cases, these symptoms may be severe and glasses may not improve them.

Infection: Infection is a potential complication following LASIK surgery. In order to minimize the risk of post-operative infection, it is critical that you use the medications and preservative-free artificial tears precisely as your doctor recommends following your surgery. Should infection occur in the cornea following LASIK, a potentially lengthy course of treatment may be necessary. This may include invasive laboratory tests, special medications requiring frequent usage, multiple doctor visits and hospitalization. Infections may result in corneal scarring, perforation, spread of infection to outside the eye and loss of vision. Since health care workers are thought to be at higher risk for such infections, it is recommended that our patients in the health care field minimize their exposure to potentially infective situations. If you have had infections in the past, please let your doctor know prior to surgery.

Corneal Scarring: Corneal scarring or haze is generally controlled with steroid drops used after surgery, but may occur after LASIK. If it occurs, there may be a permanent loss in vision. Not complying with the post-operative medication regime increases the risk for scarring.

Loss of Best-corrected Vision: This may occur with flap complications, infections, scarring or due to poor healing. It may be permanent. Irregularities in corneal shape may result from LASIK, and in severe cases, undetected keratoconus can be exacerbated (made worse) by the procedure. Although we do our best to rule out keratoconus, rare cases of keratoconus following LASIK have occured.

Epithelial Ingrowth: Because LASIK involves the creation of and manipulation of the flap, cells from the outside layer of the cornea (epithelium) may find their way under the flap. In most cases, these cells simply die and pose no consequence. Rarely these cells continue to grow, causing vision problems, irregularities in the flap and/or discomfort. Should this occur, cleaning the cells out from under the flap may be necessary. This is a simple, outpatient procedure done in the office.

Ptosis: Drooping of the upper eyelid is a rare occurrence following LASIK. The cause is not fully understood. Generally, it is mild in degree and resolves spontaneously over several months.

Cataracts: LASIK has not been directly and conclusively associated with the development of cataracts. A cataract is an opacification of the lens within the eye that develops slowly over time. They are commonly found at an early stage in anyone over fifty years of age. Prolonged use of post-operative medications may increase the risk of cataracts.

Retinal Detachment: LASIK has not been directly and conclusively associated with retinal detachments. Nearsighted individuals are at higher risk for having a spontaneous detachment or other retinal complication than the general population, and this may occur at any time unrelated to your LASIK procedure.

Elevated Eye Pressure: Part of the LASIK procedure involves elevating the eye pressure above the normal level to create the flap. During this time, the patient may experience pressure or discomfort, and a loss or dimming of vision. The loss of vision is thought to result from loss of blood flow to the nerve in the eye. This only lasts about 30 seconds, after which the blood flow and vision return to normal. Although there are no cases in the literature where this vision loss is permanent, there is some concern that this may occur. Patients with known blood vessel problems or increased susceptibility to blood clotting disorders are not considered good candidates for LASIK.

Specific Occupations: Having refractive surgery, including LASIK, could conceivably disqualify you from some professions (particularly military) and it is your responsibility to investigate any requirements and/or exclusion criteria for any profession and/or sport/hobby in which you are interested.

Pregnancy: If you are pregnant or breastfeeding, you should not undergo a LASIK procedure. We require three months pass after delivery and/or cessation of breastfeeding prior to surgery. If you are able to become pregnant, you must agree to use birth control for at least one month after surgery, and possibly up to three months, because this is when the majority of healing takes place.

In addition to the above mentioned, it is possible to experience unknown or as yet unreported complications following LASIK, in spite of the fact that we have nearly 50 years experience with lamellar refractive surgery and nearly a decade of experience with excimer refractive surgery. As noted above, complications can occur after LASIK and it is conceivable that, if severe enough, these may cause partial loss of vision or even blindness or may require prolonged treatment and/or further surgery.

ALTERNATIVES TO LASIK

LASIK is an elective procedure. There are alternatives to LASIK. These include:

- Glasses
- Contact lenses
- Radial keratotomy (RK) surgical alternative where the surgeon makes cuts on the cornea to change your refractive error
- Photorefractive keratectomy (PRK) surgical alternative where the surgeon gently removes the epithelium of the cornea and uses the excimer laser to resurface the eye
- Conductive keratoplasty (CK) and Laser thermal keratoplasty (LTK) surgical alternative for patients requiring correction of small amounts of hyperopia using small burns in the corneal periphery

If you have any questions at any time during this process, please feel free to call **651/321-8881** and our technicians and doctors will be happy to assist you.

CONSENT

In signing this consent form for LASIK, I state that I have read this document completely or that it has been read in full to me, and that I understand its content and purpose. I understand that no warranty or guarantee is being made to me regarding my outcome, the effectiveness or the safety of LASIK. I further state that I have no questions regarding LASIK and my questions have been answered to my satisfaction.

_____ I have read and understand the information presented in this consent form.

_____ I hereby give permission for Dr. Ming Wang to perform LASIK on my eye(s). By signing this form, I have not waived any of my legal rights, which I otherwise would have as a participant in a research study.

_____ I am willing to accept the fact that I may need glasses or contact lenses or further surgery following LASIK to achieve my best possible level of vision.

_____ I understand that 20/20 vision is not guaranteed. My healing may be variable, and I understand that Dr. Wang and his staff have no control over my body's healing ability. My healing may aftect my final result.

_____ I understand that dry eye is a side effect of LASIK, which although it is rare, may not resolve.

_____ I understand that night glare may increase after LASIK surgery.

_____ I understand that if both eyes are corrected for distance vision, I will require reading glasses.

_____ I understand that even with monovision, I many still need reading glasses for some tasks.

Uncommonly, a patient might experience a corneal complication, such as severe infection, corneal scarring or other problems that would require consultation and treatment to another specialist. If this situation arises, I understand that I am financially responsible for those consultations and treatments. I understand that prescription eye drops and oral medications, along with post-operative optical appliances such as contact lenses and glasses are also my financial responsibility.

I am making an informed decision in giving my permission to have LASIK performed on: (please circle your choice) Both eyes Right eye Left eye

I understand that I may receive a copy of this consent form if I request it.

Patient's signature

Witness's signature

Doctor's signature

Date

Date

Date