

TAILORED EYES

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INFORMED CONSENT FOR LASER-ASSISTED IN SITU KERATOMILEUSIS (LASIK) WITH FEMTOSECOND OR INTRALASE LASER FLAP CREATION

INTRODUCTION

This information is provided so that you can make an informed decision about having elective refractive surgery to improve your vision. LASIK is one of a number of options for correcting or improving blurry vision caused by nearsightedness, farsightedness and astigmatism.

Indications for Alcon WaveLight EX500 Laser:

The WaveLight Excimer Laser Systems are approved for the following specific LASIK treatments and ranges: Reduction or elimination of nearsightedness of up to - 12.00 diopters of sphere and up to 6.00 diopters of astigmatism. Reduction or elimination of farsightedness up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism, with a maximum manifest refraction spherical equivalent of + 6.00 diopters. Reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 diopters.

The WaveLight Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism), who have documented evidence that their refraction did not change by more than 0.50 diopters during the year before their preoperative examination.

PROCEDURE STEPS

LASIK is a two-step refractive surgery. In LASIK, either a microkeratome or a femtosecond laser (Alcon WaveLight FS200 or Johnson and Johnson IntraLase laser) is used to create a corneal flap on the surface of the eye. This flap is lifted to expose the deeper layers of the cornea called the stroma. A second laser called an excimer laser is then used to reshape the cornea by removing corneal tissue (ablation). If your eye is nearsighted (myopia) then the laser will remove tissue to flatten your cornea to improve your vision. If you are farsighted (hyperopia) then the laser remove tissue to steepen your cornea to improve your vision. After the ablation excimer laser treatment, the corneal flap is then repositioned back in place without sutures.

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LASIK in which a femtosecond laser is used to create the corneal flap is called All Laser LASIK as no microkeratome is used. 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 vision. 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, your vision result might be affected or you could end up with worse vision.

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 (for example Photorefractive Keratectomy, Implantable Collamer Lens, SMILE, and Refractive Lens Exchange).

PATIENT CONSENT

In giving my permission for All Laser LASIK with Femtosecond Laser corneal flap creation, I understand the following: We may not know all of the long-term risks and effects of All laser 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 femtosecond laser used for flap creation or the excimer laser used to ablate the cornea 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 the microkeratome or the femtosecond laser used for flap creation could make a free cap instead of a flap and that rarely the cap could be lost. If preserved, I understand that my doctor would put this tissue back on the eye after the laser treatment and likely suture the cap in place. It is also possible that the flap incision could result in an incomplete flap, a flap with a button hole, 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 or to do a PRK treatment instead.

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3. I understand that irregular healing or wrinkling of the flap could result in a distorted vision. 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.
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 or, if very severe, corneal transplantation or even loss of the eye.
6. I understand that I could develop keratoconus. I understand that rubbing my eyes (especially after LASIK) can increase my risk of Keratoconus. Keratoconus is a degenerative corneal 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 can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus after laser vision correction surgery. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
7. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning or warping (ectasia), new floaters or a change in floaters, and retinal tear or detachment, hemorrhage, venous and arterial blockage, damage to the optic nerve, cataract formation. I understand that after the surgery I may have decreased vision or loss of vision that may not improve with glasses or contact lenses, 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 may also be permanent.
2. I understand that there is an increased risk of eye irritation and vision fluctuation and dry eye after LASIK. These symptoms may be temporary (lasting roughly 6 months) or may be permanent. Dry eye after LASIK may require frequent application of artificial tears, closure of the tear duct openings in the eyelid, or other dry eye treatments.

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3. I understand that an overcorrection or undercorrection of my vision could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. 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. After refractive surgery, a certain number of patients experience glare, starbursting, a halo effect around lights, or difficulty with night vision that may interfere with the ability to drive at night or see well in dim light. For most patients, this is a temporary condition that slowly resolves over several months 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.
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 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 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.
7. I understand that, after LASIK, I am at risk of my corneal flap dislocating or wrinkling even from minor eye trauma and the eye may always be more fragile. 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 after LASIK. I understand I should 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.

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11. I understand that unforeseen complications or side effects from LASIK could possibly occur.
12. I understand that the 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. I therefore, understand that I must not drive the day of surgery 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. If the enhancement is performed within the first six months following surgery, there generally is no need to make another flap cut in the cornea. 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 or the decision may be made to use a different refractive procedure called PRK. In order to perform an enhancement surgery, there must be adequate corneal tissue thickness remaining. If there is not enough tissue, it may not be possible to perform an enhancement as removing additional tissue could destabilize the cornea.
17. For women only: I am not pregnant or nursing. I understand that pregnancy and breast feeding could adversely affect my treatment result.
18. 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.

FOR PRESBYOPIC PATIENTS – THOSE REQUIRING READING GLASSES

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The option of monovision, setting one eye for distance vision and one eye for near vision to reduce my dependency on reading glasses, has been discussed with my ophthalmologist.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I understand that during LASIK surgery, a flap is cut in the cornea and corneal tissue is vaporized.

- Corneal tissues and nerves cut during this process must heal following surgery. Corneal nerves may not fully recover resulting in dry eyes and/or chronic pain.

- Even after the corneal flap has fully healed, the cornea will not be as strong as it was before surgery.

Patient Initials: _____

CONSIDERATIONS FOR A GOOD LASIK CANDIDATE

I understand that I should not have LASIK surgery while I have an active eye inflammation or infection.

I understand that I am not a good candidate for LASIK if:

- I have severe dry eyes.
- My cornea(s) is not thick enough.
- My doctor has told me that I have a condition that causes thinning or bulging of the cornea, such as keratoconus or pellucid marginal degeneration.
- I have problems resulting from a past herpes eye infection.
- I have an autoimmune disease or connective tissue disease (like lupus or rheumatoid arthritis), glaucoma, or diabetes.

Patient Initials: _____

WHAT TO EXPECT IN THE FIRST 6 MONTHS

I understand that dry eye following surgery is common, and the symptoms of dry eye, including blurred vision, can vary from mild to severe. Based on the estimates below, I am prepared to regularly use lubricating eyedrops to manage dry eye symptoms. I understand that, following LASIK surgery, estimates of certain common risks are as follows:

- One (1) week following surgery, up to 85% of patients experience dry eye symptoms.
- At six (6) months following surgery:
 - o Up to 27% of patients experience dry eye symptoms.
 - o About 41% of patients may experience visual symptoms such as glare, halos, starbursts, and double images (with or without glasses or contact lenses).

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- o Around 4% of patients may have “very” or “extremely” bothersome symptoms.
- o Around 2% may have “a lot of difficulty” or “so much difficulty that I can no longer do some of my usual activities” when not wearing glasses or contact lenses.

Patient Initials: _____

LONG TERM RISKS

- I understand that, although rare, there have been reports that some patients who have had LASIK have experienced severe depression or suicidality that they believe to be a result of complications following the procedure. A definitive causal link between LASIK and these reported psychological harms has not been established.

- I understand that dry eye may persist beyond six (6) months.

- I acknowledge the following estimates of the percentage of patients experiencing the persistence of certain symptoms five (5) years after surgery:
 - o Around 17% of patients may still need to use eye drops daily for dry eye.
 - o Less than 2% of patients notice some visual disturbance, such as glare, halos, starbursts, and double vision.
 - o A decreased ability to see under low light conditions; around 8% of patients may have moderate difficulty or a lot of difficulty driving at night.
 - o Very rare reports (estimated rate of less than 0.8%) of severe, constant pain that may prevent normal activities.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient labeling for the specific LASIK laser that will be used during my LASIK surgery and that I have had time to discuss the items in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of LASIK surgery for me, given my specific health conditions. I have considered alternatives to LASIK, such as contact lenses, eyeglasses, and PRK, and their risks and benefits

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 on my:**

Please initial this page after reading_____

_____ **RIGHT EYE** _____ **LEFT EYE**

_____ Patient Initial I have been offered a copy of this consent form.

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 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

Witness Signature

ADDENDUM: CONSENT FOR BILATERAL SIMULTANEOUS LASIK

While many patients choose to have both eyes treated during the same surgery, 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.

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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.

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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.

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

Date

Please initial this page after reading _____