

PATIENT INFORMATION AND CONSENT FORM

Procedure: Lasik with an Excimer Laser in the Surgical Treatment of Refractive Errors: Myopia or Hyperopia with or without Astigmatism

Surgeon: Gary R. Tylock, M.D.

Location: Tylock Eye Care and Laser Center

Telephone: 972/258-6400

Do not sign this form until you have read it fully and understand what it says. You may take as much time as you wish and are encouraged to ask any questions you may have at any time.

INTRODUCTION

It is important that you read and understand the following explanation of the following proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts and precautions of lasik surgery. It also describes the available alternatives. No guarantees or assurances can be made as to the results of the surgery.

If you are not completely truthful with your doctor regarding your health history, you may harm yourself by undergoing this procedure.

BACKGROUND

This information is given to you so that you can make an informed decision about having surgery for your refractive error (vision problem of nearsightedness or farsightedness, with or without astigmatism). The procedure is called Laser In Situ Keratomileusis or Lasik. The procedure combines the use of a device known as a keratome, either mechanical or femtosecond laser and an excimer laser to reduce your nearsightedness or farsightedness and/or astigmatism.

While we have made every effort to inform you of the risks, benefits, and alternatives to Lasik, the decision to have it performed is ultimately yours. It is never “necessary” to have Lasik. Lasik is a purely elective procedure. There is no emergency condition or other reason, which requires or demands that you have Lasik surgery. You could continue wearing contact lenses or glasses and have adequate sight. There is no urgency for you to make your decision, and you may decide not to make any decision concerning this surgery. You should take as much time as you wish to study this and other information before making your decision about signing this informed consent document and undergoing Lasik surgery.

PURPOSE

This laser and others similar to it are used in changing the shape of the cornea in an attempt to correct nearsightedness or farsightedness and/or astigmatism. This laser is being used for Laser Intrastromal Keratomileusis (Lasik), a surgical technique for correcting vision problems that uses the combination of a keratome (a special instrument, either mechanical or laser, for cutting the cornea which is the clear covering on the front of the eye) and a laser (a focused cool laser beam) to perform the procedure.

An excimer laser produces a powerful beam of ultraviolet light. The laser is controlled by the doctor. It produces a series of rapid pulses that removes small amount of corneal tissue. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, retina) undisturbed.

The following have been explained by Dr. Tylock and/or the staff:

- 1. Your diagnosis is: Myopia or Hyperopia with or without astigmatism.**
- 2. The Surgeon intends to surgically lift the front portion of your cornea (called the “flap” or “cap”) with the keratome, remove a portion of the exposed inner cornea using the excimer laser, then replace the cap into its original position.**
- 3. The purpose is to improve uncorrected vision by reducing the refractive error. Additional retreatment procedure(s) for astigmatism or residual nearsightedness or farsightedness may be needed at a later date.**
- 4. Your eye will be numbed with drops prior to your surgery. Antibiotic eye drops will also be placed in your eye before and after surgery to reduce the risk of infection. You will also be given a prescription for eye drops to use in your eye after the surgery along with specific instructions for their use.**
- 5. Your eye may be patched after surgery and the patch should only be removed at the visit after your surgery.**
- 6. You may be given a sedative at the time of your surgery. You agree to arrange for somebody to drive you home after your procedure and to not drive until you are comfortable with your vision both day and night.**
- 7. You will return for follow-up care and eye examinations at 1 day, 1 week, 1 month, 3 months, 6 months (9 months if the 6 month is missed) and 1 year. You must understand that keeping your follow-up visits is an important part of your care. Most of the eye tests that were done before the surgery will be repeated at some or all of these visits.**
- 8. It is important to follow all pre and postoperative instructions and to keep all scheduled appointments. You should also call or visit the office anytime you have concerns.**

THE MATERIAL RISKS OF LASIK CAN BE DIVIDED INTO TWO CATEGORIES:

I. Vision Threatening Complications

- 1. It is possible that there could be a loss of some or all-useful vision. This could be caused by an eye infection (internal or external) that could not be controlled by antibiotics or other means.**
- 2. Irregular healing, swelling or scarring of the cap could result in a distorted corneal surface (irregular astigmatism) which would not allow eyeglasses or contact lenses to correct your vision to what was possible before your Lasik.**
- 3. It is possible that an unintended perforation of the cornea could require suturing to close the perforation, could possibly require a full-thickness corneal transplant, or could even cause a cataract to form.**
- 4. The cap of the cornea could be irreversibly damaged in which case it would be necessary for donor corneal tissue to be used to restore useful vision.**
- 5. The cap of the cornea could become loose after surgery resulting in distorted vision and/or astigmatism. This may require additional surgery to either reposition or replace the cap. Replacing the cap would require donor corneal tissue from an eye bank. It is possible that even with this further surgery your best-corrected vision may not be restored to what it was before surgery.**
- 6. It is possible that the cap on the cornea may be completely removed during the procedure. If the cap comes off, the surgeon may elect to do the laser procedure with the cap off and then place the cap back into position.**
- 7. The keratome could malfunction, causing the procedure to be stopped before completion. The procedure may be able to be repeated at a later date or additional surgery may be needed.**
- 8. The excimer laser could malfunction and cause the procedure to be stopped before completion. The laser could malfunction causing an unintended adverse result, including the possibility of loss of useful vision in the eye.**
- 9. Other possible complications and risks include, but are not limited to, corneal swelling, corneal failure, retinal detachment, hemorrhage, blood vessel blockage, glaucoma, cataract formation, total blindness and even the loss of the eye.**

II. Non-Vision Threatening Complications

Everybody experiences at least some of these for a short period of time.

- 1. You may become over-corrected. This over-correction may be permanent.**
- 2. You may not get full correction from your Lasik or it could cause astigmatism not present before the surgery. This could require future surgical enhancement such as another Lasik procedure, or, (if the surgeon feels this would be unwise) the use of contact lenses or eyeglasses.**

- 3. There may be an increased sensitivity to light, glare, and a fluctuation in the sharpness of vision. These conditions usually persist only during the normal stabilization period of one to three months, but they may also be permanent.**
- 4. At night, there may be a “halo” effect around lights. This usually diminishes with time, but could be permanent. Vision may not seem as sharp at night as during the day and you may need to wear glasses for best vision at night.**
- 5. There may be a “balance” problem between your two eyes after Lasik has been performed on one eye, but not the other. This phenomenon is called Anisometropia. This could cause eyestrain and make judging distance or depth perception more difficult. Surgery for the second eye usually can be performed whenever you and the doctor agree that it is advisable. However it might be several months before your eyes are visually comfortable and sufficiently stabilized. The decision to have Lasik on the second eye however, will be yours to make along with the surgeon’s approval.**
- 6. The eye may be more fragile to trauma from an impact. Protective eye wear is strongly recommended for activities that could result in eye trauma, such as racquetball, tennis, softball and karate. A severe blow to the eye could result in loss of the eye.**
- 7. You may experience a worsening of vision initially after the Lasik procedure, and it may take several weeks, or in some cases months, for your vision to stabilize.**
- 8. There is a natural tendency of the eyelids to droop with age and eyesurgery may hasten this process.**
- 9. There may be pain, particularly during the first forty-eight hours following surgery.**
- 10. You may not be able to see as well in situations with low illumination and low contrast as you see during the day; these situations may include, but are not limited to, nighttime, fog, and dimly lit rooms. It is possible that you may have difficulty driving at night. You should be careful until you know if you can see well enough to drive or perform other activities that require you to see well under these conditions. It is also possible that your eyes will become more tired than usual toward the end of the day.**

The eye drops used during the surgery and afterward could cause side effects; you should call the doctor if you notice any persistent itching, burning, redness or sudden changes in your vision.

As in all surgery, there is the possibility of other complications due to anesthesia, drug reactions, or other factors, which involve other parts of the body, which cannot be fully described in this document.

ALTERNATIVES TO LASIK

You may decide not to have this operation at all. If you decide not to have this operation for the correction of your refractive error, there are other methods of obtaining useful vision. These alternatives include, and are not limited to:

- 1. Spectacles: These are the traditional means of correcting refractive error.**
- 2. Contact Lenses: These often provide better vision than spectacles.**
- 3. Radial Keratotomy (RK): This is an established surgical procedure for low to moderate degrees of nearsightedness. The surgeon places between two and sixteen radial incisions on the surface of the cornea.**
- 4. Astigmatic Keratotomy (AK): Astigmatism surgery consists of making microscopic incisions on the surface of the cornea for the purpose of flattening the steepest part of the cornea in an attempt to obtain a more spherical cornea.**
- 5. Automated Lamellar Keratoplasty (ALK): This corneal shaping procedure uses a microkeratome. The microkeratome is used first to lift a flap of corneal surface. For the correction of nearsightedness, the microkeratome is used a second time to remove and discard a second layer of corneal tissue, after which the cap or flap is replaced. This is a mechanical alternative to using the excimer laser device.**
- 6. Photorefractive Keratectomy (PRK): This is a procedure that uses the excimer laser to modify the surface of the cornea to decrease dependence on glasses or contact lenses. Its effect is limited to similar ranges as RK.**

PATIENT COSTS

You will be responsible for paying the standard costs associated with the surgery. The cost of surgery covers the cost of the facility fee and surgical fee as well as post-operative care for one year. You are responsible for any charges for services not directly related to this surgical procedure or for consultations with other doctors. After one year, there may be additional fees for an enhancement procedure or another procedure to treat an eye condition.

EMERGENCY CONTACT

During the course of your treatment, if you experience any medical problems, please contact Dr. Tylock at 972/258-6400.

CONSENT FOR SURGERY

This surgery, like all surgery, presents certain risks. Many of these are listed in this consent. However, as with any surgical procedure, you should understand that there may be other risks or side effects with the Lasik procedure, that are currently unforeseeable or unknown at this time. Despite the best of care, complications and side effects are possible. Should these occur, the result could be to make your vision worse than before your surgery.

ADDITIONAL ACKNOWLEDGEMENTS

Temporary glasses for either distance or reading might be necessary while healing occurs. More than one pair of glasses may be needed. These will be at your own expense.

The follow-up effects of Lasik surgery are unknown for more than four years and the long-term effects (follow-up of ten years or more) are not known at this time. Unforeseen complications or side effects may occur at a later time. Long term follow-up may reveal additional visual complications that were not known at the time of your procedure, or before the creation of this consent form.

Some agencies who have physical or visual requirements for participation, governmental, military, FAA, police and possibly others, may at the present or may in the future decide to impose limitations on various physical conditions, including possibly having had surgery to eliminate eyeglasses. We cannot be responsible for keeping current on the rules and regulations of every local and national organization. If there is a particular group that you are either a member of or anticipate the possibility of joining as a member, you should verify the impact on your career or hobbies that might be imposed by government or groups as a result of having had cornea surgery.

CONCLUSION

As with any surgery, there is no guarantee as to the success of your particular case. There is always a possibility of one or more late complications that were not known or anticipated at the time of this writing (2000). Lasik is an FDA approved surgery. The safety and effectiveness of Lasik has been studied by the FDA and medical researchers in this country.

Having Lasik does not necessarily mean total freedom from spectacles, and there is a good chance that you will have to wear at least some sort of spectacle correction in the future. The correction, which you can expect to obtain from Lasik, may not be perfect. It is not realistic to expect that Lasik will result in perfect vision, at all times, under all circumstances, for the rest of your life. At best, you can expect that you will use glasses at times in order to refine your vision for some purposes. Your particular expectations may not be met and you may need to live with a result not as good as or less desirable than you had hoped.

The details of the surgical procedure know as Laser Intrastromal Keratomileusis (Lasik), including: alternative treatments, an explanation of Lasik and associated treatment, possible benefits as well as disadvantages, and possible risks and complications of Lasik and of not having Lasik, have been presented and explained in detail in this document and by the doctor and/or staff. Although it is impossible for the doctor to inform you of all known information or every possible complication that might occur, the doctor and/or members of the staff have answered your questions to your satisfaction.

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I understand that at the time of my procedure, my physician may discover other or different conditions which require additional or different procedures than those planned. I authorize my physician, and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

By signing this informed Consent for LASIK surgery below, you are declaring that you have read this document entirely (or it has been read to you), and you fully understand it. Furthermore, you are confirming that you fully understand the possible risks, complications, and benefits that can result from Lasik surgery. You acknowledge the receipt of a signed copy of this document to keep.

I hereby request Lasik by Dr. Gary R. Tylock on my:

Right Eye **Left Eye** **Both Eyes**

Person giving consent: _____

Date signed: _____ **Witness:** _____

Surgeon or Designee: _____

LASIK INFORMED CONSENT QUIZ

Please answer the following True/False questions to assure us that you understand the information presented to you about Laser Intrastromal Keratomileusis (Lasik). Please circle the correct response.

You may take as long as you like and ask questions about anything you do not understand.

- 1. True or False** The results of my Lasik have been guaranteed by the surgeon.
- 2. True or False** Lasik is the only alternative to correct my refractive error.
- 3. True or False** If I experience a regression of the effect of my surgery, I can always have an enhancement procedure.
- 4. True or False** People over 40 years of age are more likely to have to wear reading glasses even after Lasik.
- 5. True or False** The Lasik procedure involves the surgeon removing or lifting a portion of my cornea and later replacing it in the same position.
- 6. True or False** Laser surgery is completely safe and not subject to the risks associated with other types of surgery.
- 7. True or False** Even if my surgery does not eliminate all of my refractive vision problem, glasses or contacts can always correct me to 20/20 vision.
- 8. True or False** There is a good chance that my eyes will regress to the refractive error as before the surgery.
- 9. True or False** Regardless of my occupation, I will be able to function at 100% capacity two to three days after my operation.

- 10. **True or False** At night I may experience a halo effect when looking at lights.
- 11. **True or False** My eyes may be unusually sensitive to light after the surgery.
- 12. **True or False** I will not experience noticeable changes in my vision during the months and years after the surgery.
- 13. **True or False** The Doctors and staff have informed me of a complete list of possible complications associated with Lasik.
- 14. **True or False** The excimer laser used for my procedure has been studied and approved by the FDA.

PATIENT SIGNATURE _____ **DATE** _____

Reviewed by _____ Additional counseling (if needed) by _____

Lasik Informed Consent Quiz

Correct Answers and Explanation

1. False It is impossible for any surgeon to guarantee a specific result for even the most ideal candidate.
2. False Glasses and contact lenses are also alternatives.
3. False If there is a significant regression of under-correction, you can have an enhancement procedure *only* if the Surgeon feels it would be in your best interest.
4. True People over 40 are more likely to need reading glasses, if only part-time.
5. True The surgeon uses a microkeratome to shave a portion of the cornea.
6. False Laser surgery is associated with the same risks as any other surgery.
7. False In certain cases, it is possible to lose some best-corrected visual acuity. That is, you may not see as well as before even with glasses or contacts.
8. False There is practically no chance that your vision will regress completely.
9. False You should not drive until you feel comfortable with your vision. You may be somewhat over-corrected initially afterwards, making reading difficult.

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10. True You will probably see a halo around lights at night, and this usually diminishes with time.
11. True Your eyes may be light sensitive for some time after surgery.
12. False Lasik will not prevent future changes in vision which may occur due to the aging process or other causes.
13. False To state all complications of any surgery would be impossible.
14. True The VISX Star S4 excimer laser used for my procedure has been approved by the FDA.