

SEE CLEARLY VISION

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LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) FOR THE CORRECTION OF NEAR-SIGHTEDNESS, FAR-SIGHTEDNESS, OR ASTIGMATISM INFORMED CONSENT

You are entitled to be informed about the use of the excimer laser for performing laser assisted in-situ keratomileusis (LASIK) including the risks of the procedure and alternatives. Please read this document thoroughly and discuss the content with your doctor so that all of your questions are answered to your satisfaction.

This information is provided so that you can make an informed decision regarding the use of the excimer laser for performing LASIK to treat your myopia (near-sightedness), astigmatism, or hyperopia (far-sightedness).

In the LASIK procedure, the surgeon uses an instrument called a microkeratome, which creates a flap in the cornea. Following this, the excimer laser is used to remove a small amount of tissue from beneath the corneal flap. The excimer laser uses a mixture of gases to produce a narrow beam of invisible ultraviolet light energy, which when focused through a lens system, results in the removal of tissue. This causes a change in the shape of the cornea to correct the refractive error. The corneal flap is then replaced on the cornea. This causes the surface to reshape with the effect of decreasing near-sightedness, far-sightedness and/or astigmatism. The LASIK procedure is performed under topical anesthesia (eyedrops).

The alternatives to LASIK include eyeglasses, contact lenses or other refractive surgery procedures. The other alternative refractive surgical procedures include:

- ALK or automated lamellar keratectomy, which involves the use of a microkeratome device, which is designed to surgically remove thin layers of the cornea or outer layer of the eye. The device is passed over the cornea twice; the first pass creates a flap and the second pass removes a small amount of tissue from the cornea.
- CK or conductive keratoplasty, which reshapes the cornea using radiofrequency energy.
- Intacs, which are ring segments surgically implanted in the cornea.
- IOL or intra-ocular lens implants, which corrects the existing refractive error.
- LASEK or Laser assisted sub-epithelial keratomileusis, which uses a trephine, or saw like blade, rather than a microkeratome to create the corneal flap.
- LTK or laser thermal keratoplasty, which uses laser energy to shrink the eye's collagen to reshape the cornea.
- PRK (photorefractive keratectomy which is flattening of the cornea using the excimer laser).
- RK or Radial keratotomy, in which a number of spoke-like incisions are made with a surgical knife in the cornea.

Any questions that you have regarding LASIK or other alternative therapies for your case should be directed to your doctor.

Please initial after reading: _____

PATIENT STATEMENT

I have myopia, hyperopia and/or astigmatism, which require me to wear corrective lenses in order to see clearly for my daily activities. I have been clearly informed of the alternatives including eyeglasses, contact lenses and refractive surgery. I have decided to undergo Laser-Assisted In-Situ Keratomileusis (LASIK) with the excimer laser.

In giving my permission for the LASIK procedure, I declare that I understand the following information:

1. The goal of the LASIK procedure with the excimer laser is to reduce myopia, hyperopia and/or astigmatism, thereby reducing my dependence on contact lenses and/or eyeglasses.
2. I understand that as with all forms of treatment, the results in my case cannot be guaranteed. I understand I will not completely eliminate my reliance on eyeglasses and/or contact lenses. It is possible that the treatment could result in undercorrection or overcorrection, requiring the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age. The treatment may also result in a change in my astigmatism that could require the use of glasses and/or contact lenses. I understand further treatment may be necessary, including a variety of eyedrops, the wearing of eyeglasses or contact lenses (hard or soft), or additional surgery.
3. I understand that if I currently need reading glasses, I will likely still need reading glasses after this treatment. I also understand that if I do not currently need reading glasses, I may need them at an earlier age.
4. FEMALES ONLY: I am not pregnant. If it is possible that I am pregnant, then I will take a home pregnancy test to ascertain that I am not pregnant, since pregnancy could adversely affect my treatment result. If the results of the test are positive, I will not undergo treatment until the results are proven incorrect. I will notify my eye doctor immediately.
5. I understand the treatment should not be performed on persons with uncontrolled collagen vascular disease or autoimmune disease. Patients who are immunocompromised or on drugs or therapy that suppresses the immune system should not have treatment. I will tell the doctor if I have any of these or other medical conditions.
6. I understand that if I have Herpes Simplex or Herpes Zoster the UV of the laser can cause reoccurrence of symptoms.
7. I understand the treatment should not be performed on persons with signs of keratoconus or a history of keloid formation and that I should tell my doctor if I am aware that I have either of these conditions.
8. I have been informed, and I understand that as a result of the LASIK surgery, which uses the excimer laser, it is possible that my vision could be made worse. There are certain complications and risks, which include the following:
 - Abrasion or Epithelial Irregularity: Damage to the corneal tissue.
 - Corneal Scarring/Anterior Stromal Reticular Haze: Haze or scar dense enough to affect vision may occur after the procedure.
 - Corneal Ulceration: An ulcer of the cornea, which is the clear transparent outer layer of the eye.

Please initial after reading: _____

- Corneal Perforation: During removal of the corneal flap the cornea may be perforated. This may necessitate corneal transplantation.
- Decrease in Best Corrected Vision: A decrease in best-corrected visual acuity (vision with eyeglasses or contact lenses) may occur.
- Difficulty Wearing Contact Lens Postoperatively: May occur after refractive surgery.
- Diffuse Lamellar Keratitis: Inflammation under the corneal flap.
- Diffuse Nebulae: A scattered cloudiness of the cornea.
- Double Vision: Perception of two images from a single object; may be horizontal, vertical, or diagonal.
- Ectasia: Stretching or forward bulging of the cornea.
- Endophthalmitis: Inflammation of tissues in the eye due to infection.
- Endothelial Cell Loss: A loss of overall endothelial (the inner layer of the cornea) cell density, increase in cell irregularity or cell size, or change in cell shape could occur.
- Foreign Body Sensation: Patients may experience foreign body sensations or a feeling that something is in the eye. Over a period of a few weeks these foreign body sensations usually diminish.
- Ghost Images: Double or blurry images.
- Glare: Glare, especially from bright lights at night, may be experienced, and can cause discomfort or annoyance.
- Growth Beneath the Flap (Epithelial in-growth): Epithelial cells may grow beneath the corneal flap, causing clouding and necessitating repeat surgery, removal of the flap or, in some cases, corneal transplantation.
- Guttata: Small whitish deposits on the inner layer of the cornea.
- Halo: Halos or hazy rings surrounding bright lights may be seen particularly at night after the procedure.
- Hyphema: Hemorrhage in the anterior (front) chamber of the eye.
- Hypopyon: Accumulation of white blood cells in the anterior (or front) chamber of the eye.
- Overcorrection or Undercorrection: It is possible that the procedure could result in undercorrection or overcorrection and it may be necessary for the patient to continue to wear glasses or contact lenses. Overcorrection may also result in the eye becoming farsighted or hyperopic, which may or may not require the continuing wear of corrective lenses. It is possible that overcorrection may increase dependence on reading glasses or require the use of reading glasses at an earlier age.
- Induced Regular/Irregular Astigmatism: A change in the astigmatism of the eye which may then distort vision and may or may not require the patient to continue to wear corrective lenses.
- Intraocular Infection: An eye infection may result as with any type of eye surgery.
- Intraocular Pressure Elevation: An increase in the inner eye pressure due to post treatment medications, which is usually resolved by drug therapy or discontinuation of post treatment medications.
- Iron Lines: An epithelial iron line, iron stain or Hudson-Stahli line are commonly seen after any refractive surgery, with no observed reduction in vision.
- Lens Opacity: Opacity or cloudiness of the lens in the eye that may prevent a clear image from appearing on the retina.
- Lid Droop: Some patients may experience temporary or permanent slight drooping of the eyelid.

Please initial after reading: _____

- Malposition or Loss of the Corneal Flap, Free Flap, and Incomplete/ Irregular Buttonhole Flap: During surgery, the corneal flap may become damaged or lost. This may leave scarring in the cornea, which may affect vision.
 - Microbial Keratitis: Inflammation of the cornea due to infection.
 - Pain: Ocular pain may occur immediately or in the long-term postoperative period.
 - Perforation or Tearing of the Flap: May occur during or after the LASIK procedure potentially resulting in the need for a corneal transplant procedure.
 - Persistent Cornea Edema: It is normal for a certain amount of swelling of the corneal tissues beyond the normal healing period.
 - Additional postoperative symptoms may include postoperative pain, contrast sensitivity loss and tearing. There is the rare possibility of the need for a corneal transplant procedure due to the problems with healing during or after the treatment. There is also a future risk of complications from injury or infection.
9. I understand that the doctor will prescribe certain medications as part of the treatment. The doctor is prepared to answer any questions I may have regarding the prescribed drugs and any side effects.
 10. I understand the doctor may elect to use a bandage contact lens over the treated area. The benefit of the lens is to reduce discomfort after the treatment. There is a small risk of inflammation known as keratitis and infection, which may need antibiotic treatment.
 11. I understand that this is an elective treatment and that I do not have to have this treatment. I understand that the LASIK procedure is not reversible.
 12. I understand that Laser In-Situ Keratomileusis will require follow-up care at frequent intervals after treatment and I agree to return for required examinations.
 13. I have been told that some patients may require additional LASIK procedures in order to correct remaining mild to moderate levels of myopia, hyperopia and/or astigmatism.

Since it is impossible to state every complication that may occur as a result of surgery, I have been told that the list of complications stated in this form is not complete. There also may be risks and discomforts that are not yet known. I have also been told that the long-term effects of this procedure are unknown.

If I choose to have LASIK on one eye at a time and if my unoperated eye is significantly different in correction, this may result in a condition called anisometropia, where my two eyes do not naturally focus in the same place. As a result of this some people experience headache, double vision and/or asthenopia (eye strain). I may have to wear a contact lens in my unoperated eye to correct this condition, or I may still need to wear spectacles because of the difference in correction in my unoperated eye.

If I choose to have LASIK treatment on both eyes at the same time, I understand that greater risk is involved. This includes, but is not limited to, risks related to the possibility of infection or the functioning of the laser.

Please indicate your choice of treatment today: _____ One Eye _____ Both Eyes
Patient's Initials: _____

Please initial after reading: _____

STATEMENT OF CONFIDENTIALITY

All information in my patient records will be kept in confidence but my examination data may be maintained in a central database for future evaluation of the LASIK treatment. While my specific treatment data will be kept confidential, generic compilation of data possibly including (without identification) my results may be utilized in advising future patients of the safety and efficacy of the treatment. However, no specific patient data relating to my treatment will be released except as required by law.

In signing this Informed Consent Form for the use of the excimer laser for performing Laser In-Situ Keratomileusis, I am stating that I have read this Informed Consent (or it has been read to me) and I fully understand it and the possible risks, complications and benefits that can result from the treatment. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all my questions to my satisfaction.

By signing below, I agree that:

- The Laser In-Situ Keratomileusis procedure has been explained to me in terms that I understand;
- I have had the opportunity to have my questions answered;
- I fully understand the possible risks, complications and benefits that can result from treatment.

My decision to undergo the Laser In-Situ Keratomileusis procedure has been my own and has been made without duress of any kind.

PATIENT NAME (Print) DATE

PATIENT SIGNATURE DATE

PHYSICIAN SIGNATURE DATE

SCVG REPRESENTATIVE DATE