

CLEARLIGHT LASER CENTER

INFORMED CONSENT FORM

LASER IN-SITU KERATOMILEUSIS (LASIK) FOR MYOPIA AND ASTIGMATISM

- I. I, or the patient I represent, hereby consent to have _____, perform laser-assisted in-situ keratomileusis (LASIK) for nearsightedness and/or astigmatism.

Place to be Administered: Clearlight Laser Center

- II. Background:

The procedure (called laser in-situ keratomileusis or LASIK) uses an excimer laser along with an instrument called a microkeratome to potentially correct nearsightedness (myopia), far sightedness (hyperopia) and astigmatism, with the goal of reducing dependency on glasses or contact lenses.

In the LASIK procedure, the surgeon uses an instrument called microkeratome which works like a carpenter's plane to create a pancake-like (lamellar) flap of the cornea. Following this, the excimer laser is used to remove a small amount of tissue from the cornea beneath 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, causing a change in the shape of the cornea. The LASIK procedure concludes when the corneal flap is replaced on the eye. When the corneal flap is replaced, it lies in the bed of excimer laser removed tissue, causing the surface to flatten with the effect of decreasing nearsightedness.

In the LASIK procedure for the treatment of myopia (nearsightedness), hyperopia (far sightedness) and astigmatism, the excimer ultraviolet laser beam removes small amounts of tissue in the areas of the cornea necessary to correct astigmatism in addition to myopia.

Initial _____

LASER IN-SITU KERATOMILEUSIS (LASIK)

III. I understand the procedure described above is surgery and may have risks. Since it is impossible to state all potential risks of any surgical procedure, this form does not provide a comprehensive listing of every conceivable risk or problems.

IV. I have been told that LASIK is designed to treat my myopia (nearsightedness) hyperopia (far sightedness) and/or my astigmatism. The goal of the surgery is to improve my uncorrected visual acuity and to decrease my dependence on corrective lenses (spectacles and/or contact lenses). As with that, I may not completely eliminate my reliance on corrective lenses. I have been told that if I currently need reading glasses, I will likely still need reading glasses after this procedure. I have also been told that if I do not currently need reading glasses, I still may need them as I get older (presbyopia). Lasik does not correct presbyopia. Presbyopia is an inability to see close work due to the aging of the eye's lens.

I have been told that as a result of LASIK surgery, it is possible that my vision could be made worse. Possible complications or risks may include, but are not limited to, improper correction (under or overcorrection), decrease in best corrected visual acuity, irregular astigmatism, glare, halo, double vision, foreign body sensation, corneal hazing and scarring, infection, corneal flap complications, lid droop, and difficulty wearing contact lenses.

Definitions of some of the aforementioned adverse reactions, complications, and risks:

Corneal Hazing or Scarring:

A haze or scar dense enough to affect vision may occur after the procedure.

Initial _____

Flap Complications:

During surgery, the corneal flap may become damaged or lost. This may leave scarring in the cornea that may affect vision. During removal of the corneal flap, the cornea, or clear part of the eye, may be perforated. This may also cause scarring. Epithelial cells may grow beneath the corneal flap, causing clouding and necessitating repeat surgery. Folds or wrinkle in the flap may occur requiring a repeat surgical procedure. In some cases, corneal transplantation may be necessary.

You must protect your eyes from trauma as the corneal flap is susceptible to dislodgment or even loss should you sustain significant injury, especially in the first two years.

Corneal Infection:

An infection of the cornea may lead to scar or ulcer.

Decrease in Best Correct Visual Acuity:

Although uncommon, as a result of the complications discussed above, a decrease in best correct visual acuity (vision with eyeglasses or contact lenses) may occur.

Difficulty Wearing Contact Lenses Postoperatively:

May occur after refractive surgery.

Lid Droop:

Some patients may experience temporary or permanent slight drooping of the eyelid.

Discomfort, Foreign Body and Dry Eye Sensations:

Patients may experience foreign body sensations or a feeling that something is in the eye. Ocular discomfort may occur immediately or in the long-term postoperative period.

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.

I have been told that some subjects may require a second procedure in order to correct mild to moderate levels of myopic astigmatism that remain after the first procedure or to correct complications. Retreatment, however, may not correct problems in some cases.

Initial _____

If applicable: To the best of my knowledge I am not pregnant, nursing, or plan to become pregnant in the near future. If I do become pregnant, I will notify my doctor immediately.

I have been told that the procedure should not be performed on persons with uncontrolled collagen vascular disease or autoimmune disease, or on patients who are immunosuppressed or on medications or therapy which suppress the immune system, so I will tell the physician if I have any of these or other medical conditions. I have been told that the procedure should not be performed on persons with signs of keratoconus or a history of keloid formation and I should tell my physician if I am aware that I have either of these conditions.

I understand that the LASIK procedure is not reversible.

- V. I understand that the following alternatives of treatment that are available and possibly advantageous to me are:

Alternative procedures or corrections: (1) eyeglasses; (2) contact lenses; (3) surgical alternatives: One alternative refractive surgical procedure is radial keratotomy (an operation in which a number of spoke-like incisions are made with a surgical diamond/metal knife in the cornea). Radial keratotomy is most commonly performed in lower to moderate degrees of myopia (less than 8 diopters). Another refractive surgical procedure is excimer laser photorefractive keratectomy which uses a laser to reshape the surface of the cornea. Another procedure, automated lamellar keratoplasty (ALK) uses the microkeratome to remove tissue beneath the corneal flap in a procedure similar to LASIK. Another procedure uses intracorneal rings (Intacs) that are plastic ring segments implanted into the cornea to correct myopia from 1 to 3 diopters. These ring segments are removable. Another procedure for hyperopia is Conductive Keratoplasty (CK). This procedure uses a radio frequency probe to reshape the cornea.

- VI. I understand that there may or may not be additional costs resulting from injury after the LASIK procedure. I understand that any charges not covered by my insurance company will be my responsibility to pay. I understand that monetary compensation for injury is not available nor can the medical treatment rendered as a result of an injury be offered free of charge.
- VII. This form has been explained to me in language and such a way that I understand the contents and implications of this form and have had time to consider and reach a decision. I may contact Dr. _____ in the event of injury and otherwise at any time and he/she will answer any questions.

Initial _____

VIII. As an assurance that you have been properly informed regarding the LASIK procedure, please copy the following in your own writing.

The doctor and his staff have fully explained the risks, benefits, and alternatives of the LASIK procedure. All of my questions have been answered to my satisfaction.

Date

Patient's Signature or
Signature of Legal Representative

Date

Physician's Signature

WITNESS to signature of this reading
and explanation of this document