

INFORMED CONSENT FOR LASER IN-SITU KERATOMILEUSIS (LASIK)

Introduction

This information is provided so you can make an informed decision about the use of a device known as an excimer laser, combined with the use of a device known as a keratome, to perform a procedure called "Laser in-situ Keratomileusis" or "LASIK" in an attempt to correct your nearsightedness (myopia), farsightedness (hyperopia) and/or astigmatism. The results of LASIK, when performed on carefully selected patients, usually, but not always, include improved vision and patient satisfaction.

This information is presented to assist you in balancing the benefits against the possible risks and complications associated with the LASIK procedure. Also, realize that this cannot be an absolutely complete discussion of all possible topics related to LASIK. You are encouraged to ask any and all questions. Please take as much time as you wish to study this consent form, other available references, and consult other persons before signing this document. **IT IS IMPORTANT INFORMATION - YOU NEED TO READ AND UNDERSTAND ALL OF IT BEFORE UNDERGOING THE LASIK PROCEDURE.**

Alternative Treatments to LASIK include, but are not limited to:

- Spectacles & Contact Lenses - The most common method of correcting vision when a refractive error exists.
- Radial Keratotomy (RK) / Astigmatic Keratotomy (AK) - Procedures that consist of placing microscopic incisions on the surface of the cornea to decrease nearsightedness and/or astigmatism.
- Photo-Refractive Keratectomy (PRK) - A procedure that uses an excimer laser to modify the surface of the cornea to decrease nearsightedness, farsightedness, and/or astigmatism.
- Small Incision Lenticule Extraction (SMILE) - A femtosecond laser makes cuts within the cornea, creating a disc-shaped piece of tissue that is removed through a small incision in the surface of the cornea. This tissue removal causes the shape of the cornea to change, which corrects the nearsightedness.
- Implantable Collamer Lens (ICL) - A lens is implanted in the eye behind the iris and in front of the natural lens.
- Intraocular Lens (IOL) - A procedure that replaces the natural lens with an intraocular lens to decrease nearsightedness, farsightedness, and/or astigmatism.

Laser in-situ Keratomileusis (LASIK)

After reviewing alternative treatments, you may decide that LASIK is the most appropriate procedure to improve your visual performance. In LASIK, which is performed under anesthetic eye drops, a microkeratome or femtosecond laser is used to create a corneal flap, which is opened like the page of a book. An excimer laser is then used to remove ultra-thin layers from the cornea to change its shape, and accordingly, decreases nearsightedness, farsightedness and/or astigmatism. The flap is then returned back to its original position. Although the goal of LASIK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed. In some cases, both surgeon and patient may choose to enhance the original procedure for visual improvement several months later when vision has stabilized. After a hyperopic treatment, vision takes longer to stabilize than after a myopic treatment. The amount of laser treatment able to be performed may be limited by the amount of corneal tissue remaining.

LASIK does not correct presbyopia (or aging of the eye) which occurs in most people around age 40 and will at some time require wearing reading glasses for close-up work. **People over age 40 that have their vision corrected will find that, like other people over 40, they will also need reading glasses for close (near) vision.** You should understand that LASIK will not prevent you from developing naturally occurring eye conditions such as cataracts, glaucoma, floaters, retinal degeneration, or retinal detachment.

If you are pregnant or nursing, it is important that you notify your doctor. You should also inform your doctor if you are taking any medications, have any vascular, autoimmune diseases (i.e. rheumatoid arthritis) and/or infectious diseases (i.e. hepatitis, HIV).

It is never "necessary" to have LASIK because it is an elective procedure. LASIK, like any procedure, presents risks. Many risks are listed below. However, there may be other risks not listed and those that are not known, but become known later. The vast majority of people have refractive error treated within the FDA-approved range of correction; however, not all. Please ask your surgeon if you have any questions about your own refractive error. Despite the best of care, possible complications can happen. Although the overall incidence of a given complication may be low, if it happens to you, the incidence is then 100 percent in your case.

LaserVue Eye Center provides your pre-operative and post-operative care; however you may choose to see another eye care professional for these visits. You will then make payments directly to that provider for their services. LaserVue neither establishes their fees nor reimburses the provider for their services.

Complications

- The laser or other equipment could malfunction and the procedure may be interrupted.
- Instead of making a hinged corneal flap, the entire portion of the corneal cap could come off. If this occurs, this piece of cornea may not be replaceable or may necessitate sutures. The surgeon may elect to do the laser treatment without replacing the corneal cap. This may not be able to correct your vision to what was possible before LASIK.
- An irregular corneal surface may result due to abnormalities of the flap and/or an irregular ablation by the laser. This may require surgical retreatment, removal of the corneal flap, or the use of glasses and/or rigid contact lenses. This may not be able to correct your vision to what was possible before LASIK.
- An infection, inflammation (lamellar keratitis), or perforation of the cornea could occur, that may not be controlled with medications or other means causing devastating complications, including permanent loss of some or all of your vision. This may require additional surgical procedures.
- The cells on the surface of the corneal flap (epithelium) could slough and/or grow underneath the flap. This can be painful and the surgeon may elect to put a bandage contact lens on the eye to decrease discomfort. Epithelial ingrowth below the flap is generally responsive to observation or surgical intervention.
- Keratoconus is a non-inflammatory corneal ectasia (weakening) with an incidence of approximately 1 per 2,000 in the general population. The etiology of keratoconus is unclear. Clinical studies provide strong indications of a major role for a genetic etiology. The age of onset for keratoconus ranges from infancy to the early 50s. LASIK and PRK procedures remove corneal tissue that may influence the onset and/or progression of keratoconus in individuals predisposed to the condition. The treatment of Keratoconus could require other surgical procedures which may include a corneal transplant.
- Possible complications include, but are not limited to: corneal swelling, corneal ectasia (bulging), retinal detachment, hemorrhage, venous/arterial blockage, increased ocular pressure, optic nerve damage, partial or total loss of vision, and even loss of the eye.

Side Effects

- There may be increased sensitivity to light, decreased contrast sensitivity, double images, haze and fluctuation of vision. There may be a "glare" or "halo" effect around lights. These conditions frequently occur during the first several months, but may be permanent. Your vision may not be as sharp in dim light or at night as it is during the day and you may need glasses at night. You should not drive until your vision is adequate both day and night.
- You may experience or develop dry eyes following LASIK necessitating treatment. In most cases, these symptoms are temporary for the first several months, but may be permanent and require continued treatment.
- You may have an under-response or over-response to the laser resulting in under-correction or over-correction. This could be permanent, treatable, or may require the use of glasses/contact lenses all of the time. Furthermore, it is also possible to have a decrease in your best-corrected vision.
- There may be a balance problem between your two eyes, called "Anisometropia", after LASIK has been performed on one eye, but not the other. This would make judging distance or depth perception more difficult. You and your surgeon would decide the timing of the procedure of the other eye.
- The eye may be more fragile to trauma or injury after LASIK. It is advisable to wear protective eyewear when engaging in activities in which there is possibility of contact with the eye.
- There may be redness, pain, headache or a foreign body sensation after the procedure.
- There is a natural tendency of the eyelids to droop with age and LASIK may hasten this process.
- Temporary glasses/contact lenses for either distance or reading may be necessary while healing occurs.
- You may experience regression in the visual acuity initially obtained from the procedure. It is not realistic to expect your LASIK procedure to result in perfect vision under all circumstances, for the rest of your life. The vision in one eye may be better than the other eye. Like the rest of your body, your eyes will continue to age. You may need glasses and/or contact lenses to refine your vision for purposes requiring detailed eyesight.
- Medication will be given in conjunction with the procedure, and your eye may be patched. As with any type of a procedure, there is a possibility of complications due to anesthesia, drug reactions, allergies, or other factors, which may involve other parts of your body. Unforeseen complications or side effects may occur at a later time.

It is impossible to state every possible complication that may occur as a result of the LASIK procedure. The list of complications and side effects in this form may not be complete.

Many patients request LASIK on both eyes at the same time. It is important to consider the following before making your final decision:

- LASIK is predictable; however, it is not 100% predictable. Complications may occur requiring glasses/contact lenses, which may not correct your vision to what was possible before the procedure. If one eye is done at a time, you can elect not to proceed with your second eye, or appropriate changes can be made to the operative plan for the second eye.
- The return of useful vision is quite rapid in most cases; in rare instances, the return of useful vision can be delayed. If this happened to your first eye (if you elected to have one eye done at a time), the procedure on your second (functional) eye could be postponed until your first eye stabilized.

After your procedure, you will be given medications and instructions to help prevent infection and control healing. It is your responsibility and imperative that you follow ALL instructions and return for post-operative visits as directed.

Patient Statement of Acceptance and Understanding

The details of the Laser in-situ Keratomileusis (LASIK) procedure have been presented and explained to me at LaserVue Eye Center and in this document. These details include: alternative treatments, an explanation of LASIK - possible risks, complications and side effects of the procedure. I understand that LASIK does not correct the condition known as presbyopia (or aging of the eye) which occurs in most people around age 40 and will at some time require me to wear reading glasses for close-up work. Although it is impossible to inform me of every possible complication that might occur, all of my questions have been answered to my satisfaction. I have received no guarantee as to the success of my particular case.

I understand that LASIK is a newer procedure and as yet has not been completely and exhaustively reported in the scientific literature. I give permission to televise and record my procedure for purposes of educating others, and/or research and to use data about my procedure to further understand LASIK.

I have been offered the opportunity to seek a second opinion concerning the proposed procedure. I understand that conditions may arise which are unforeseen at this time and that it may be necessary and advisable to perform procedures different from, or in addition to, the procedure described. I authorize and consent to the performance of such additional or different procedures as are considered necessary and advisable. I understand that I may be given a sedative at the time of my procedure. I agree to arrange for someone to drive me home after my procedure and to refrain from driving myself until I am comfortable with my vision both day and night.

By signing this Informed Consent for LASIK, I am declaring that I have read this Consent (or it has been read to me), and I fully understand it. Furthermore, I am confirming that I fully understand the possible risks, complications and side effects that can result from LASIK. I accept the fact that I may need glasses, contacts or further procedures following LASIK to achieve my best possible vision. I am also confirming that I have had all of my questions answered to my satisfaction.

I wish to have LASIK performed by ☐ **Stephanie Wangyu, MD** ☐ **Jay Bansal, MD**

on my: ☐ **right eye** ☐ **left eye** ☐ **both eyes**

Patient Signature

Date

Patient Name (Print)

Witness Signature