



Patient Authorization for Laser Vision Correction Surgery

1. *General information*

The following information is intended to help you make an informed decision about having Laser Vision Correction (LVC) surgery. It is impossible to list ALL of the potential risks and complications associated with these procedures. Risks and complications that are considered to be unforeseeable, remote, or not commonly recognized are not discussed. In addition, because LVC utilizes recently developed procedures, there may be long-term effects not yet known or anticipated. The Food and Drug Administration (FDA) has approved the excimer laser for use in Photorefractive Keratectomy (PRK) and Laser-Assisted In Situ Keratomileusis (LASIK). We have been performing LASIK surgery (prior to formal FDA approval) since 1996. The CRS LASIK study provided data that convinced the FDA to approve the excimer laser for use in LASIK surgery in 1999. The LASIK procedure has been practiced in many other countries, such as Canada, Germany and Australia, since 1994. In 2001, we also began performing Laser-Assisted Sub-Epithelial Keratomileusis (LASEK, or “Epi-LASIK”), which is a modification of the PRK procedure. Beginning in August 2003, we began performing wavefront-guided “custom ablation” LVC procedures.

2. *An Overview of LVC Procedures*

Diagnosis: You have been diagnosed with myopia (nearsightedness), hyperopia (farsightedness), with or without astigmatism, with a desire for better (not perfect) “un-corrected” distance vision, or with presbyopia (another type of farsightedness) with a desire for better un-corrected NEAR vision.

Procedures which may be performed: There are several procedures, which may help decrease your dependence on glasses or contact lenses. Your surgeon will discuss which procedure would be best for you.

PRK Surgery: In PRK (surface ablation), an excimer laser is used to permanently change the shape of the cornea. After topical anesthetic drops are placed on the eye, the surface (epithelial) cells are removed from the cornea. The excimer laser then will remove a pre-determined amount of deeper corneal tissue (stroma) from your eye. The amount and location of the tissue removal depends on your prescription and whether you are nearsighted, farsighted, and/or have astigmatism. The removal of very small amounts of tissue causes the cornea to flatten (when treating nearsightedness), steepen (when treating farsightedness), or become more round/less oval (when treating astigmatism). Antibiotic and anti-inflammatory, and cortisone drops are administered, and a soft “bandage” contact is placed on the eye for 3-4 days. During this time, you may experience moderate discomfort, and oral pain medications may be prescribed. Visual recovery can take up to 2 weeks.

LASEK (or “Epi-LASIK) Surgery: LASEK is a modification of the PRK procedure. In PRK, the surface (epithelial) cells of the cornea are removed and discarded prior to applying the excimer laser. However, in LASEK, the epithelial cells are carefully dissected, and eventually replaced after excimer laser treatment is applied to the cornea. This epithelial “flap” is lifted, or “peeled back. Unlike LASIK, no “cut” is made into the cornea. LASEK is a hybrid procedure, having some of the advantages of LASIK (more rapid visual recovery and less discomfort), and some of those associated with PRK (no “cutting” into the corneal stroma).

We generally recommend one of the above “surface ablation” procedures if your correction is too high, your pupil is too large, and/or your cornea is irregular or too thin to allow you to safely undergo LASIK.

LASIK Surgery: LASIK is performed using topical anesthetic eye drops. This procedure, which is the most commonly performed LVC procedure at the present time, involves cutting a thin layer of corneal tissue (the corneal “flap”) with a microkeratome (a surgical instrument much like a carpenter's plane). Once the flap has been made and folded back, the excimer laser is used to remove a thin layer of corneal stromal tissue. The flap is then replaced, and it rapidly adheres, without the need for sutures. The advantage of LASIK is that visual recovery is faster than with PRK or LASEK, and there is less post-operative discomfort with LASIK.

Limits of LVC: Although the goal of LVC is to improve your vision so that you are not **dependent** on glasses or contact lenses, sometimes the end result is that you need to wear thinner (weaker) glasses. Results cannot be guaranteed for every patient. Additional procedures, spectacles or a contact lens may be required in order for you to achieve vision that is adequate for your particular needs. LVC does not correct presbyopia (aging of the eye), which occurs in most people some time after the age of 40, causing the need for reading glasses for near vision. **If you presently need reading glasses over your contact lenses, or bifocals without them, you will still need them after this treatment.** If you do not need reading glasses now, you will definitely need them eventually, unless you opt for “mono-vision”. Mono-vision is when we deliberately “under-correct” one eye, leaving distance vision (in that eye only) slightly blurry, which enables you to use that eye for near vision (see below). LVC surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment, nor will it prevent you from undergoing treatment for these conditions, should the need arise.

3. Patient consent

In giving my permission for LASIK, I understand the following: The long-term risks and effects of LASIK are unknown. 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, femtosecond laser (Intralase®) or the excimer laser 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, in using the microkeratome or femtosecond laser (Intralase®), instead of making a flap, an entire portion of the central cornea could be cut off, and very rarely could be lost. If preserved, I understand that my doctor would put this tissue back on the eye after the laser treatment, using sutures, according to the ALK procedure method. It is also possible that the flap incision could result in an incomplete flap, 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.
3. I understand that irregular healing of the flap could result in a distorted cornea. 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 that

may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.

6. I understand that I could develop keratoconus or ectasia. 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 following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, 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 related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
3. I understand that an overcorrection or undercorrection 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, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time 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, the eye may be more fragile to trauma from impact. 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, at least for the first year following LASIK. I understand it would be advisable for me to 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.
11. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
12. I understand that 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 cut with the microkeratome. 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. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
17. 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.

Risks of Bilateral Surgery: By having treatment on both eyes at the same time you must recognize that you could have one or more of these problems in both eyes at the same time. Although some surgeons feel that bilateral surgery is not appropriate for this reason, the majority of patients undergoing LVC, in our center and elsewhere, do prefer to have both eyes operated on at the same sitting.

Specific ophthalmological issues facing patients who have undergone LVC procedures: Your cornea will be permanently “thinner” as a result of having undergone any of these procedures, making it more difficult to detect or monitor glaucoma, should you develop that condition in the future. Should you need cataract surgery, it may be more difficult to accurately calculate the power of the intraocular lens (IOL) implant that will be placed in your eye. In addition, eye pressure checks for glaucoma can under-estimate the true eye pressure after the cornea is sculpted during LVC. It is important that you make any future eye care practitioners aware of the fact that you have had LVC surgery, as it may not be readily apparent to a subsequent treating

physician. Should you move, it is important that you obtain a copy of your medical records from us (which we will be happy to provide once you sign a release form), and/or give us permission to send your records to your new eye doctor.

Risks of Not Undergoing LVC: The risks of not having the surgery are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses and the risks of trauma to the eye caused by breaks of spectacle or contact lenses in the eye.

Contraindications: In many cases, LVC should **not** be performed on persons with uncontrolled systemic vascular or autoimmune diseases, who have severely dry eyes, who are immune-compromised or on immunosuppressive therapy, with keratoconus (steepening of the cornea), who are pregnant, nursing, or expecting to become pregnant within 3 months of surgery, or patients with recurrent, or active ocular disease(s) or infections. If you even suspect that you have any of these conditions, you should inform our staff and determine if this is a matter for concern. If you have **any** other concerns or possible conditions that might affect your decision to undertake LVC surgery, you should discuss them with your physician.

Risks If You Have Had other Eye Surgeries Previously

If you are having LVC after you have had previous surgery such as LASIK, Radial Keratotomy, Automated Lamellar Keratoplasty, INTACS, corneal transplantation, or other types of eye surgery, the incisions/wounds from these surgeries may not withstand LVC surgery. Should this occur, it might necessitate additional surgical procedures to correct.

4. *Alternatives to LVC*

LVC is an elective procedure and you may decide not to have this operation. Among the alternatives are eyeglasses, contact lenses, refractive lens exchange, conductive keratoplasty (CK), and radial keratotomy (RK), and phakic intra-ocular lenses.

5. *Pre- and Post-Treatment Care*

Before LVC Surgery

Pregnancy: Pregnancy could adversely affect your result, since refractive error and wound healing can fluctuate. If you are pregnant, or expecting to become pregnant, then you should not undertake the LVC procedure until 3 months after the delivery. If it is possible that you are pregnant, then you should be tested so as to resolve the issue. If you become pregnant within 3 months following treatment, you should notify your eye doctor immediately.

Other medications and allergies: You should inform us of any medications you are taking so as to minimize the risk of allergic reactions, drug reactions, and other potential complications during the LVC surgery and subsequent treatment. You must not wear mascara or other eye makeup prior to the procedure, and follow our instructions for lid cleansing prior to surgery. Please ask our staff if you have not been so instructed.

Post-Treatment Precautions

Eye Protection and Water Exposure: Avoid exposing the eye to tap water in the bath or shower, and do not swim **for one week** following surgery, as non-sterile water may expose the eye to an increased risk of infection. The eye shields should be taped over your eyes prior to your nap following surgery, and when you go to bed the first evening. Avoid rubbing the eye or scuba diving for one month. The eye is somewhat more vulnerable to all varieties of injuries after LASIK, at least for the first year after surgery. It is advisable to wear protective eyewear when engaging in contact or racquet sports or other activities in which the possibility of a fall, projectile, elbow, fist or other traumatizing object contacting the eye may be high.

Operating Motor Vehicles: After surgery, you may experience starburst-like images or "halos" around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the LVC procedure, you must bring a driver with you.

Pain and Discomfort: The amount of pain and discomfort that can be expected soon after the LVC procedure varies with the particular procedure performed and with the individual. Patients undergoing PRK will experience more discomfort than those undergoing LASIK. Vision may be blurry and you may experience some redness and/or swelling. Some patients report the sensation of a foreign object in the eye.

6. Patient Statement

I have read this Informed Consent Form. The LVC procedure has been explained to me in terms that I understand. I have watched the "Informed Consent" video corresponding to the procedure that has been selected, and I have read over the information provided by my physician. I have been informed about the possible benefits and known potential complications associated with LVC. I understand that it is impossible for my doctor to inform me of every conceivable risk, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers. I understand that no guarantee of a particular outcome was given and that my vision could become worse following treatment. My decision to undertake the LVC procedure was not made under duress. I understand that LVC is an elective procedure, and my myopia, hyperopia, and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses or other forms of refractive surgery. It is hoped that LVC will reduce or possibly eliminate my dependency on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed. I authorize the physicians and other personnel involved in performing my LVC procedures and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my LVC procedure that they deem relevant.

Please copy the following sentence **in your own handwriting** (notify us if you do not understand it):

"If I am over 40 and have good near and intermediate vision when I am not wearing my glasses or contacts, my '***uncorrected near vision***' will actually get worse after this procedure".

I consent to have PRK / LASEK / LASIK (circle one), performed on my RIGHT / LEFT / BOTH eyes (circle one) by the doctor indicated below, and/or his assistants:

Patient Name: _____

Patient Signature

Date

Witness Name: _____

Witness Signature

Date

Physician

Signature

Date

CO-MANAGEMENT SERVICES AGREEMENT

REFERRING DOCTOR: _____

I agree to be followed and "co-managed" (as described in our handout on this subject, which I have also read over), by my referring doctor and/or his/her associate during the post-operative period.

Patient Signature

Date