

OPHTHALMOLOGY ASSOCIATES

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Informed Consent for Laser Vision Correction Surgery

Patient Authorization for Laser Vision Correction Surgery (7/25/05 Revision, after OMIC, edited 8/3/06)

1. General information

The following information is intended to help you make an informed decision about having Laser Vision Correction (LVC) surgery. Please initial each page as you read it over, PRIOR to the day of surgery, and bring this entire signed document WITH YOU to surgery or we may NOT be able to do your surgery as scheduled. 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).

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). 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 (when treating astigmatism). Antibiotic, 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, oral pain medications are prescribed, and 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. **Risks and Complications** include, but are not limited to:

Loss of Vision: LVC surgery can, very rarely, cause loss of vision or loss of best-corrected vision. This can be due to infection, sterile inflammation, scarring, flap complications, or other problems. Unless successfully treated, some of these conditions could even cause loss of the eye. Vision loss can be due to healing abnormalities, which could make wearing glasses or contact lenses necessary or even to a loss of useful vision. Abnormal corneal wound healing can also result in a distorted corneal surface (irregular astigmatism) so that distorted vision or “ghosting” occurs, requiring a rigid gas permeable contact lens to obtain useful vision. A condition consisting of sterile corneal inflammation, known as Diffuse Lamellar Keratitis (DLK) afflicts approximately 1 out of every 1,000 patients who undergo LASIK. The earliest symptom is subtle visual loss within the first week after surgery. It is usually treatable with high doses of topical steroids, but occasionally requires lifting and irrigation under the flap.

Common Side Effects: Other complications and conditions that can occur following LVC surgery include: anisometropia (difference in refractive power between the two eyes causing imbalance when the eyes are done one at a time); epithelial ingrowth (surface epithelial cells growing underneath the corneal flap); double vision; hazy vision; fluctuating vision during the day and from day to day, increased sensitivity to light that may be incapacitating for some time,

glare and/or halos around lights, which may not completely disappear. Many patients experience “dry eye” symptoms (irritation, foreign-body sensation, or tearing), which can be very uncomfortable, for the first few months after LVC. These symptoms generally resolve within 6-12 months, but can be permanent. We frequently recommend the insertion of temporary, silicone “punctal plugs” (a simple office procedure) to help with this condition.

Overcorrection or Undercorrection: It may be that LVC surgery will not provide the result you desired. Some procedures will leave the eye undercorrected or over-corrected, due to variability in individual healing responses. If this occurs, it may be possible to have additional surgery to fine-tune or “enhance” the initial result. It is possible that your initial result could regress (diminish) over time. In some, but not all cases, retreatment, glasses, contact lenses, or other surgical procedures could be effective in restoring your vision.

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.

Other Risks: Other, rarely reported complications include: optic nerve damage, ptosis (droopy eyelid), corneal infections, ulcers or swelling, contact lens intolerance, retinal detachment and hemorrhage. A condition known as the “interface fluid syndrome” can result from elevated intraocular pressure, usually due to the cortisone drops. Complications could also arise requiring further corrective procedures including either partial (lamellar) or full thickness corneal transplant using donor corneal tissue. These complications can include a loss of the corneal flap, flap decentration, and progressive corneal thinning, or ectasia.

(Ectasia is a steepening of the cornea that can worsen with time and can lead to a reduction in visual acuity. In some cases, ectasia may be associated with keratoconus or related corneal disorders. Keratoconus is a relatively rare 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 and related disorders may occur naturally, there is no absolute test that will ensure a patient will not develop ectasia following laser vision correction. Severe ectasia may need to be treated with a corneal transplant while mild ectasia can be corrected by glasses or contact lenses).

Microkeratome complications can also include free, partial, incomplete, or irregular flaps, which may result in an inability to undergo LASIK at some point in the future. There are also potential complications due to the anesthetics and/or other medications that may involve other parts of your body (systemic reactions). It is also possible that the microkeratome or the excimer laser could malfunction, causing us to have to stop the procedure prior to its completion. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem that could occur.

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. 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.

Late Complications: LVC is a technique that has only recently been developed. You should be aware that other complications might occur that have not yet been reported, and that late complications that have not been anticipated can occur. After the procedure, you should continue to have routine checkups to assess the condition of your eyes. Charges for post-procedure care for one year is included with our fee.

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, INTACS, conductive keratoplasty (CK), phakic intraocular lenses (Verisyse, ICL), and IntraLASIK (use of a second laser to cut the corneal flap instead of the microkeratome).

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 or 3 months after you stop breastfeeding. 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- This does NOT apply to patients who have chosen "mono-vision"):

"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 (Epi-LASIK) / 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 (Ophthalmology Associates Employee)

Date

Dennis H. Goldsberry, M.D., P.E.
Physician

Signature

Date