

# MIDWEST EYE PHYSICIANS

## Patient Authorization for Laser Vision Correction Surgery September, 2001 Revision

### 1. *General information*

The following information is intended to help you make an informed decision about having Laser Vision Correction (LVC) surgery to improve your vision. 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). LASIK was originally considered an "off label" use of an approved device, as the excimer laser was initially approved for only for PRK. However, the CRS LASIK study, (which our practice participated in), provided data that convinced the FDA to approve the excimer laser for LASIK 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), which is a modification of the PRK procedure, initially developed in Italy.

### 2. *An Overview of LVC Procedures*

**Diagnosis:** You have been diagnosed with myopia (nearsightedness) or 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 in decreasing your dependence on glasses and contact lenses. Your surgeon will discuss with you which procedure would be best for you.

**PRK Surgery Described:** In PRK, 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 and less oval (when treating astigmatism). Antibiotic and anti-inflammatory 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 Surgery Described:** LASEK is a modification of the PRK procedure. The excimer laser has not been specifically approved by the FDA for LASEK. The FDA considers LASEK an "off-label" use of the excimer laser, which can be legally performed as a "practice of medicine" decision by individual doctors. 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 without using a microkeratome. Thus, unlike LASIK, no "cut" is made into the cornea. LASEK is a hybrid procedure, having some of the advantages of LASIK, and some of those associated with PRK.

**LASIK Surgery Described:** LASIK is performed using a topical anesthetic (drops in the eye). 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 considerably 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. A given result 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, or other causes. Unless successfully treated, some of these conditions could even cause loss of the eye. Vision loss can be due to irregular corneal healing, which could make wearing glasses or contact lenses necessary or even lead to a loss of useful vision. Irregular corneal healing could 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 “Sands of the Sahara” syndrome (SOS), or 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); 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 give you 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 Reported Risks:** Other rarely reported complications include: optic nerve or retinal damage, corneal ulcers; ptosis (droopy eyelid); corneal swelling, contact lens intolerance; retinal detachment and hemorrhage. Complications could also arise requiring further corrective procedures including either partial (lamellar) or full thickness corneal transplant using donor corneal tissue. These complications include: Loss of the corneal flap, flap decentration, and progressive corneal thinning (ectasia). 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.

**Late Complications:** LVC is a technique that has been recently developed. You should be aware that other complications might occur that have not yet been reported. After the procedure, you should continue to have routine checkups to assess the condition of your eyes. Charges for post-procedure care for two years are included in the cost of the LVC procedure.

**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:** Some believe that 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). If you even suspect that you have any of these conditions, you should inform our staff. 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 transplant or other types of eye surgery, incisions from these surgeries may not withstand LVC surgery. This may require additional surgical procedures.

#### **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, INTACS and radial keratotomy (RK).

#### **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 I have selected, and read information provided by my physician's office. 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 [or 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.

