

SLADE AND BAKER VISION CENTER

INFORMED CONSENT FOR LASER VISION CORRECTION (LVC)

**PLEASE READ THE FOLLOWING PAGES CAREFULLY AND INITIAL AND SIGN WHERE INDICATED.
PLEASE DO NOT SIGN ANY SECTION THAT YOU HAVE NOT READ OR DO NOT UNDERSTAND.**

SECTION 1: GENERAL INFORMATION ON INFORMED CONSENT

The results of LVC performed by a skilled and experienced surgeon are overwhelmingly positive. So good, in fact, that many eye surgeons and their family members have had LVC themselves. However, as with any medical procedure, complications can and do happen. It is our hope to inform you of the side effects, limitations and complications of LVC. Remember, we try to include all complications and conditions but LVC is not limited to the ones we list. It is important to understand that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent form in combination with the consultation process is designed to enhance your understanding of the potential for complications with both the procedure and the healing process.

Many of our patients are surprised by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing LVC, as most of our patients will never encounter any serious complications, and the vast majority of patients are thrilled with the improvement they achieve. It is our intention to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated with LVC or be better prepared to deal with any unexpected complication or side effects if they do choose LVC. LVC is a purely elective procedure, and you may decide not to have this operation at all. In fact, the only way to completely avoid surgical risk is by not proceeding with surgery.

SECTION 2: LASER VISION CORRECTION BACKGROUND

LVC reshapes the part of the eye known as the cornea to attempt to reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness), hyperopia (farsightedness) and astigmatism. There are two primary techniques for reshaping the cornea with the excimer laser, PRK and LASIK. PRK or photorefractive keratectomy reshapes the surface layers of the cornea while LASIK reshapes the inner corneal layers. The excimer laser produces a beam of ultraviolet light energy, capable of removing very precise amounts of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision.

LVC is performed on an outpatient basis and takes only 15 to 20 minutes to complete. Although patients often feel some pressure sensation, both procedures are typically painless. Topical anesthetic drops are used to numb the eye and an eyelid holder is used to prevent blinking. In LASIK, a protective corneal flap is created using a microkeratome.

We use either a mechanical or a laser microkeratome depending on the individual or patient preference. In our own studies the two have very similar outcomes. Please ask your doctor if you have any further keratome questions.

A suction ring holds the eye in position while the keratome creates the protective flap. Patients are unable to see the corneal flap being made as the vision becomes gray when the suction is applied and the red target light disappears until the flap is completed. Most patients sense some pressure, but the flap creation is typically painless. When the laser pulses are completed, the corneal flap is replaced and the natural suction within the cornea seals the corneal flap. A protective eye shield rather than a patch may be needed, but only while sleeping. Although the vision is blurry immediately following LASIK, patients are able to blink normally and there is rapid overnight visual improvement. In PRK the epithelium is removed and the laser directly applied to the cornea. A bandage contact lens may be used.

SECTION 3: LVC INDICATIONS, RELATIVE AND ABSOLUTE CONTRAINDICATIONS and PERI-OPERATIVE CARE

Patient Initials _____

- LVC is indicated for the treatment of myopia (nearsightedness), hyperopia (farsightedness) and astigmatism. The FDA has determined limits of approved treatment for each laser. You may be treated beyond these limits but this would be an off label use of the approved laser.
- Candidates should be over 18 years of age
- Candidates should have a stable refraction although the procedure will not change the natural growth or aging of the eye
- Candidates must be aware that this is an elective procedure and that there are alternative forms of vision correction that are both non-surgical and surgical including eyeglasses, CK, lens exchange, contact lenses or other technologies. One of these options may be better for you. Please ask your doctor if you have any further questions.
- Candidates should ideally be free of certain eye diseases including but not limited to kerataconus, cataracts and certain retinal and optic nerve diseases for the best results. In LVC with kerataconus or corneal disease additional risks are present. In some patients corneal dystrophies such as kerataconus and pellucid might not be able to be diagnosed. If LVC is performed on such a patient, it could accelerate the course of the dystrophy and result in loss of vision and/ or the need for a corneal transplant or other further procedures.
- Candidates should be free of certain active eye viruses including herpes simplex or herpes zoster
- Candidates should be free of certain health problems including but not limited to uncontrolled diabetes or any medication or condition that renders the patient immunocompromised for the best results.
- Candidates must make their surgeon aware of eye problems including but not limited to amblyopia (lazy eye), strabismus (muscle imbalance), dry eyes, or any recurrent, residual or active eye condition that may affect healing. As LVC changes the focus of the eye, muscle imbalances or crossed eyes could be made worse.
- Candidates must make their surgeon aware of general health conditions including but not limited to keloid scarring with previous surgical healing, back problems, claustrophobia or other psychological problems, which may affect the surgery or recovery.
- Candidates must make their surgeon aware of any implants including a cardiac pacemaker, insulin implant or other electronic implanted device.
- Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid potential drug interactions and allergic reactions.
- The FDA considers pregnancy and nursing contraindications, although their effects on LVC have not been studied. Female patients must disclose to their surgeon if they are pregnant, could potentially be pregnant or plan to become pregnant within the next 6 months.

The screening examination performed by your eye doctor is intended to assess candidacy for refractive surgery based upon the corneal shape, prescription and other ocular and visual findings, but not to identify or treat all eye disease.

Certain eye diseases such as dry eyes, kerataconus, pellucid and other eye conditions may not be able to be diagnosed before surgery and could be worsened by the surgery. Ocular disease may be present prior to refractive surgery or may develop after surgery and may be unrelated to laser surgery. Refractive surgery will not treat ocular disease. You should have a complete eye examination with retinal evaluation prior to refractive surgery and annually thereafter to identify and treat ocular disease. In general, patients with higher degrees of myopia have a higher risk of retinal problems and reducing the degree of myopia with laser vision correction does not lower the risk. Patients who wear contact lenses should discontinue their use prior to LVC to allow the cornea to return to its natural contour. Post-operative follow-up care with an eye care professional is required to monitor LVC healing. The final clinical results are dependent upon properly following your post-operative care instructions.

SECTION 4: PRESBYOPIA AND THE MONOVISION OPTION:

Most people around the age of 40 begin to have trouble reading up close due to the natural weakening of their focusing muscles, which is known as ‘presbyopia’. LVC will not prevent the natural aging of the eyes or the need for reading glasses as you age, even if you do not require them now. Although farsighted patients usually improve their reading ability with LVC, it is possible that nearsighted patients may need reading glasses sooner or even right away. Monovision may allow for improved reading ability in both nearsighted and farsighted patients after age 40. The monovision option is typically only selected by candidates over 35 years of age, and simply means that one eye is left a little nearsighted after LVC. For nearsighted patients your myopia is undercorrected in one eye, and for farsighted patients, your hyperopia is a little overcorrected to provide you with some reading ability as you age. Monovision may not eliminate your need for reading glasses for all close work, but may be useful for reading your watch, opening your mail or reading price tags without readers. The disadvantage is that your distance sharpness or contrast sensitivity may not be as good and you may have more depth perception difficulty with activities such as driving at night or with sports such as golf or tennis. Night

driving glasses may be needed with monovision to reduce night glare. If you are in monovision contact lenses already, then the monovision option may be ideal for you. A trial of monovision contact lenses by your eye doctor may be beneficial. In our experience, most patients over age 40 still prefer the best distance vision possible in both eyes and wear reading glasses when needed, and decline the monovision option.

SECTION 5: LEGAL RESPONSIBILITIES, DISCLOSURES and FDA APPROVAL

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Slade and Baker Vision Center and its affiliates, the Excimer laser manufacturer and the governmental regulatory authorities. The data may be utilized for scientific presentations, statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any use of data. While the FDA approves both our lasers for LASIK, higher nearsighted and farsighted treatments are still investigational and are off label..

SECTION 6: RISKS AND COMPLICATIONS

As discussed earlier, all forms of surgery carry a certain degree of risk for adverse effects and complications. Problems can be related to the workup, surgical component of LVC or the healing component. Most surgical problems are related to the creation of the corneal flap and most healing problems develop within the first month following LASIK. PRK problems are often related to wound healing. Complications do happen and can be permanent. Most complications improve or resolve within 6-12 months or with retreatment, but some surgical or healing complications may result in permanent visual blurring, decrease in quality of vision and/or life, glare, discomfort, night vision disturbances, loss of contrast sensitivity (crispness) or need for corrective contact lenses. The risk of a severe complication is not only dependent upon the functioning of the keratome and surgical technique but upon other factors including but not limited to the prescription, orbital structure and corneal shape. In general, there is a small risk of experiencing a complication and a very small risk, less than 1 in 1,000 of a severe sight-threatening complication. But people have lost sight from refractive surgery. Please read this section carefully for a better understanding.

1. Post-operative Side Effects, Adverse Effects and Complications

There are several adverse effects that may be encountered early in the post-operative period. These may include foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dryness of the eyes, tearing and fluctuation in vision. Persistent pain is uncommon following LASIK and may indicate a disturbance of the epithelial protective layer, displacement of the corneal flap or possible infection and should be evaluated promptly by your doctor. PRK patients will be less comfortable than LASIK but typically only for the first few days. Corneal infection following LVC is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases, infections can even result in blindness. Corneal inflammation can also be produced from medication or healing reactions, which may be allergic, toxic or immune in nature. Diffuse interface keratitis (also known as Sands of the Sahara) is the most important inflammatory reaction and can produce corneal hazing, blurred vision, farsightedness, astigmatism that may result in permanent corneal irregularities. Treatment may involve topical steroids or further surgery and may or may not restore vision fully. A common long-term side effect is dryness of the eyes, which often precedes LVC but may be exacerbated or created permanently by the surgery. Another potential long-term side effect is night glare, starbursting, haloes or simply reduced visual quality under low light conditions (night vision disturbances). It is common to have night vision disturbances early during the recovery course and night glare may be more common when only one eye has been treated. The quality of vision may be decreased in night or day viewing. It may be more common in very nearsighted patients or related to pupil size. Some patients benefit from night driving glasses and most, but not all patients, improve substantially over 6-12 months. In a small percentage of patients night vision disturbances may be permanent and affect your night driving or functioning abilities in low lighting.

2. Refractive Complications

Refractive problems may be encountered including but not limited to over correction, under correction, a prescription imbalance between eyes or aggravation of muscle imbalance problems. Depending upon the severity of the original prescription, the individual healing pattern of the patient and other surgical variables, regression may occur causing the eyes to return toward their original prescription, partially or very rarely, completely. LVC may result in overcorrections and undercorrections due to the variability in patient healing

patterns and other surgical variables, leaving patients nearsighted, farsighted or with astigmatism. This may or may not require patients to wear spectacles, contact lenses or undergo further surgery. Patients may also permanently lose best-corrected vision after refractive surgery due to irregular astigmatism that glasses may not help. Differences in refraction between eyes may result in a loss of depth perception, eyestrain, headache, double vision or the need for contact lenses

3. Protective Corneal Flap

The primary benefits of LASIK over PRK are related to the creation of the protective corneal flap. The corneal flap must be of clinically adequate quality, thickness and size to proceed with laser treatment. In some cases where an inadequate flap is formed a second attempt may be made to create a useable flap at the time of surgery or later. Corneal flap complications range in severity from those that simply require the procedure to be postponed, to those that create permanent corneal irregularities resulting in lost of vision. A free corneal cap may be produced which is not hinged to the cornea. If the free corneal cap is of excellent quality then the procedure is completed, but special care must be taken during the first 24-48 hours not to displace or lose the corneal cap. Loss of the corneal cap may result in scarring, and permanent corneal irregularity and the need for more invasive surgery. A severe LASIK complication is that of corneal perforation. Corneal flap complications that occur after the LASIK procedure during the recovery period include displacement and wrinkling of the corneal flap and epithelial ingrowth. An epithelial abrasion can occur at the time of surgery but would typically not cause the surgery to be canceled. This could delay recovery though.

- Corneal flap displacement, partial or complete, may occur days to weeks later. Care should be taken to protect the eyes from trauma, as well as, avoiding rubbing the eyes or forcefully closing the eyes during the first week following LASIK. Partial displacement of the corneal flap may result in corneal striae or wrinkles, which blurs vision both qualitatively and quantitatively. Most corneal striae are treatable but some may be resistant to treatment especially in more nearsighted patients. Complete displacement of the corneal flap is often painful and requires urgent replacement. There is a higher risk of epithelial ingrowth and infection with corneal flap displacement.
- Epithelial ingrowth typically occurs during the first month following LASIK but may occur later and is more likely to occur in patients with an abnormal or weakly adherent epithelium, for which age is a factor. Epithelial ingrowth is produced when epithelial surface cells grow underneath the corneal flap during the healing of the corneal flap incision. Epithelial ingrowth is more common with any trauma or breakdown of the epithelium, which is more common in LASIK enhancement procedures and long-term contact lens wearers. Treatment of this condition involves lifting the flap and clearing the cells away. Although most small areas of epithelial ingrowth need only need to be monitored, untreated large areas of epithelial ingrowth may distort vision and may actually damage the flap integrity if severe and progressive.

4. Corneal Healing Complications

The protective corneal flap of LASIK reduces the healing component of LASIK refractive surgery compared to PRK, but significant healing is still required which can affect the quality and vision of the final result. An important aspect of corneal healing following LASIK or any other form of refractive surgery is the development of corneal irregularities that may permanently affect the quality, crispness and sharpness of the final visual result. Corneal irregularities or irregular astigmatism is produced when the cornea heals in an irregular pattern, which may or may not follow LVC. Corneal irregularity may also be produced from abnormalities and complications of the laser treatment, including central islands and decentrations which may produce blurring, shadowing, glare and doubling of vision. Some corneal irregularity is commonly expected for the first several weeks following an uncomplicated LVC, however if it persists beyond six months it is considered abnormal and may be permanent. Most corneal irregularity improves over 6-12 months and some causes of corneal irregularity may be surgically managed but other causes are permanent. Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that a patient may be unable to read the bottom few lines of the eye chart even with spectacle or contact lens correction. Specifically, the best vision a patient measures after surgery even with lens correction may not be as good as the patient enjoyed before refractive surgery.

In certain cases, the vision may be severely impaired and affect the ability of a patient to drive legally, this is most important in patients who already have reduced visual acuity from other causes. Conventional LVC is not intended to increase the visual potential of a patient and many candidates with high prescriptions often are unable to read 20/20 before surgery and should not expect to read 20/20 after surgery. Furthermore, a patient

who is best corrected before surgery to 20/40 is already borderline for legally driving and any loss of best-corrected vision from healing or surgical complications may prevent legal driving.

5. Risk of Corneal Ectasia

The eye is a fluid filled globe and is under pressure from the inside to maintain its shape. The cornea, therefore, must be healthy to keep from thinning and warping or bowing forward. When this thinning and warping happens, it is know as "Ectasia". Ectasia can severely distort the vision and require further surgery to fix. Ectasia can result in a permanent loss of vision as well. Some patients have corneal dystrophies that result in ectasia such as Kerataconus or Pellucid Marginal Degeneration. These dystrophies tend to be inherited and can take years to be detectable or to progress. In most cases of moderate and severe dystrophies corneal mapping and other tests can detect the process. In the early stages however, a patient may have a corneal dystrophy that does not show in the diagnostic tests. If such an eye is operated on, surgery can accelerate the dystrophy process and create the need for further corneal or other surgery to attempt to correct the vision. While we are dedicated to diagnosing such dystrophies, we cannot guarantee to be able to detect all dystrophies at all stages of development. In some cases a flap that is cut too thickly can result in a corneal ectasia. The FDA has suggested safe limits, but it is impossible to guarantee safety for every eye.

6. Other Complications

It is important to note that it is impossible to list every conceivable complication. There are risks and complications that are considered to be unforeseeable, remote or not commonly known. In addition, there may be long-term effects not yet known or anticipated at the present time. The most severe possible complications may necessitate more invasive or repeated corneal surgery, including corneal transplantation and could potentially produce partial or complete loss of vision.

SECTION 7: EXPECTATIONS OF THE PROCEDURE

The goal of LVC is to achieve the best visual result in the safest way. LVC cannot always eliminate glasses and contacts completely but rather aims to reduce your dependence upon them in an attempt to help improve your quality of life. Night driving glasses and reading glasses may always be needed even when an excellent visual result is achieved. It is also important to recognize that even 90% clarity of vision is still 10% blurry and glasses may still be needed for certain activities that require fine or detailed vision.

Enhancements will be considered on a case-by-case basis and performed only if the benefits outweigh the potential risks. Enhancements within the first year of surgery are subject to a \$300/eye supply fee and any enhancements after 1 year are subject to \$1345/eye. Adequate corneal tissue must be available to proceed with an enhancement procedure and a repeat measurement of the residual corneal thickness will be taken. There are always risks that may be higher with enhancement procedures and must be balanced against the benefits of performing further surgery. Also the safety and efficacy of the lasers have not been proven or approved by the FDA for retreatments and it is considered off label.

Complications are an inherent part of surgery and despite our best efforts, training and skill; we recognize that some patients will experience problems. It is simply our hope to educate you as to what those problems may be so that you can make an informed decision whether or not to proceed. No one ever believes that they will be in the small percentage of people that develops a significant complication, so it is important for all candidates to appreciate that there are truly no guarantees.

SECTION 8: TREATMENT OF ONE OR BOTH EYES

There are both advantages and disadvantages of having LVC on both eyes on the same day. The benefits of surgery on both eyes during the same session begin with the simple fact that patients often prefer this option, as it is more convenient, with respect to either work or home life. Patients may also feel that their vision feels more balanced, with improved depth perception and night glare may dissipate more rapidly. Some patients find they have less anxiety, while others prefer the safety of treating only one eye at a time to allow visual recovery of the first eye prior to proceeding with the second eye.

The primary risks of treating both eyes on the same day are related to unrecognized surgical complications or more commonly, unexpected healing complications, which can produce either temporary or permanent visual blurring. Adequate visual recovery from laser vision correction for activities such as driving, as well as

returning to work, may take 1 day or 1 month, or even longer in patients who respond abnormally, whether one or both eyes are treated. If both eyes are treated, then visual recovery may be prolonged and there is no way to predict who will take longer to heal. There is also no opportunity to learn from the healing pattern of the first eye. If there is an undercorrection or overcorrection in one eye, this is likely to occur in both eyes and both eyes will require retreatment. Other healing complications may also affect both eyes; most importantly the risk of infection may result in severe scarring, corneal transplantation and even complete loss of vision in both eyes.

I would like to have my _____ treated today.
[right eye, left eye, or both eyes]

SECTION 9: COMANAGEMENT

For your convenience you may chose to have your own doctor do the preoperative evaluation and follow-up visits. In this case he will charge for your evaluation and follow-up. Remember you are always free to call us here at Slade and Baker Vision Center at any time for questions or to be seen. Comanagement is your own decision.

SECTION 10: WRITTEN CONFIRMATION

Please write in your own handwriting the following statement to confirm that you have understood and accept that LVC is an elective surgical procedure and as with all surgical procedures, the result cannot be guaranteed. That you acknowledge that although vision-threatening complications are rare, it is possible that partial or complete permanent loss of vision or visual quality may be produced as a result of a surgical or healing complication. That the procedure may not eliminate all of your myopia, hyperopia or astigmatism and that additional correction with glasses, contact lenses or further surgery may be required. That you have had all your questions answered.

I understand the above, there are risks and no guarantees and I may still need to wear glasses.

SECTION 10: VOLUNTARY CONSENT

Please sign below to affirm that you have carefully reviewed this informed consent document and that you have had an opportunity to have any questions that you may have had answered. By signing below you also indicate that you are aware that LVC is an elective procedure, that you do not have to have this procedure and that you understand your other surgical and non-surgical alternatives for vision correction.

PATIENT NAME (Please print) _____

PATIENT SIGNATURE and DATE _____

WITNESS SIGNATURE and DATE _____

SURGEON SIGNATURE and DATE _____