



LASER IN SITU KERATOMILEUSIS (LASIK)

Informed Consent for Excimer Laser

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

It is our intention to fully inform you concerning side effects, limitations, and complications of LASIK surgery. 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 is designed to enhance your understanding of the potential for difficulties that may be encountered during the procedure and the healing process.

Patient

Initials:

SECTION 2: BACKGROUND SUMMARY

LASIK, a form of laser vision correction, reshapes the part of the eye known as the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of nearsightedness, farsightedness, and astigmatism. There are two primary techniques for reshaping the cornea with the excimer laser, PRK and LASIK. In both procedures, the clear covering (cornea) over the colored part of your eye (iris) is reshaped with your prescription. PRK reshapes the surface layers of the cornea while LASIK, reshapes the inner corneal layers with the excimer laser. The excimer laser produces a cool beam of ultraviolet light energy capable of removing precise amount of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision.

Both PRK and LASIK are performed on an outpatient basis and take only about ten to fifteen minutes to complete. Actual laser time ranges from several seconds to several minutes. Although patients often feel some pressure sensation, both procedures have little if any discomfort. No needles or injections are required. The eyes are made numb with topical anesthetic drops. An eyelid holder is used to prevent blinking during the procedure. Patients focus on a red blinking light during both procedures. In the LASIK procedure, a protective corneal flap is created using a sophisticated surgical instrument known as a microkeratome. A LASIK suction ring holds the eye in position while the automated microkeratome creates the corneal flap. During this process vision is dim or dark, and patients cannot see the flap being created or the

fixation target. Once the flap is created and the microkeratome is removed from the eye, the fixation target becomes visible again. When the flap is lifted vision becomes somewhat blurry as if looking through watery eyes. Patients are then asked to stare at the fixation target and the laser treatment begins. The laser treatment makes a tapping sound, and once the treatment is completed, the flap is laid back in place. The natural suction within the cornea seals the flap within one to five minutes. No sutures are needed. Although vision will be blurry immediately after the procedure, patients are able to blink normally, and there is rapid overnight visual improvement.

Patient

Initials:

SECTION 3: INDICATIONS, CONTRAINDICATIONS, and PERI-OPERATIVE CARE

- LASIK is indicated for the treatment of nearsightedness, farsightedness, and astigmatism.
- Candidates must be at least eighteen years of age and have a stable refractive error or prescription as the procedure will not change the natural growth or aging of the eye.
- Candidates must be aware that this is an elective procedure, and there is no medical reason why patients should have LASIK. Alternative treatments are available such as contact lenses, glasses, intracorneal rings, PRK (photorefractive keratotomy), and implantable contact lenses, etc.
- Candidates must be free of certain eye diseases including clinical keratoconus, vision threatening cataracts, and certain retinal and optic nerve diseases.
- There are some relative contraindications such as diabetes, glaucoma, strabismus (turned eye), amblyopia (lazy eye), monocular patients, severe dry eyes, keloid scarring, ocular herpes, autoimmune diseases, collagen vascular diseases, medications or conditions which render patients immunocompromised or with an ocular muscle imbalance. Implants such as pacemakers, insulin, or other electronic implanted devices or other disorders can also impact the procedure or the recovery. Patients must make their eye care professional aware of any of the above conditions prior to the surgery.
- Patients should make their eye care professional aware of any medication allergies and any medications they are taking to avoid any potential drug interactions and allergic reactions.
- The FDA considers pregnancy and nursing contraindications, although their effects on LASIK have not been studied. Female patients agree to disclose to their eye care professional if they are pregnant, could potentially be pregnant or plan to become pregnant within the next six months.

Pre- and Post-Procedure Care:

Refractive Surgery will not treat ocular disease. Patients 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 a higher degree of myopia have a higher risk of retinal problems and reducing the degree of myopia with laser vision correction does not lower that risk. Patients who wear contact lenses must discontinue their use prior to LASIK to allow the cornea to return to its natural contour. Soft contact lenses must be removed at least seven to ten days prior to LASIK, and the overnight use of soft contacts requires two to three weeks' removal prior to the procedure date. Patients who wear rigid gas permeable contact lenses must discontinue their use one to three months prior to LASIK. Post-procedure care is recommended for a full year following LASIK in order to monitor healing and annually thereafter. If an enhancement procedure is needed or a complication occurs, a patient may be required to return to Joplin Eye Laser Center or lengthen their stay at their expense. The final clinical results are dependent upon properly following your post-operative care instructions.

Patient

Initials:

SECTION 4: PRESBYOPIA AND MONOVISION OPTION

Presbyopia, or the inability to see close-up objects, usually becomes apparent to most individuals in their early forties. LASIK will not prevent this natural aging of the eyes or the need for reading glasses as you age; even if you do not need them now. Some patients, usually over forty, may elect to correct their vision in one eye while treating the other eye to be slightly nearsighted. This technique is called monovision and may allow improved distance vision with one eye and may allow the other eye to be effective for reading your watch, reading price tags, etc. However, not everyone adapts well to monovision. If you were successful with monovision contact lenses, then you should do equally as well with monovision LASIK. The disadvantage of monovision is that your distance vision will not be as good. Many patients experience more difficulty driving at night so glasses may be needed to reduce night glare. A trial of monovision contact lenses by your eye care professional is beneficial prior to making the decision to have monovision. Please initial the appropriate statement below:

I would like to have the best distance vision in both eyes

I would like monovision

SECTION 5: LEGAL RESPONSIBILITIES AND DISCLOSURES

Confidentiality:

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted by Joplin Eye Laser Center and its affiliates to the excimer laser manufacturer and the governmental regulatory authorities. The data will be used for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Governing Law/Jurisdiction:

By initialing below, you agree that the relationship and resolution of any and all disputes between yourself and the surgeon shall be governed by and construed in accordance with the laws of Missouri in which the LASIK procedure is performed. You also acknowledge with your initials that the courts of Missouri shall have jurisdiction to entertain any complaint, demand, claim, or cause of action, whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in Missouri and irrevocably submit to the exclusive jurisdiction of the courts of Missouri.

Patient

Initials:

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 surgical component of LASIK or the healing component. Most surgical complications are related to the creation of the corneal flap, and most healing problems develop within the first month following the procedure. Most complications improve or resolve within the first six to twelve months or with retreatment, but some surgical or healing complications may result in permanent visual blurring, glare, discomfort, or the need for corrective contact lenses. The risk of a severe complication is not only dependent upon the functioning of the microkeratome, blade, and surgical technique but upon a number of other factors including prescription, orbital structure, and corneal curvature. In general, there is a small risk in the range of 1-5% of experiencing a complication and a very small risk, less than 1% of a severe sight-threatening complication. Please read this section carefully for a better understanding and initial below.

The risks of LASIK revolve around five primary areas:

1. Post-operative Side Effects, Adverse Effects and Complications
2. Refractive Complications
3. Corneal Flap Complications
4. Corneal Healing Complications
5. Other Miscellaneous Complications

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

There are several adverse effects which may be encountered early in the post-operative period, which 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 flap or possible infection and should be evaluated promptly by your doctor. Corneal infection following LASIK is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant. 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 Sahara) is the most important inflammatory reaction and can produce corneal hazing, blurred vision, farsightedness, or astigmatism that may result in permanent corneal irregularities. Treatment may involve topical steroids or further surgery and may or may not restore vision fully. The most common long-term side effect is dryness of the eyes, which often precedes LASIK but may be exacerbated by the procedure. The most important long-term side effect is night glare, star-bursting, haloes, or simply reduced visual quality under low light conditions. It is very common to have night glare early on in the recovery process, and night glare is more common when only one eye is treated or when the monovision option is chosen. It is more common in nearsighted patients with severe prescriptions and large pupils. Some patients benefit from night driving glasses and most, but not all patients, improve substantially over six to twelve months. In a small percentage of patients, night glare may be permanent and affect your night driving abilities.

2. Refractive Complications

Refractive problems that may be encountered include too much correction, too little correction, or prescription imbalance between the eyes, aggravation of muscle imbalance problems, or a loss of effect from regression. LASIK may result in over-corrections and under-corrections 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. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is typically achieved. Patients may also heal differently between eyes, based on the difference between the eyes in pre-operative prescriptions, corneal curvature, and variation in healing or other surgical variables. Differences in prescriptions between the eyes is termed anisometropia; this is most severe when only one eye is treated, and may result in a loss of depth perception, eyestrain, headache, double vision and the need for contact lenses. Both farsightedness and anisometropia may result in worsening of the pre-

existing muscle balance problems, causing an eye to wander more or to produce more fatigue. Lastly, 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. Further enhancement surgery may be performed when medically stable; if adequate corneal tissue is available and no other medical complications are present.

3. Corneal Flap Complications

The primary risks of LASIK 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. Corneal flap complications range in severity from those that simply require the procedure to be postponed by three to six months, to those that create permanent corneal irregularities resulting in blurred vision. The most severe LASIK complication is that of corneal perforation which has been reported several dozen times worldwide. Corneal flap complications that occur after the LASIK procedure during the recovery period include displacement of the flap, wrinkling of the flap, and epithelial in-growth.

Corneal flap problems include, but are not limited to:

- Corneal flaps of inadequate size preventing laser treatment, and requiring the LASIK procedure to be repeated in three to five months. Typically, no serious visual disturbance occurs although glare and shadowing may occasionally be produced.
- Corneal flaps of inadequate thickness, may or may not be adequate for laser treatment, and may result in the procedure being stopped and repeated in three to six months. A thin corneal flap may result in a slow visual recovery over weeks to months and possibly permanent blurred vision with or without laser treatment.
- Corneal flaps of inadequate quality or smoothness include a variety of corneal flap problems which may produce serious permanent corneal irregularities and significant visual blurring. Corneal flap irregularities may be produced because of inadequate suction pressure, inadequate orbital size, inadequate patient cooperation, malfunction or problems with the microkeratome, blade or suction apparatus.
- Corneal flaps are routinely hinged either nasally or superiorly beneath the upper eyelid. A corneal hinge is not required for a good visual result, but a hinged corneal flap is more secure and typically heals faster and more smoothly. It is possible depending upon the corneal shape, the suction ring alignment and the microkeratome, that a free corneal cap may be produced which is

not hinged to the cornea. Although the laser treatment can still be performed, if any irregularities in flap quality or thickness are noted, the corneal disc is immediately replaced and allowed to heal. If the free corneal cap is of excellent quality then the procedure is completed, but special care must be taken during the first twenty-four to forty-eight hours not to displace or lose the corneal cap. Loss of the corneal cap may result in scarring, permanent corneal irregularity, and the need for more invasive surgery.

- Corneal perforation is the most serious LASIK complication. Corneal perforation is prevented by the microkeratome depth plate, which is checked before each and every procedure. Some microkeratomes have fixed corneal depth plates. Perforation of the cornea requires corneal suturing and the need for an intraocular lens implant, as the natural lens is usually lost or damaged. It should be appreciated that corneal perforation may also potentially result in infection, the need for a corneal transplant, or even rarely blindness.
- Corneal flap displacement, partial or complete, occurs during the early post-operative period, typically during the first twelve to twenty-four hours, but may occur days to weeks later with trauma. 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 highly nearsighted patients. Complete displacement of the corneal flap is often painful and requires urgent replacement. There is a higher risk of epithelial in-growth and infection with corneal flap displacement.
- Epithelial in-growth occurs during the first month following LASIK. This condition is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a factor. Epithelial in-growth is produced when the epithelial surface cells grow underneath the corneal flap during the healing of the corneal flap incision. Epithelial in-growth 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 in-growth need only be monitored, untreated large areas of epithelial in-growth 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. Corneal healing problems with LASIK are more likely to be experienced by patients corrected for higher degrees of nearsightedness, farsightedness, and astigmatism, which may potentially slow visual recovery and increase the need for enhancement procedures for over and under-corrections. Corneal healing may not only affect the speed of visual recovery but the smoothness, and may produce visual blurring. Rarely, corneal scarring may be produced with LASIK. The most important aspect of corneal healing following LASIK or any other form of refractive surgery is the development of corneal irregularities which may permanently affect the quality, crispness, and sharpness of the final visual result. Corneal irregularity or irregular astigmatism is produced when the cornea heals in an irregular pattern, which may or may not follow a surgical flap complication. 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 LASIK; however, if it persists beyond six months, it is considered abnormal and may be permanent. Most corneal irregularity improves over six to twelve months and some causes of corneal irregularity may be surgically managed but other causes are permanent. The greatest limitation of the healing problems is that further surgical intervention does not guarantee better healing and may in fact, result in a further reduction of visual quality.

Irregular astigmatism from both healing and surgical complications may result in a loss of best-corrected vision. This 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 some cases, patients will actually gain best-corrected vision.

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. LASIK 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 be expected to read 20/20 after surgery. Furthermore, a patient who is best-corrected before surgery is 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. Other Miscellaneous Complication

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

Patient

Initials:

SECTION 7: EXPECTATIONS OF THE PROCEDURE

The goal of LASIK is to achieve the best visual result the safest way. The goal is not to eliminate glasses and contacts completely, but to dramatically reduce your dependence on 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 be needed for certain activities that require fine or detailed vision.

Enhancement procedures can be performed when stable, unless medically unwise or unsafe. If the patient decides on an enhancement procedure, an additional fee will be required. Adequate corneal tissue must be available to proceed with an enhancement procedure, and a repeat measurement of the residual corneal thickness will be taken. Typically, patients considered for an enhancement procedure should have at least 1.00 diopter of residual hyperopia, myopia, or astigmatism or unaided vision of 20/40 or worse. Enhancement procedures are performed after four to five months, once adequate corneal healing and stability is achieved. Enhancement procedures are typically performed by lifting the original flap during the first few months before full healing occurs or by creating a new corneal flap. There are always risks which must be balanced against the benefits of performing further surgery.

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 LASIK 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 also may feel that their vision is 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 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 LASIK for activities such as driving, as well as returning to work, may take one day or one 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 under-correction or over-correction in one eye, this is likely to occur in both eyes and both eyes will require further treatment. 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.

Please FILL IN the blank below to indicate the treatment you choose to have today.

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

SECTION 9: WRITTEN CONFIRMATION

Please write in your own handwriting the following two statements to confirm that you have understood and accept that LASIK is an elective surgical procedure, and as with all surgical procedures, the result cannot be guaranteed. Also, that you acknowledge that although vision-threatening complications are quite rare, it is possible that partial or complete loss of vision may be produced as a result of a surgical or healing complication. You are also aware 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.

I understand that “there are risks and no guarantees.”

I understand that “I may still need to wear glasses.”

SECTION 10: VOLUNTARY CONSENT

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

Patient Full Name (print):

Patient Signature:

Witness Full Name (print): _____

Witness Signature:

Surgeon Name (print): _____ Marc _____ Abel,
D.O.

Surgeon Signature:

Co-managing Doctor:

Date of Procedure:
