



CAMPUS EYE GROUP LASER CENTER

INFORMED CONSENT FOR REFRACTIVE SURGERY INCLUDING LASER IN-SITU KERATOMILEUSIS (LASIK), PHOTOREFRACTIVE KERATECTOMY (PRK), AND ENHANCEMENTS AND SECONDARY PROCEDURES

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

It is our hope to fully inform you concerning the limitations, side effects and potential complications of refractive surgery (including but not limited to LASIK, PRK, enhancements, or flap lifts). We continually strive to balance the benefits of laser surgery with the known and unknown risks. It is important to understand that it is impossible to perform any type of surgery without the patient accepting a certain degree of risk and responsibility. This consent form in combination with the extensive educational materials provided and the entire consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both the procedure and the healing process.

Many of our patients are surprised and some are upset 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 laser surgery, as most of our patients will never encounter any serious complications, and the vast majority is 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 or be better prepared to deal with any unexpected complication or side effects which may arise. Refractive surgery is a purely elective procedure, and you may decide not to have this operation at all.

SECTION 2: Laser Vision Correction Background Summary

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 myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (ovalness). There are two primary techniques for reshaping the cornea with laser surgery, PRK and LASIK. Both procedures are able to treat myopia, hyperopia and astigmatism but have benefits, limitations and risks. In both forms of laser vision correction, the transparent cornea at the front of the eye is reshaped with your prescription. PRK or photorefractive keratectomy 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 very precise amounts 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 5 to 15 minutes per eye to complete. In both procedures, topical anesthetic drops are used to thoroughly numb the

eye and an eyelid holder (speculum) is used to prevent blinking. Patients focus on a green target light throughout both procedures.

In the LASIK procedure, a protective corneal flap is created using either a very sophisticated surgical instrument known as a microkeratome or a femtosecond laser. The average corneal thickness is between 500 and 550 μm . The microkeratome creates corneal flaps that are approximately 150 μm in thickness. The femtosecond laser creates corneal flaps that are approximately 110 μm in thickness. A LASIK suction ring holds the eye in position during the creation of the corneal flap. Patients are unable to see the corneal flap being made as the vision becomes gray when the suction is applied and the target light disappears until the flap is completed. Most patients sense some vibrating pressure, but the incision is generally painless. When the excimer laser pulses are completed, the corneal flap is replaced and the natural suction within the cornea seals the corneal flap within 1 to 5 minutes. No sutures are needed as the corneal flap seals rapidly. A bandage contact lens is not typically required with LASIK, however may be utilized in certain instances. A protective eye shields will be provided and required while sleeping. Although the vision is blurry immediately following LASIK, patients are able to blink normally and there is rapid overnight visual recovery.

In PRK, the surgeon first removes the corneal epithelium or protective layer of the cornea. The Excimer laser then applies computer-controlled pulses of light energy to the corneal surface to reshape the eye. A bandage contact lens is typically inserted following PRK for a few days. The epithelium grows back over 3 to 4 days and the vision gradually improves once the protective layer is healed.

In PRK, the removal of the surface protective layer increases the risk of pain, infection and corneal scarring or haze. The creation of the corneal flap with LASIK allows the protective layer to be preserved and provides for a more rapid and comfortable visual recovery. The surface corneal layers are more sensitive than the inner corneal layers treated with LASIK; therefore healing time with LASIK is reduced compared to PRK. The intra-operative risks with LASIK, however, are greater with LASIK than PRK, primarily because of possible complications with the creation of the protective corneal flap with the microkeratome or femtosecond laser. Candidacy for either procedure is discussed during your consultation and examination process.

SECTION 3: Indications, contraindications and peri-operative care

- Refractive surgery is indicated for the treatment of myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (ovalness).
- Candidates must be over 18 years of age
- Candidates must have a stable refraction with no more than 0.50 diopter change within the previous year 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 that there are alternative forms of vision correction that are both surgical and non-surgical
- Candidates must be free of certain eye diseases including keratoconus, advanced glaucoma, advanced cataracts and certain retinal and optic nerve diseases
- Candidates must be free of certain eye viruses including herpes simplex and herpes zoster
- Candidates must be free of certain health problems including uncontrolled diabetes, autoimmune or collagen vascular disease, any medication or condition which renders the patient immunocompromised
- Candidates must make their surgeon aware of certain eye problems including amblyopia

(lazy eye), strabismus (muscle imbalance), severe dry eyes, or any recurrent, residual or active eye condition, which may affect healing

- Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgical healing, back problems, claustrophobia or other physical 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 reaction
- The FDA considers pregnancy and nursing contraindications, although their effects on LASIK have not been studied. Female patients agree to disclose to their surgeon if they are pregnant, could potentially be pregnant or plan to become pregnant within the next 6 months

SECTION 4: Pre-procedure and Post-procedure care

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 disease. Ocular disease may be present prior to refractive surgery or may develop after surgery, but it is unrelated to laser surgery. Refractive surgery will not treat ocular disease. You should have a complete eye examination 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 must discontinue their use prior to refractive surgery to allow the cornea to return to its natural contour. Soft contact lenses must be removed at least 7 days prior to surgery and overnight use requires lenses to be discontinued at least one to two weeks prior to the procedure date. Candidates with rigid gas permeable lenses must discontinue their use one to three months prior to refractive surgery. Stable corneal integrity is necessary. We will not rush into doing any procedure and therefore may require discontinuing contact lenses for a longer period to help insure the best outcome possible.

Post-operative follow-up care is required for one (1) year to monitor LASIK healing, then yearly for routine eye care.

SECTION 5: Presbyopia and Monovision

Monovision may allow for improved reading ability in both nearsighted and farsighted patients after the age of 40. Many 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. Refractive surgery 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 refractive surgery, it is possible that nearsighted patients may need reading glasses sooner. The monovision option is usually only selected on candidates over 35 years of age, and simply means that we leave one eye slightly nearsighted after refractive surgery. 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 will not eliminate your need for reading glasses for fine print, but is useful for reading your watch, opening your mail or reading price tags without readers. The disadvantage

is that your distance sharpness will not be as good and you will have more 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 is beneficial. Most patients over age 40 prefer the best distance vision possible in both eyes and wear reading glasses when needed, declining the monovision option.

SECTION 6: Risks and Complications

As discussed earlier, all forms of surgery carry a certain degree or risk for side effects and possible complications. Problems can be related to the surgical component of refractive surgery or the healing component. Most potential complications are treatable, but some surgical or healing complications may result in permanent visual blurring, glare, discomfort or need for corrective contact lenses. In general, there is a small risk in the range of 1 to 5% of experiencing a complication and a very small risk, less than 1%, of a severe sight-threatening complication. Please read the following section carefully for a better understanding.

a) Post-operative Side effects and Adverse effects

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 corneal flap or possible infection and should be evaluated promptly by your doctor. Corneal infection following refractive surgery is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases, blindness. Corneal inflammation can also be produced from medication or healing reactions, which may be allergic, toxic or immune in nature. Inflammatory reactions can produce corneal hazing, blurred vision, farsightedness, or astigmatism that may result in permanent corneal irregularities. Treatment may involve topical steroids or further surgery. The most common potential long-term effect is dryness of the eyes, which often precedes refractive surgery but may be exacerbated. There are treatment modalities we can use prior and or post refractive surgery to help reduce or minimize this affect. The most important long-term side effect is night glare, starbursts, halos or simply reduced visual quality under low light conditions. It is very common to have night glare early during the recovery course and night glare is more common when only one eye has been treated. Night visual disturbances are typically produced by the pupil size exceeding the laser treatment area. However, with new advances in technology, we can perform refractive surgery on a broader range of pupil size, which may decrease and or eliminate glare and or starburst affects. It is more common in nearsighted patients with severe prescription and large pupils. Some patients benefit from night driving glasses and most, but not all patients, improve substantially over 6 to 12 months. In a small percentage of patients, night glare may be permanent and affect your night driving ability.

b) Pupil Size and Refractive Surgery

The PUPIL is the central opening of the iris. The pupil allows light to enter the eye, like the shutter of a camera. Muscles in the iris respond to changing light conditions and cause the pupil to change size. The brighter the light, the smaller the pupil gets and the dimmer the light, the larger it gets. In addition to light, the pupil responds to a focusing mechanism in the eye called accommodation, and to various medications.

The safety and effectiveness of laser in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) has been repeatedly demonstrated. However, patients with large pupils (greater than 7 millimeters) in dim light conditions may experience night vision difficulties such as halos around lights, glare, and ghosting. These symptoms are caused when the pupil is larger in dim light than the area treated in the center of the cornea. The higher the prescription, the smaller the effective area of treatment and the greater potential for halos.

An expanded treatment area can be used during your treatment to try to minimize these effects and try to improve your outcome, but there is no guarantee that they will be eliminated entirely. If halos persist following refractive surgery and are problematic, you may get some relief with the use of an eye drop that can be used on a daily basis to help constrict your pupil. Not all patients like to use this drop so if your doctor thinks you may be at high risk for halos, you may want to see if you tolerate these drops by trying them before you undergo laser vision correction.

If you are already experiencing these symptoms at night with your contact or glasses, you should expect them to continue after refractive surgery.

Large pupils are not, by themselves, a contra-indication to refractive surgery. It is, however, a fact that must be taken into consideration. Please, feel free to discuss any questions you may have with your surgeon.

c) Refractive Changes

Refractive changes may be encountered including too much correction, too little correction, a prescription imbalance between eyes, aggravation of muscle imbalance problems or a loss of effect or regression. LASIK and PRK 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 glasses, 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 upon differences between eyes in pre-operative prescriptions, corneal curvature, variation in healing or other surgical variables. Differences in refraction between 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 pre-existing muscle balance problems, causing an eye to wander more or produce eye 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 contraindications are present.

d) Corneal Flap and Healing Complications CAN OCCUR WHICH MAY RESULT IN

- The procedure being stopped with it repeated later. A thin corneal flap may result in a slow visual recovery over weeks to months and possibly permanently blurred vision with or without laser treatment.

- It is possible 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.
- Corneal perforation is the most serious refractive surgery complication. When this occurs the procedure may be aborted. After adequate healing time, the corneal integrity will be reassessed to see if it is safe to proceed with the procedure again.
- 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 ingrowth and infection with corneal flap displacement.
- Epithelial ingrowth occurs during the first month following refractive surgery and is more likely to occur in patients with an abnormal or weakly adherent protective layer, 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 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 be monitored, untreated large areas of epithelial ingrowth may distort vision and may actually damage the flap integrity if severe and progressive.

e) Corneal Healing Complications

The protective corneal flap of LASIK reduced 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 refractive surgery 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 undercorrection. Corneal healing may not only affect the speed of visual recovery, but also may produce visual blurring. Rarely, corneal scarring may be produced with refractive surgery.

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 some cases, patients will actually gain best-corrected vision.

Refractive surgery 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 legal driving and any loss of best-corrected vision from healing or surgical complications may prevent legal driving.

f) Raised Eye Pressure

Increased intraocular pressure can occur in patients who use topical steroid drops following refractive surgery procedures. Typically intraocular pressure returns to normal, with no long-

term ill effects once the use of steroid eye drops has been discontinued. However, if intraocular eye pressure is elevated on a long-term basis, permanent loss of vision can occur. Since raised intraocular eye pressure is often painless, periodic evaluations by an eye doctor is imperative. Monitoring intraocular pressure is an important part of the follow-up care provided by your eye care professional.

g) PRK Risks and Other Considerations

Many patients experience mild discomfort for a few days following PRK, although patient reactions range from no discomfort at all to moderate pain. Loss or extensive movement of the protective contact lens can be quite painful. If a patient should lose the bandage contact lens an eye doctor should be contacted immediately to reinsert the lens. Eyes should remain shut until the lens is replaced. Most patients describe the discomfort as the sensation of having grains of sand or an eyelash in their eyes. Some sensitivity to light exists among most patients during the healing of the epithelium.

During the period in which the bandage contact lenses are in place (approximately 2-4 days), vision is blurry for the majority of patients. The healing edges of the epithelium distort the clarity of light rays entering the eye. Once the protective lens is removed, vision when looking at distant objects will appear as if looking through a glass coated with petroleum jelly. This condition clears for most people in a week or two as the surface of the eye heals and becomes smooth. Complete smoothing of the surface tissue of the treated eye may take up to six months. During this period fluctuations in vision may exist. The healing process is individualized and varies patient to patient.

Most patients find it difficult to read in the first few days following PRK. People with greater levels of correction and those over forty who are experiencing the effects of Presbyopia may have a greater difficulty reading without the use of corrective lenses for longer periods immediately following the procedure. PRK cannot be used to correct Presbyopia which occurs naturally as one ages.

Corneal haze, which in most cases can only be detected by an eye care professional using a microscope, is typical following PRK. Corneal haze, if present, is most noticeable two to four months following refractive surgery. Haze generally has little to no effect on vision and is usually not present after six months. A few patients, however, do experience excessive corneal haze and require treatment. Additional treatment with the Excimer laser can generally correct the problems of excessive haze; thus haze has rarely caused permanent vision impairment.

The epithelium is removed just before the laser procedure begins. The epithelium heals in two to four days, but occasionally it heals at a slower rate than expected. In such cases, there may be increased pain and risk of infection.

Some patients experience sensitivity to any contact with the surface of the eye following PRK. The condition tends to diminish over time, but increased sensitivity could be a concern for some professions.

h) Other Miscellaneous Complications

Some patients may experience complications that require a second procedure to be performed. On the rare occasion that a complication like this occurs, the surgeon may be required to lift the flap made in the cornea a second time at any given point in time during the healing process.

This may occur for several reasons including but not limited to, striae or debris that has formed under the flap. The process generally has successful results, and is typically painless. The patient can expect to retain visual acuity in most circumstances.

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 to be 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 could potentially produce partial or complete loss of vision.

SECTION 7: Expectations of The Procedure

The goal of refractive surgery 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 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.

Refractive surgery cannot address the changes that occur in the human crystalline lens. Aging progressively decreases the amplitude of accommodation making it more difficult to see near objects (without glasses) despite a clear view of distance objects. While this does not usually become problematic before the age of 40, it will occur and warrants consideration before having refractive surgery. If you demand bilateral clear vision both far and near, regardless of age and will not wear reading glasses, refractive surgery is not for you. Please understand that if you currently do not require reading glasses and are over 40, you will probably require reading glasses immediately or soon after refractive surgery, even if you can currently take your glasses off to read. If you are younger, it is possible that dependence on reading glasses will occur at an earlier age.

Enhancements, or touch ups, are needed when there is residual prescription. This occurs because every cornea absorbs the laser energy differently. Enhancement procedures can be performed when stable unless medically unwise or unsafe. 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 enhancement procedures 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 at least three months, once adequate corneal healing and stability is achieved. 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 refractive surgery 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.

SECTION 9: Legal Responsibilities and Disclosures

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be utilized for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Patient initials: _____

SECTION 10: Written Confirmation

Please write in your own handwriting the following statements to confirm that you have understood and accept that refractive surgery 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 quite rare, it is possible that partial or complete loss of vision 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. Also, that you understand that refractive surgery is not reversible.

Re-write the following:

I understand that “there are risks and no guarantees”

I understand that “I may still need to wear glasses or contact lenses”

I understand that “I will need reading glasses at some point in my life-time”

SECTION 11: Voluntary Consent

Please sign below 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 refractive surgery is an elective procedure, that you do not need to have this procedure and that you understand your other surgical and non-surgical alternatives for vision correction.

Patient Full Name (Print): _____

Patient Signature: _____

Witness: _____

Surgeon Name (Print): _____

Date of Procedure: _____