



PHOTOREFRACTIVE KERATECTOMY (PRK)

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 PRK 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

PRK, a form of laser vision correction, reshapes the front surface of the eye 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. The procedure results in a permanent change to the shape of the cornea and is not reversible. The United States Food and Drug Administration (FDA) approved the use of the excimer laser manufactures by VISX Incorporated for PRK procedures to correct or reduce nearsightedness, astigmatism, and farsighted ness.

Patient

Initials:

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

- PRK 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 PRK. Alternative treatments are available such as contact lenses, glasses, intracorneal rings, LASIK (Laser In Situ Keratomileusis), 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 contradictions 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 PRK 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 PRK to allow the cornea to return to its natural contour. Soft contact lenses must be removed at least seven to ten days prior to PRK, 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 PRK. Post-procedure care is recommended for a full year following PRK 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. PRK 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 PRK 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

The majority of reactions/complications after the PRK procedure occur in association with the healing process that takes place after the procedure and are usually resolved within one to three months after the procedure. However, it is possible that some of these reactions/complications could be longer-term or permanent.

- **PAIN** may be experienced during the first 24-72 hours after surgery. It is very common to experience a foreign body sensation during this time similar to an eyelash in your eye. Patients may be light sensitive. Eye tearing is common and the eye may be red or swollen. Patients experiencing pain will be provided with medication to take if necessary. Fortunately pain is not always a sign of complication, but daily or more frequent examinations may be required if pain is persistent.

Patient

Initials:

- **NIGHT VISION DIFFICULTY** or **NIGHT GLARE** or **HALOS** is very common early on in the healing process and is more common when only one eye has been treated. Glare is a sensation produced by bright lights causing discomfort and annoyance. Halos are hazy rings surrounding bright lights at night. A patient's vision may not seem as sharp at night as during the day, and the patient may need to wear glasses at night. Typically, six months after both eyes have been treated, only a small percentage of patients still experience significant night glare or halos or other difficulty with their night vision which interferes with their night driving. Patients with large pupils and severe myopia are at the greatest risk for night glare.

Patient

Initials:

- BLURRINESS/LOSS OF BEST CORRECTED VISUAL ACUITY:** Blurriness is very common during the healing process. After PRK, there is considerable improvement in vision within the first several days. It generally requires 3-7 days until vision is clear enough to drive, however, it may take even longer. Approximately 80% of visual recovery occurs within the first several days, with the last 20% of vision improving over 3-6 months and up to a year. A patient who loses sharpness will have vision that is permanently worse. All forms of eye surgery possess the same or higher risk. In the FDA clinical trials for the VISX Excimer laser, fewer than 1% of patients experienced blurriness. Loss of best corrected visual acuity means that the best vision you achieved with glasses or contacts after PRK may not be as good as the best vision you achieved with glasses or contacts before PRK. Therefore, it is possible that a patient may not be correctable to 20/20 after the procedure (even though they were before the procedure) should a healing or surgical complication occur. In the VISX FDA clinical trials, a loss of best corrected visual acuity occurred in less than 1% of patients at one of more years after the procedure.

Patient

Initials:

- INFECTION:** There is a risk of infection during the healing of the outer protective layer (epithelium). This generally takes 3 days, however it can take a week or even longer. The patient is most at risk for infection until the epithelium is completely grown back. The vision remains blurry during the surface healing. Make-up, swimming and possible contamination should be avoided during this time. A serious corneal infection can result in scarring, a permanent reduction in vision, and even complete loss of vision. However, the risk of severe corneal infections is rare. No patients experienced infection in FDA clinical trials for the VISX Excimer laser.

Patient

Initials:

- OVER-CORRECTION:** PRK may result in over-correction with the eye becoming farsighted for a nearsighted patient or nearsighted for a farsighted patient as a result of the healing response of the eye, which may or may not require the continuing wear of corrective lenses or increased dependence on reading glasses.

The occurrence of over-correction in the FDA clinical trials for the VISX Excimer laser was less than 1% of patients at one year after treatment. If this occurs and you are annoyed by the over-correction, you may be eligible to have an additional laser procedure to alleviate the over-correction. While an enhancement procedure does not guarantee improvement, it very often does significantly improve your distance vision.

Patient

Initials:

- **UNDER CORRECTION:** A patient may not get the full correction desired from PRK, and some degree of nearsightedness or farsightedness could remain as a result of the healing response of the eye. A patient may need to continue to use glasses or contact lenses. The occurrence of under-correction in the FDA clinical trials for the VISX Excimer laser was less than 1% of patients at one year after treatment. In many cases, but not all, an additional enhancement procedure may be done to further improve vision. While an enhancement procedure does not guarantee improvement, it very often does significantly improve your distance vision.

Patient

Initials:

- **REGRESSION/OTHER CHANGES TO THE EYE:** You may experience regression in the visual acuity initially obtained from PRK, so vision may partially, or, very rarely, completely return to the level where it was prior to having this procedure. This might occur soon after surgery or years later. Again PRK does not stop the natural aging process. In addition, PRK will not prevent you from developing naturally occurring eye problems, such as glaucoma, cataracts, or retinal degeneration or detachment.

Patient

Initials:

- **IRREGULAR ASTIGMATISM:** This means the smooth surface of the cornea heals in an irregular pattern. Some irregularity is common for the first several weeks. If irregular astigmatism persists beyond six months, we then consider it abnormal and in rare cases it could be permanent. This can result in blurriness and loss of best corrected visual acuity. In the FDA clinical trials for the VISX Excimer laser, irregular astigmatism occurred in less than 1% of patients.

Patient

Initials:

- **CENTRAL ISLANDS:** With this condition, the cornea heals in an irregular fashion within the central 3.0 mm. This results in decreased best corrected and uncorrected acuity, doubling or shadow images. If this does occur, it is usually self-limiting, resolving on its own within 3 to 12 months. If it does not resolve itself within that time then an additional laser procedure may be necessary. In the FDA clinical trials for the VISX Excimer laser, this occurred in less than 1% of patients.

Patient

Initials:

- **DECENTERED ABLATION:** This condition means the laser's ablation or "zone" of correction is not aligned with the patient's visual center or axis. If this occurs, it can result in glare, especially at night. An additional laser procedure may be needed to try to correct this condition. However, in rare cases may not be treatable. In the FDA clinical trials of the VISX Excimer laser, a decentered ablation occurred in less than 1% of the patients.

Patient

Initials:

- **SCAR TISSUE or HEALING HAZE:** Healing haze consists of collagen proteins which develop on the surface of the eye during the normal PRK healing process. Mild haze may not be noticeable by the patient and usually clears over time. However, more severe haze presents usually as a dirty windshield type of appearance to your vision. Haze is not the initial blurriness you will experience but may become evident after surgery developing over weeks or months. Even if scar tissue develops, it can usually be treated with another laser procedure. Scarring may be persistent or infrequently recurrent, requiring multiple surgeries and possibly producing loss of visual sharpness or overcorrection. In the FDA clinical trials for the VISX Excimer laser, the above complications occurred in less than 1% of cases.

Patient

Initials:

- **OTHER COMPLICATIONS:** Other possible complications that may be associated with the PRK procedure include elevation of intra-ocular pressure, no-reepithelialization of a treatment spot or corneal epithelial defect, cataract (cloudiness of the lens), corneal scarring, corneal swelling, corneal ulceration or inflammation, dryness of the eye, irregularities of the cornea (corneal deposits, microcysts), endothelia cell loss (a loss of endothelial cell density, increase in irregularity of cell size or shape which may result in corneal swelling), inflammation of the iris, retinal detachment, hemorrhage, itching, double vision, drooping of the eyelid, contact lens intolerance, and reading difficulty. Although these conditions are rare, it is possible that complications may result in the need for corneal surgery (i.e. corneal transplant) or even blindness. There are also potential complications due to anesthesia and mediations that may involve other parts of your body. It is important to note that it is impossible to list every conceivable complication that could occur with Excimer laser surgery and that there could be a complication not listed above. Risks 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.

Patient

Initials:

- **STERIOD COMPLICATIONS:** Post operative drops are typically used for up to 2 months (in some cases, up to 6 months), tapering monthly. Patients must be monitored monthly while on the topical steroid drops. For best results, patients must use the medication as prescribed. Your doctor may stop the drops early if you appear to be healing slowly. Your doctor may continue drops once a day after 4 months, if needed, to help stabilize the final result. It is very important that you follow your doctor's instructions regarding the use of eye drops after the PRK procedure, as this can affect your final visual outcome.
 - **Purpose:**

Early on:	Reduces redness; swelling; light sensitivity
Later:	Promotes normal healing; reduces haze; slows healing to fine-tune results.
 - **Caution:** Excessive use can increase eye pressure; produce eyelid drooping; promote farsightedness; and rarely promote cataract changes.

Rapid discontinuation can promote regression towards nearsightedness and can increase haze. Patient monitoring while on topical steroid drops will reduce the risk of such occurrences.

Patient

Initials:

- **RISKS OF SEVERE COMPLICATIONS:** Although only about 1% of patients may develop severe complications, NO ONE ever believes they will be that 1%. Theoretical risks mean they just have not happened as of yet. There are no guarantees. No guarantees of perfect vision, no guarantees of zero glasses or contact lenses. No guarantees that you will not be among the few people that have significant complications.

Patient

Initials:

SECTION 7: EXPECTATIONS OF THE PROCEDURE

The goal of PRK 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 three to four 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.

Patient

Initials:

SECTION 8: IMPROVEMENT OF VISUAL POTENTIAL

Patients who do not see 20/20 or 100% before the surgery even with the strongest prescription cannot expect or anticipate 20/20 or 100% after the surgery. That is, after surgery the best vision a patient can attain is the vision they experienced pre-operatively with their glasses or contact lenses. Rigid gas permeable lenses may actually provide certain patients with better vision than glasses, soft lenses and refractive surgery. This surgery does not improve visual potential. Nearsightedness represents multiple visual problems, of which your prescription is only one. That is why each patient will continue to require routine annual eye examinations to rule out several other associated conditions, primarily to assess the retinal nerve tissue quality which this procedure does not directly affect. It is the reduced retinal nerve tissue quality which prevents some individuals from reading 20/20 with full correction. Approximately 20/40 is legal driving vision, if you cannot achieve corrected vision of 20/40 or better you may not qualify to renew your driver's license. Patients, with borderline visual function must understand that loss of sharpness may prevent them from driving legally.

Patient

Initials:

SECTION 9: POST TREATMENT PRECAUTIONS

After surgery, you may experience starburst-like images or halos around lights, your depth perception may be slightly altered, and your 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. Ask your doctor when it is appropriate for you to drive. On the day of the PRK procedure, you should arrange to be driven home after the procedure.

Patient

Initials:

SECTION 10: TREATMENT OF ONE OR BOTH EYES

There are both advantages and disadvantages of having PRK 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 PRK 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]

Surgeon Signature:

Co-managing Doctor:

Date of Procedure:
