CAMPUS EYE GROUP

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PRK (Photorefractive Keratectomy)
CONSENT FORM

Photorefractive Keratectomy, of PRK, is a permanent vision correction procedure in which tissue is removed from the surface of the eye (the cornea) using an excimer laser. Precise control of tissue removal and management of the healing process can result in reduced dependence on corrective lenses for distance vision for most patients.

The Food and Drug Administration (FDA) regulate the manufacture and use of the excimer laser in the United States. The excimer lasers currently being used has been approved by the FDA for treatment of nearsightedness with and without astigmatism and farsightedness with and without astigmatism on the surface of the cornea.

This patient consent form generally describes the PRK procedure and outlines certain risks and possible benefits. Before electing to undergo PRK, you must have a complete eye examination and should fully discuss the potential risks, complications and time for healing our eye care professional. You are encouraged to ask questions at any time about PRK or about any statements made in this form.

How the Eye Works

To better understand PRK and how the excimer laser can be used to correct vision problems resulting from refractive error, a short review of how the eye works may be helpful. Refractive errors (nearsightedness or myopia, farsightedness or hyperopia, and astigmatism) generally result from an abnormally or irregularly shaped eye.

When light enters the eye, it is bent (refracted) by a clear, strong tissue at the front of the eye called the cornea. The cornea, in effect, acts like a lens to focus incoming light onto the retina at the back of the eye.

In nearsightedness, or myopia, light entering the eye does not focus on the retina as it should, but instead focuses images at a point in front of the retina. Nearsightedness is frequently caused either by an eye shape, which is abnormally long, or by an excessively steep curvature of the cornea. The result of nearsightedness is that distant objects appear blurry, while objects near to the viewer can be seen in focus.

In astigmatism, the problem is not the length of the eye, but the fact that the cornea is not spherical and contains different curvatures and is typically shaped more like a football than a basketball. The result of astigmatism is that objects are not focused into a single image and vision is distorted or blurry. Often, people who have nearsightedness also suffer from astigmatism.

In farsightedness, or hyperopia, light entering the eye focuses images at a point behind the retina. Farsightedness is frequently caused by an eye shape, which is abnormally short, or by an excessively flat cornea. The result of farsightedness is that objects near to the viewer appear blurry, while objects in the distance may be seen in focus.

Presbyopia, or the inability to see close-up objects, usually becomes apparent to most people in their early forties. This condition occurs normally with age and results from a change within the eye in which the internal lens loses its ability to focus on close-up objects.

PRK, which only treats the surface tissue of the eye, cannot correct Presbyopia. At some point, you will need to wear reading glasses.

Vision Correction Alternatives

Vision problems resulting from refractive errors are typically corrected either with eyeglasses or contact lenses. Currently, PRK is used for treating nearsightedness, farsightedness and astigmatism.

LASIK, or Laser In-Situ Keratomileusis, is another procedure for treatment of nearsightedness. With LASIK an ophthalmologist uses a microkeratome, an automated device with a blade to create a layer of tissue about 160 microns thick (one third of the cornea) across the surface of the eye. This flap of tissue, which remains attached on one side, is folded back and the excimer laser is used to remove the underlying stromal tissue. Following laser treatment, the flap is laid back in place. Sutures are not typically used to hold the flap in place. If laser re-treatment is required, the flap can be lifted for re-treatment of the underlying tissue since the stromal tissue does not regenerate itself and the flap is primarily held in place by the epithelium, or thin protective layer of tissue on the surface of the eye.

The Excimer Laser

PRK uses an excimer laser for vision correction. No blades are used and no incisions are made to the eye. In PRK, the cornea is reshaped using the energy from pulses of light emitted by an excimer laser.

Ultraviolet light with wavelengths less than 300 nanometers will not penetrate through the surface of the eye. Because of this particular phenomenon, the excimer laser with a wavelength of 193 nanometers does not transmit energy through the cornea to the internal tissue of the eye. Instead, the ultraviolet light is absorbed in the surface cells of the eye giving the excimer laser its unique ability to reshape these surface tissues. As the ultraviolet light is absorbed by the surface of the eye, tissue is vaporized. The energy of the laser is controlled so that each pulse precisely removes thin layers of tissue from the cornea, 1/4000 of a millimeter at a time. In fact, it would take about 200 pulses from the excimer laser just to etch through one human hair. The laser is programmed

specifically for each patient and is controlled by a computer which determines the location, number of pulses and surface area to be impacted by the laser light beam based on that individual patient's particular vision problems and correction needs.

Patients who wear contact lenses

Contact lenses can distort the curvature of the cornea. Therefore, before being evaluated for PRK and before the treatment can be performed, the shape of the eye must be allowed to stabilize in its natural shape.

Patients who wear gas permeable or hard contact lenses must totally stop wearing such lenses at least one month prior to the procedure. Patients who wear soft contact lenses must totally stop wearing their soft contact lenses at least one week prior to the procedure. You must confirm compliance with these requirements prior to undergoing PRK. The period required to stabilize the natural shape of the cornea may be longer for some patients. You must contact your eye doctor is you suspect that your vision is continuing to fluctuate as your eye returns to its normal shape following removal of your contact lenses.

Contraindications

An individual is a poor candidate for PRK if any of the following conditions exist: unstable refractive error, history of keloid formation, keratoconus (progressive thinning/steepening of the cornea) keratitis sicca (advanced dry eyes), diabetes, glaucoma, expectant or nursing mothers, cataracts, heart condition requiring pacemaker regulation, recurring ocular herpes simplex, or active ocular inflammatory disease. If you know that you have any of these conditions, you must inform your eye doctor.

The Laser-PRK Procedure

Before proceeding with the PRK procedure, a final check of your eyes will be completed. Eyes to be treated are measured and mapped and the information is reviewed to detect and isolate any irregularities in the shape of the cornea. Before performing the procedure, a physician will be available to review the procedure with you, answer any questions and conduct additional examinations as appropriate.

Most patients dress casually and comfortably. You are not allowed to wear make-up, colognes, perfumes or scented lotions, as this will affect the performance of the laser. We encourage patients to bring a companion with them to see the PRK procedure since you will not be permitted to drive home by yourself after the procedure. Your companion may accompany you through the entire process.

You will not be given a general anesthetic. In fact, the only medications administered during the procedure are eye drops. (Anesthetic, antibiotic and /or non-steroidal, anti-inflammatory medications may be used, as appropriate. While allergic reactions to these medications are rare, please advise your eye doctor of any allergies you may have).

In the laser room, you will be lying flat on a table and placed in proper position with respect to the laser used for performing PRK. The eye that is not being treated will be covered. Then, an instrument called an eyelid speculum will be placed between your upper and lower eyelids to prevent you from blinking.

To begin the actual PRK treatment, the surgeon will remove the protective layer on the surface of your eye, which is called the epithelium. There are various ways the epithelium can be removed. The surgeon can either remove the epithelium: 1) exclusively with the laser, or 2) partially with the laser and wiping the remainder away with a special instrument, or 3) by exclusively wiping with a special instrument, or 4) with a small rotating brush. You will not be able to feel any of the contact with your eye at this point. However, the sensation of seeing the surgeon wiping the surface of your eye may surprise you.

Next, you will be asked to stare at a blinking red light. The surgeon will then activate the excimer laser and begin re-shaping your cornea. The red light will become more difficult to see as the laser treatment progresses. While the laser is in use, you will be asked to keep your head and eye as still as possible. However a small amount of eye movement should not affect the outcome of this procedure. If significant movement is apparent, the surgeon will stop the laser until re-alignment has been established. The laser treatment time for most patients is typically less than 60 seconds per eye.

During the procedure, you will notice distinctive sounds and smells. For example, the machine makes a clicking or snapping noise whenever the laser is in use. The surgeon will let you know before the pulse begins so that the noise will not startle you. Laser treatment of the eye tissues also produce an odd odor.

Once reshaping of the cornea is complete, additional eye drops are instilled, a protective soft contact lens is inserted and the eyelid speculum is removed.

If you are having both eyes treated on the same day, it will take a few minutes to program the computer and prepare for laser treatment of the other eye. The total time in the laser room is usually less than 20 minutes.

Post Procedure Expectations

After the procedure, you will be advised to rest for the remainder of the day and to continue using prescribed eye drops as instructed. During your PRK procedure, the protective layer of tissue on the surface of the eye, the epithelium, is removed from the central portion of the cornea. This protective tissue regenerates itself, and normally over a two to four day period the healing process is sufficiently completed such that the epithelium once again covers the entire surface of the eye.

During this healing process, some patients will experience varying degrees of discomfort. This can vary from a mild scratchy, burning, or foreign body feeling to more severe pain, which is only minimally responsive to normal oral medications. Two options are available to reduce discomfort and promote healing. An eye patch can be applied to keep the eye closed or a soft contact lens can be inserted to protect the treated area while healing is under way. Studies have shown that most patients are more comfortable with the contact lens and eye drops than if the eye is patched.

Patients who have difficulty wearing contact lenses may not be able to successfully wear the protective lenses and may experience greater than normal discomfort following PRK.

Although there is minimal risk of infection with either the use of the contact lenses or the patch, the risk is thought to be slightly higher with the contact lens. In addition to the probability of experiencing less post-procedure discomfort, patients with the contact lens have their eye open, permitting useful (although blurry) vision, which is obviously not possible, if the eye is patched.

Before you leave the laser center, you will be supplied a kit containing antibiotic and anti-inflammatory eye drops along with a schedule for their use. You may also be provided anesthetic eye drops, which may be used during the first 24 hours following PRK. These anesthetic drops are to be used only in the case of significant discomfort. Care must be taken to avoid any contact with the eye during the period in which the sensitivity of the eye is reduced through use of the anesthetic drops. Because of the reduced sensitivity of the eye while using anesthetic eye drops, you might accidentally damage your eye without feeling the contact. You may also be provided with a prescription of oral medications, which can be used, should you experience discomfort, pain or difficulty in getting to sleep.

You are likely to be sensitive to light and may not be able to see well enough to accomplish even simple tasks like reading a menu for two to three days following PRK. You will appreciate having a companion along. You should certainly not drive during this period.

Patients typically return to the office the day following the procedure to confirm the fit of the protective contact lens and to ensure that the healing process is progressing satisfactorily. The epithelium usually regenerates itself sufficiently to cover the treated area within two to four days. During this period, a visit to our office or to your co-managing doctor may be required if discomfort persists.

If all is healing, as anticipated and no particular discomfort is present, your eye doctor removes the protective lens on the third or fourth day following the procedure. In some cases, an additional day or two is required prior to removing the protective lens to ensure that the healing process is adequately advanced.

You should refrain from driving until your vision is sufficiently restored to make driving safe.

Your eye doctor will monitor your recovery and your continued use of eye drops. Steroid eye drops are often used after the procedure to reduce redness, eye irritation and to regulate healing response. Regular follow-up visits are required as the use of steroid eye drops can cause an increase in internal eye pressure for some patients. Follow-up evaluation visits are generally scheduled within ten days after the procedure, then as needed for the next 12 months after the procedure. After the 12-month post-operative period, yearly eye exams are recommended.

Risks and other Considerations

No vision correction procedure is risk free. In addition, because Photorefractive Keratectomy, or PRK, is a relatively new procedure introduced in 1987, there may be longer-term risks, which are unknown at this time.

1. Discomfort. Many patients experience mild discomfort for a few days following PRK, although patient reactions range from no discomfort at all to moderate pain. Some patients may experience a burning sensation for a few moments when instilling the eye drops in the first two to three days following the procedure. Loss or excessive movement of the protective contact lens can be quite painful. Patients losing the protective contact lens should keep their eye closed and contact an eye doctor to reinsert a protective lens. Most patients who have discomfort describe it as the sensation of having grains of sand or an eyelash in their eyes or having a torn contact lens. Some sensitivity to light exists among most patients during the period in which the epithelium is healing.

2. Blurry Vision. During the period in which the protective tissue on the surface of the eye, the epithelium, is healing (generally two to four days), vision is blurry for most patients because of the presence of the protective lens and because 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 objects within six to ten feet will appear as if looking through glasses coated with a thin film of petroleum jelly. This condition clears for most people in a week or two as the surface of the eye heals and again becomes smooth. However, complete smoothing of the surface tissue of the treated eye may take as much as six months. During this period, some fluctuation in vision may exist. The healing process is very much individualized and varies from patient to patient.

3. Reading Difficulty. Most patients will 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 greater difficulty reading without the use of corrective lenses for longer periods immediately following the procedure. PRK cannot currently be used to correct Presbyopia, which occurs naturally as one ages.

4. Corneal Haze. 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 in the period two to four months following the laser procedure. Haze generally has little or 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 problems of excessive haze; thus haze has rarely caused permanent vision impairment.

5. Loss of nighttime Visual Acuity. Some patients who have undergone PRK experience a halo or glare effect from the edge of the treatment zone or from excessive haze. This effect is noticeable in dim light conditions, particularly for those patients with large pupils, and can interfere with night driving. Significant corneal haze can also result in loss of visual acuity in dim light condition.

6. Raised Eye Pressure. Increased intraocular pressure can occur in patients who use topical steroid drops following the PRK procedure. 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 result. Since raised intraocular eye pressure is often painless, periodic evaluation by an eye doctor is imperative. Monitoring intraocular pressure is an important part of the follow-up care provided by your eye care professional.

7. Slow Healing of the Epithelium. The epithelium is removed just before the laser procedure begins. The epithelium usually 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.

8. Undercorrection. There is no guarantee that, for a particular patient, PRK will be successful in providing the desired level of vision correction. The chance of being under corrected increases in cases where higher grades of nearsightedness are being treated. If the desired level of vision correction is not achieved, corrective lenses may still be necessary for good vision. Corrective lenses may also continue to be necessary for certain activities (such as reading or close work). In some, but not all cases, undercorrection can be retreated with an enhancement procedure. Retreatment is usually not performed until vision has totally stabilized, typically about six months after the original procedure.

9. Overcorrection. In some cases, too much tissue can be removed from the central area of the cornea resulting in an overcorrection. In such circumstances, the patient will be farsighted and will not be able to clearly distinguish “near” objects. Corrective lenses would be required.

10. Regression. In some patients, the vision correction effects of the procedure diminish several months after the procedure. This complication is more common in patients who are very nearsighted. In some, but not all cases of significant regression, another PRK procedure helps remedy the effect.

11. Presbyopia. Patients with Presbyopia or approaching Presbyopia (the need for reading glasses, prevalent over 40 years of age) must understand that PRK vision correction does not treat this age related process.

12. Loss of Best Corrected Visual Acuity. Some patients can lose the ability to read one to two lines on the eye chart in comparison to their previous best-corrected vision. This loss of acuity can occur as a result of decentration. Once cause of decentration

is significant eye movement on the part of the patient when the laser is pulsing. A small amount of eye movement will typically not affect the outcome of the procedure, however.

13. Inconvenience Between Procedures. In the event that a patient has PRK performed on just one eye at a time, the two eyes may not work well together in the time between the performance of the procedure on the first eye and the performance of the procedure on the second eye. A patient's ability to work and drive may be impaired unless the patient procures a temporary set of corrective lenses. Glasses may not adequately compensate for the difference in refraction between the eyes. Contact lenses are more likely to provide acceptable vision correction in cases of significant differences in the refractive capabilities of one's eyes. Contact intolerant patients must consider the implications in cases where both eyes are not treated at the same time. However, the FDA guidelines suggest a three-month waiting period before PRK is performed on your fellow eye.

14. Sensitivity. Some patients, experience increased 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 in some professions.

15. Remote Risks. As with any procedure of this type, there is a remote possibility of infection, drug reaction, or other rare complication, which could cause partial loss of vision.

16. Long Term Effects. Because Photorefractive Keratectomy, or PRK is a relatively new procedure, the long term effects and consequences of the procedure have not been fully determined.

Possible Benefits

In many cases, PRK results in a person's reduced dependence on eyeglasses and contact lenses. Studies conducted by laser manufacturers and reviewed by the US Food and Drug Administration suggest that more than 94% of patients achieve 20/40 or better distance vision (sufficient to qualify for a driver's license without corrective lenses in most states and provinces) with one PRK treatment when correcting nearsightedness of less than –6.0 diopters of refractive error.

Some patients may elect to correct their distance vision in one eye while leaving the other eye slightly nearsighted. This technique called monovision may allow improved distance vision with one eye and may allow the other eye to be effective for reading, forestalling the effect of Presbyopia and the need for reading glasses. There may also be psychological and social benefits for patients who feel that they look better, or can function better without glasses or contacts.

Consent to Laser PRK

1. I have read this consent form.
2. I have discussed it with my eye doctor and have been given the opportunity to ask questions. All of the questions, which I have asked, have been answered to my satisfaction. I understand how PRK is performed and acknowledge its possible risks and complications.
3. I understand that:
    a. The US Food and Drug Administration (FDA) regulate the manufacture and use of the excimer laser for refractive surgery.
    b. PRK is an elective procedure. There is no health or medical reason why I need to have PRK.
    c. Alternative treatments to PRK, including eyeglasses and contact lenses are available.
    d. The results of the PRK procedure cannot always be predicted. The safety and efficacy of PRK cannot be guaranteed. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.
    e. PRK is not risk free. Complications from the procedure, as described in this consent form, are possible. Retreatment may be necessary, but there is no guarantee that retreatment will be successful. As with any procedure of this type, there are remote risks, such as partial loss of best-corrected visual acuity.
    f. Adherence to the recommended eye drop regimen and periodic follow-up visits with any eye doctor after the PRK procedure are required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.

4. I confirm that I am neither pregnant nor a nursing mother and that I will notify my doctor if I become pregnant in the period following PRK treatment. I understand that pregnancy may affect my healing response. I also understand that some medications may pose a risk to an unborn or nursing child.
5. My decision to undergo PRK has been my own and has been made without duress of any kind. I understand that, if at any time prior to my procedure, I decide that I do not want to go forward with PRK, I may withdraw my consent.
6. I authorize the eye doctors involved in performing my PRK procedure and in providing my pre and post procedure care to share with one another any medical information relating to my health, my vision, or my PRK procedure, which they deem relevant to providing me with care.
7. I understand that information gathered about my procedure and my post procedure care may be used to study the PRK procedure. I give permission for my medical records to be released to persons involved in such studies and for my case to be presented at professional or scientific meetings or published in journals as long as I am not identified by name. I also give permission for my PRK procedure to be observed and for the procedure to be photographed by still camera, movie camera or videotape and for these photographs, films or tapes to be shown at professional, scientific, educational, promotional, or similar meetings or published in journals so long as my name is nor revealed.

8. I understand that third parties may be contracted to provide certain services including patient scheduling, medical data processing, quality assurance analysis, patient billing, and procedure management. I give permission for the release of my medical information relating to my PRK procedure to such third parties.
9. I agree to accept personal financial responsibility for the payment of all charges and fees related to my PRK procedure, including charges for the procedure itself, for medications I may need for pre and post procedure care, for any eyeglasses or contact lenses required after the procedure, and for the expenses connected with my travel to any laser vision correction center.
10. I understand the risk in undergoing Photorefractive Keratectomy or PRK. I wish to have PRK performed and hereby consent to the procedure and to any pre or post procedure care, which my eye doctors deem necessary or advisable.
11. I verify that I will not wear/have not worn gas permeable or hard contact lenses at any time in the one month period prior to undergoing PRK and I will not wear/have not worn soft contact lenses at any time in the one week period prior to undergoing PRK.
12. I understand that I may need additional PRK vision correction. I also understand that I will be required to return to the laser facility in which the prior procedure was performed and that expenses for transportation and lodging will be my responsibility.

I consent to undergo PRK for correction of (please circle):

Right Eye Left Eye Both Eyes

I elect to wear a protective contact lens rather than a patch during the initial 2-4 day period in which my eye is healing. (please circle)

YES NO

Patient's Signature:_____ Date:_____

Patient's Name (print):_____

Witness Signature:_____ Date:_____

Surgeon's Name_____

Procedure date:_____