Eye Doctors OF WASHINGTON

PRK CONSENT FORM

Photorefractive Keratectomy

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Introduction

Photorefractive Keratectomy, or 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 most patients.

The Food and Drug Administration (FDA) regulates the manufacture and use of the excimer laser in the U.S. The use of the VISX STAR™ S4 Laser System, currently being used at UOCW Vision Centers, has been approved by the FDA for the treatment of myopia (nearsightedness) and hyperopia (farsightedness) with or without astigmatism.

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 with an 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 (myopia, 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 bend and focus incoming light onto the retina at the back of the eye. It is further bent by the crystalline lens located behind the iris (the colored part 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. Myopia is caused either by an abnormally long eye or by a steep curvature of the cornea. The result of myopia is that distant objects appear blurry, while objects near to the viewer can be seen in focus.

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

In *astigmatism*, the problem is not the length of the eye but the shape of the cornea. The cornea is not spherical and has different curvatures – it is typically shaped more like a football than a basketball, i.e., one flat curvature and one steeper curvature. The result is that objects are not focused into a single image on the retina, and vision is distorted or blurry. Myopic and hyperopic eyes can also be astigmatic.

Initials _____

Presbyopia, or the inability to see close-up objects, usually becomes apparent to most people in their early to mid-40s. This condition occurs normally with age and is caused by a change in the elasticity of the internal crystalline lens, resulting in the lost ability to focus on near objects.

PRK, which treats the surface tissue of the eye, cannot be used to correct presbyopia, although patients may select monovision correction, which will be explained later.

Vision Correction Alternatives

Vision problems resulting from refractive error (myopia, hyperopia, and astigmatism) are typically corrected either with eyeglasses or contact lenses.

Customized treatments are now available for patients with mild and moderate amounts of nearsightedness (up to -14.00D), farsightedned (up to +5.00D), and astigmatism (up to +6.00D). The use of the excimer laser and limits regarding the range of treatment are regulated by the FDA.

In addition to PRK, a procedure known as Radial Keratotomy (RK) is also sometimes used to treat nearsightedness and astigmatism and in selective cases, hyperopia. While RK sounds similar to PRK, the two procedures are different and should not be confused. In RK, the surgeon uses a hand-held blade to make a pattern of incisions in the cornea that look like the spokes of a wheel. The incisions weaken the structure of the eye and permit the cornea to flatten as scar tissue forms, thus shortening the length of the eye and correcting the refractive error.

LASIK, or laser in-situ keratomileusis, is a procedure for the treatment of refractive errors. In LASIK, the surgeon uses a microkeratome, an automated device with a blade, to create a flap about 160 microns thick (one-third of the cornea) across the surface of the eye. This flap, which remains attached on one side, is folded back, and the excimer laser is used to remove the underlying stromal tissue. Following laser ablation, the flap is laid back in place. If laser retreatment is required, the flap can be lifted for retreatment of the underlying tissue.

The Excimer Laser

PRK uses an excimer laser for vision correction. No incisions are made to the eye. The corneal epithelium is scraped away, and the cornea is reshaped using the energy from pulses of light emitted by the excimer laser. A bandage contact lens is then placed on the cornea for a few days until the corneal epithelium regenerates.

Ultraviolet light with wavelengths less than 300 nanometers will not penetrate through the surface of the eye. Because of this, the excimer laser (with a wavelength of 193 nanometers) does not transmit energy through the cornea to the internal tissues 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, or ablated. Essentially no heat is generated in the process, therefore, the risk of scarring is minimized. The energy of the laser is controlled so that each pulse precisely ablates thin layers of tissue from the cornea, 1/4000 of a millimeter at a time. It would take about 200 pulses from an excimer laser to etch through one human hair. The laser is programmed specifically for each patient. It is controlled by a computer which determines the location, number of pulses, and surface area to be impacted by the laser light beam.

Contact Lens Wear

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 to its natural shape.

Patients who wear toric (astigmatic) soft contact lenses, rigid gas permeable lenses, or hard lenses must stop wearing their lenses at least three weeks prior to the procedure. Patients who wear daily wear soft contact lenses must stop wearing their lenses at least three days 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 if 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:

1. Unstable refractive error;
2. Large pupils (greater than 7 millimeters in low light conditions);
3. History of keloid formation;
4. Keratoconus (progressive thinning/steepening of the cornea);
5. Keratitis sicca (advanced dry eyes);
6. Diabetes, uncontrolled;
7. Glaucoma, uncontrolled;
8. Expectant or nursing mothers;
9. Cataracts;
10. Heart condition requiring pacemaker regulation;
11. Recurring ocular herpes simplex; or
12. Active ocular inflammatory disease.

If you know that you have any of these conditions, you must inform your eye doctor.

The PRK Laser Procedure

Upon arriving at UOCW Vision Centers, a final check of your eyes will be completed. Your eyes 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, our clinical staff will review the procedure with you, answer any questions, and conduct additional examinations as appropriate.

Most patients dress casually – comfortably and warmly – as the room is cool for optimum laser performance. Please do not wear make-up, colognes, perfumes or scented lotions as this will affect the optics of the laser. You will be asked to remove any scents before entering the laser suite.

You may not drive yourself home after the procedure, therefore you must arrange to bring a companion or make advance arrangements for transportation. Your companion may accompany you through the entire process until you actually enter the laser suite.

You will not be given general anesthetic. We do premedicate with .5mg of Xanax for your optimal relaxation during the procedure. Medications administered during the procedure are eye drops – anesthetic (numbing), antibiotic, and/or non-steroidal, anti-inflammatory medications, as appropriate. While allergic reactions to these medications are rare, please advise clinical personnel of any medication allergies you may have.

In the laser room, you will be positioned on a bed which rotates for proper positioning. Your eyelids will be cleansed, and the eye that is not being treated will be covered. An anesthetic drop will be instilled in your eye, and an eyelid speculum will be placed between your upper and lower eyelids to prevent you from blinking during the procedure.

To begin the actual PRK treatment, your surgeon will remove the protective epithelium on the surface of your eye. This can be removed either manually or with the laser, and your surgeon will determine which method is appropriate for your eyes.

After removal of the epithelium, the surgeon will ask you to stare at the blinking red light. The laser will be activated, and the reshaping of your cornea will begin. The red light will become more difficult to see as the 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 the procedure. If significant movement is apparent, the surgeon will stop the laser and realign your eye.

Total laser treatment time for most patients is less than 60 seconds per eye. Your surgeon will tell you how you are doing throughout the procedure.

During the procedure, you will notice distinctive sounds and smells. For example, the laser makes a clicking noise when in use. The surgeon will tell you before the pulse begins so that the noise does not startle you. Laser ablation of eye tissue may also produce an odor which some patients find unpleasant. The laser is equipped with a suction device to minimize this.

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 done on the same day, your surgeon will transfer the patch from the fellow eye to the just-treated eye and the above procedure will be repeated. 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 eye drops as prescribed and instructed. The epithelium, which was removed for the procedure, regenerates itself, usually over a two to four day period. Your post-operative manager will determine when the bandage contact lens should be removed.

During the healing process – after removal of the bandage lens – some patients will experience varying degrees of discomfort, from a mild scratchy, burning, or foreign body sensation to more severe pain, which should be reported to your post-operative caregiver. In rare cases, the eye may be patched with a pressure patch to inhibit blinking and restrict eye movement.

Although there is a minimal risk of infection with either the use of the contact lens 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 a contact lens have their eye open, permitting useful (although blurry) vision, which is obviously not possible if the eye is patched.

After the procedure, you will receive a kit containing anti-inflammatory eye drops and a schedule for their use. You will also continue the antibiotic eye drops started before your surgery. You may be provided with a prescription for oral pain medications for any discomfort, pain, or difficulty sleeping.

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 not drive during this period.

Patients return to UOCW Vision Centers or their co-managing optometrist on the day following the procedure to confirm the fit of the protective contact lens and to ensure that the healing process is progressing satisfactorily.

If you are healing as anticipated and no discomfort is present, the bandage lens will be removed on the third or fourth day following the procedure. In some cases, an additional day or two is required to make sure the healing process is advancing.

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

Your 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 intraocular eye pressure in some patients. Follow-up evaluation visits are generally scheduled within ten days after the procedure, then as needed for the first six months after the procedure, with a final follow-up visit one year after the procedure.

Risks and Other Considerations

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

Risks and discomforts that might be associated with the PRK procedure are as follows:

1. *Discomfort:* Many patients experience mild discomfort for a few days following PRK, although 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. 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 two to four-day period when the epithelium is healing, vision is blurry for most patients. Once the bandage 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. Blurry vision 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, there may be some

fluctuation in vision. The healing process 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 40 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.
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. It usually has little or no effect on vision and is usually not present after six months. A few patients do experience excessive corneal haze and require treatment. Additional treatment with the excimer laser can generally correct problems of excessive haze.
5. *Diminished Night Vision:* 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 conditions.
6. *Elevated intraocular pressure:* An increase in intraocular pressure (IOP) can occur in patients who use topical steroid eye drops. Typically, IOP returns to normal – with no long-term ill effects – once the use of steroid eye drops has been discontinued. However, if IOP is elevated on a long-term basis, permanent loss of vision can result. Since elevated IOP is often painless, periodic evaluation by an eye doctor is imperative. Monitoring IOP is an important part of the follow-up care provided by your eye care professional.
7. *Slow Epithelial Regeneration:* The epithelium removed just before the laser procedure begins 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 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 myopia are being treated. If the desired level of vision correction is not achieved, corrective lenses may still be necessary to achieve the best corrected visual acuity. Corrective lenses may also continue to be necessary for certain activities (such as reading or close work). In some, but not all, cases undercorrections 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 rare cases, too much tissue may be ablated from the central area of the cornea resulting in an overcorrection. In some cases, it is possible to retreat. In some circumstances, corrective lenses would be needed.
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 to remedy the effect.
11. *Presbyopia:* Presbyopic or emerging-presbyopic patients must understand that PRK vision correction does not treat this age-related process, and they will require reading glasses for reading and other close work.
12. *Loss of Best-Corrected Visual Acuity:* Some patients may lose the ability to read one or two lines on the eye chart in comparison to their previous best-corrected vision. This loss of acuity can occur as a result of microscopic corneal surface irregularities. Loss of acuity can also occur as a result of decentration. One 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 until the fellow eye is done. 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 error. Contact-intolerant patients must consider the implications in cases where both eyes are not treated at the same time.

14. *Sensitivity:* Some patients, experience increased sensitivity to any contact with the surface of the eye following PRK. This tends to diminish over time, but increased sensitivity could be a concern in some professions.

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.

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 U.S. 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) with one PRK treatment when correcting myopia of less than six diopters of refractive error.

Some patients may elect to correct their distance vision in one eye while leaving the other eye slightly nearsighted. This option – monovision – corrects one eye for distance and the fellow eye for near. Many monovision patients may decide to get night driving glasses to fully correct their near vision eye for distance.

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 FOR PHOTOREFRACTIVE KERATECTOMY

I have read this consent form. I have discussed it with my eye doctor and have been given the opportunity to ask questions. All of my questions have been answered to my satisfaction. I understand how PRK is performed and acknowledge its possible risks and complications.

I understand that:

1. The manufacture and use of the excimer laser for refractive surgery is regulated by the U.S. Food and Drug Administration (FDA).
2. PRK is an elective procedure. There is no health or medical reason why I need to have PRK.
3. Alternative treatments to PRK, including eyeglasses and contact lenses, are available.
4. 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.
5. 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.

Initials _____

6. Adherence to the recommended eye medication regimen and periodic follow-up visits with an 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.

I confirm that I am neither pregnant nor a nursing mother and that I will notify my doctor if I become pregnant in the six-month 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.

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.

I authorize the eye doctors involved in performing my PRK procedure and in providing my pre- and/or 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 care.

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 not revealed.

I understand that third parties may be contracted to provide certain services, including patient scheduling, medical data processing, quality assurance analysis, patient billing, and practice management. I give permission for the release of my medical information relating to my PRK procedure to such third parties.

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 UOCW Vision Centers or other professional offices where I receive care. In the event that I have insurance which covers all or part of the cost of my PRK procedure and follow-up care, I authorize the release of information relating to my PRK procedure for insurance or payment purposes.

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.

I verify that I have not worn nor will I wear rigid gas permeable or hard contact lenses at any time in the three-week period prior to undergoing PRK, and I have not worn nor will I wear soft contact lenses at any time in the three-day period prior to undergoing PRK.

I understand that, in the event I need an enhancement, treatment will be performed by the surgeon who performed the prior PRK procedure, if at all possible. I also understand that I will be required to return to UOCW Vision Centers and that any expenses for transportation and lodging will be my responsibility.

Initials _____

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

Myopia	Myopia with astigmatism
Hyperopia	Hyperopia with astigmatism

_____ _____ _____am pm
Patient Signature *Date* *Time*

_____
Patient Printed Name

_____ _____
Witness Signature *Witness Printed Name*

_____ _____
Surgeon Signature *Date*

_____
Surgeon Printed Name