

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 United States. Eye Doctors of Washington Vision Centers currently uses the Wavelight Allegretto excimer laser. The FDA has approved this laser system for the treatment of myopia (nearsightedness) and hyperopia (farsightedness), with or without astigmatism, on the surface of the cornea as well as under a corneal flap.

This Consent Form and Patient Education 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 post-operative recovery with an eye care professional. You are encouraged to ask questions about PRK or about any information in this form.

How the Eye Works

A brief explanation of the eye may be of assistance in understanding the procedure. The cornea is a clear tissue located on the front of the eye. The cornea, in combination with the natural lens of the eye, focuses the incoming light onto the retina in the back of the eye.

Refractive errors (myopia, hyperopia, and astigmatism) usually result from a disparity in the shape of the cornea in relationship to the length of the eye. Please see below:

Nearsightedness, or myopia: Myopia is caused either by an abnormally long eye or by a steep curvature to the cornea. Light entering the eye does not focus on the retina, but instead focuses the image to a point in front of the retina. The result of myopia is that distant objects appear blurry, while objects near to the viewer may be seen in focus. The excimer laser can flatten the corneal curvature allowing objects to be in focus in the distance.

Farsightedness, or hyperopia: Farsightedness is caused by an abnormally short eye

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or by an excessively flat cornea. Light entering the eye focuses the image to a point behind the retina. The result of hyperopia is that objects near to the viewer appear blurry while objects in the distance may or may not be seen in focus. The excimer laser can increase the corneal curvature allowing objects to be in focus in the distance.

Astigmatism: The cornea is not perfectly round but has different curvatures – it is shaped more like a football than a basketball, i.e., one flatter curvature and one steeper curvature. The result is that objects are not focused into a single image on the retina. Vision may be distorted or blurry. Myopic and hyperopic eyes often have some degree of astigmatism. The excimer laser can adjust the corneal curvatures allowing objects to be in focus.

Presbyopia: Normally, when viewing a near object, the shape of the natural crystalline lens is altered. This change in the lens allows us to focus on the object. With the normal aging process, the elasticity (flexibility) of natural crystalline lens diminishes. This reduces or eliminates the ability of the lens to change shape. This process, presbyopia, results in a loss of the ability to focus on near objects. The inability to see up close usually becomes apparent to patients in between the ages of 40 – 50 years.

Laser procedures do not alter the natural crystalline lens. Therefore, they cannot be used to correct presbyopia; however, patients may select a monovision correction. This will be explained in detail later.

Vision Correction Alternatives

Vision problems resulting from refractive errors (myopia, hyperopia, and astigmatism) may be corrected with either eyeglasses or contact lenses. A description of the available surgical procedures is listed below.

Laser In-situ Keratomileusis (LASIK) is available for treatment of mild to moderate amounts of myopia, hyperopia, and astigmatism. In LASIK, the surgeon creates a flap about one-fifth of the corneal thickness across the surface of the eye. This flap remains attached on one side. It 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 additional laser treatment is required, the flap can be lifted for retreatment.

Photorefractive Keratectomy (PRK) is available for treatment of mild to moderate amounts of myopia, hyperopia, and astigmatism. Like LASIK, PRK uses an excimer laser to reshape the cornea. In PRK, the surface of the cornea is treated rather than creating a corneal flap. The final visual result with PRK is similar to LASIK; however, due to the need for the corneal surface to heal, the visual recovery is usually slower than with LASIK.

INTACS is available for the treatment of mild amounts of myopia (1-3 diopters). INTACS consist of two small, transparent crescents (arcs), each having an arc length of 150 degrees. The segments are made out of clear medical plastic. This material has been used in the intraocular lenses used to for cataract surgery for nearly 50 years. Different sizes of INTACS are used for different levels of myopia. Unlike LASIK, INTACS segments may be removed. Scientific studies have demonstrated that removal of the INTACS segments usually returns the patient's eye to their pre-operative state; however, a small number of patients may still describe a persistence of visual symptoms.

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Refractive Lens Exchange is available for the treatment of moderate and high levels of myopia and hyperopia. In these procedures, an ultrasonic device is used to remove the natural crystalline lens. An intraocular lens (IOL or “implant”) is inserted. The intraocular lens power can be calculated so that once implanted, it can reduce or eliminate the eye’s refractive error.

Phakic Intraocular Lens Insertion is available for the treatment of moderate and high myopia. In this procedure, an intraocular lens is inserted into the eye. The intraocular lens works to compliment the natural crystalline lens to allow for improved distance vision.

Radial Keratotomy (RK) is available for the treatment of mild myopia and astigmatism. 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.

Conductive Keratoplasty (CK) uses the controlled release of radio waves to correct mild hyperopia. A probe applies 8 – 16 spots of energy to the peripheral cornea. This radio-frequency energy shrinks the surrounding tissue, causing the corneal curvature to become steeper.

Patients Who Wear Contact Lenses

Contact lenses can change or distort the shape of the cornea. Before having a comprehensive eye exam for the LASIK procedure, the cornea must be allowed to return to its natural shape.

If you wear gas permeable or hard contact lenses, you must discontinue wearing the lenses at least 2-3 weeks for every decade of wear prior to the comprehensive eye exam. For example, if you have worn hard lenses for 20 years, they need to be out for 4 - 6 weeks (2-3 wks. x 2 decades of wear). Our staff may recommend a longer time period depending upon the length of time that you have worn rigid lenses. Patients who wear daily wear soft contact lenses must stop wearing their lenses at least 7 days prior to the examination. For toric soft contact lenses (correct astigmatism), the lenses must be out for 2 weeks.

You must confirm compliance with these requirements prior to undergoing LASIK. The period required to stabilize the natural shape of the cornea may be longer for some patients. You should tell your surgeon and eye care provider 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 may not be an ideal candidate for LASIK if any of the following conditions exist:

1. Unstable refractive error
2. Large pupils (greater than 7 millimeters in low light conditions)
3. Keratoconus (progressive thinning/steepening of the cornea)
4. Keratitis sicca (advanced dry eyes)
5. Abnormal eyelid closure
6. Active collagen vascular disease (e.g., rheumatoid arthritis)
7. History of keloid formation
8. Systemic vasculitis

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9. Corneal endothelial dystrophy (cell count <1500)
10. Diabetes, uncontrolled
11. Glaucoma, uncontrolled
12. Expectant or nursing mothers
13. Visually significant cataracts
14. Heart condition requiring pacemaker regulation
15. Recurring ocular herpes simplex
16. Active ocular inflammatory disease
17. Inadequate exposure of the eye
18. Insufficient corneal thickness
19. Previous eyelid surgery (including “facelifts”)
20. Use of certain medications:
 1. Amiodorone
 2. Imitrex
 3. Accutane

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

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.

The PRK Laser Procedure

Upon arriving at EDOW 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 be given a medication (usually 0.5mg of Xanax) to reduce anxiety 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 that rotates for proper positioning. Your eyelids will be cleansed, and the eye that is not being treated will be covered. An

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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 that some patients find unpleasant. 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 3 to 4 day period. A bandage contact lens will be placed. The lens speeds up the healing process and reduces discomfort. Even with a bandage contact lens, most 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. You will be provided with a prescription for oral pain medications for any discomfort, pain, or difficulty sleeping

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 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 EDOW 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

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cause an increase in intraocular eye pressure in some patients.

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 years of age 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, if present, is most noticeable in the period two to four months following the laser procedure. It can only be detected by an eye care professional using a microscope and usually has little or no effect on vision and is usually not present after six months. A few patients do experience excessive corneal haze that affects vision and require treatment. Additional treatment with the excimer laser can generally, but not always, 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.

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8. *Under-correction and Over-correction:* There is no guarantee that PRK will be successful in providing the desired level of vision correction.. 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 most, but not all, the cornea can be retreated with an enhancement procedure. Retreatment is usually not performed until vision has totally stabilized, typically about 3-6 months after the original procedure.
9. *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.
10. *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.
11. *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 de-centration. One cause of de-centration 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.
12. *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.
13. *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

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:

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1. The U.S. Food and Drug Administration (FDA) regulate the manufacture and use of the excimer laser for refractive surgery.
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.
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 that 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 EDOW 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.

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