

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PHOTOREFRACTIVE KERATECTOMY
(PRK)**

(Patient Label)

GENERAL INFORMATION

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of Photorefractive Keratectomy (PRK). This material serves as a supplement to the discussion you have with your physician. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your physician prior to signing the consent form. We appreciate your selecting UCLA Health System to meet your needs.

This procedure, like all surgery, presents some risks, many of which are listed below. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or commonly known are not discussed.

AN OVERVIEW OF THE PRK PROCEDURE

PRK permanently changes the shape of the cornea. The procedure is performed using a topical anesthetic (drops on the eye). The procedure involves application of solution that allows for the loosening and sliding back of the outer thin skin layer (epithelium) that covers the cornea. The cornea is not cut, so there is no need for a blade or flap creation with the microkeratome or femtosecond laser as in the Laser In Situ Keratomileusis (LASIK) and Small Incision Lenticule Extraction (SMILE) procedures. Once the outer tissue has been removed or slid back, a thin layer of corneal tissue is removed with the light from an excimer laser. A bandage contact lens is placed on the eye for a period of 3-7 days to assist in the healing process. The removal of thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea.

LIMITS OF PRK

Although the goal of PRK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve adequate vision. PRK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

PRK does not correct the condition known as presbyopia (aging of the eye), which occurs in most people around age 40 and requires them to wear reading glasses for close-up work,

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sometimes including computer distance. The key question you must ask yourself is: Can you read up close while looking through the top part of your distance glasses? If you must take off your distance glasses or use bifocals to read up close, then you have presbyopia. Patients with presbyopia who get both eyes fully corrected for distance vision will then need to use reading glasses to seeing clearly up close. This sometimes includes computer distance. Therefore, if you presently need reading glasses, you will likely still need reading glasses after treatment. If you do not need reading glasses because you take off your distance glasses to read, you will likely need reading glasses after treatment if you have both eyes corrected fully for distance. If you do not need reading glasses now, you will need them at a later age. You may consider having one eye weighted for mid-range near vision. Many patients over the age 40 make this decision and are pleased with both their distance and mid-range near vision (example: computer screen, shopping tags, grocery shelves) and then use simple reading glasses for close-range and for smaller printed materials (example: newspapers, some magazines, mobile phone).

ALTERNATIVES TO PRK

PRK is an elective procedure. There is no emergency condition or other reason that requires or demands that you have it performed. If you decide not to have PRK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. The alternatives include eyeglasses, contact lenses, and other refractive surgical procedures. You may wish to discuss these options with your physician.

RISKS AND CONTRAINDICATIONS

Risks: The risks of PRK surgery include, but are not limited to:

- **Loss of Vision:** PRK surgery can possibly cause loss of best-corrected vision. This can be due to infection (internal or external), scarring or other causes. Unless successfully controlled by antibiotics, steroids, or other necessary treatment, it could even cause loss of the infected eye. Vision loss can be due to the cornea healing with an irregular surface, which could cause astigmatism and make wearing glasses or contact lenses (soft or hard) necessary. Irregular cornea healing could result in an uneven corneal surface so that distorted vision or “ghosting” occurs. This could mean that glasses or contact lenses may not correct the vision to the level and/or quality possible before undergoing PRK. The excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
- **Visual Side Effects:** Your vision after surgery may not be clear immediately, and you might not notice improvement for several days to several weeks to several months. There may be

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increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These usually occur during the normal stabilization period for one to three months, but they may also be permanent. After refractive surgery, a certain number of patients experience glare, a “star bursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. This is more likely in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. However, for some patients this is permanent.

Other complications and conditions that can occur with PRK surgery include: haze (loss of perfect clarity of the cornea, usually not effecting vision, which usually resolves over time), epithelial irregularities; anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; reduced contrast sensitivity; diminished depth perception.

- **Residual nearsightedness, farsightedness and/or astigmatism:** It may be that PRK surgery will not give you the result you desired. Some procedures result in the eye being under corrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by over treating myopia) or nearsighted (by over treating hyperopia). It is possible that your initial results could regress over time. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision. Retreatment surgeries can be performed when vision is stable unless it is unwise or unsafe. Retreatment surgery can be performed no sooner than three months after surgery. A retreatment will only be considered if there is adequate corneal tissue. If there is inadequate tissue, it may not be possible to perform a retreatment. An assessment and consultation will be held with the surgeon at which time the benefits and risks of a retreatment surgery will be discussed.
- **Keratoconus:** It is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
- **Redness and/or dryness of eyes:** There is a chance that the whites of the eyes may temporarily appear pink or red for several days to several weeks after surgery. There is an increased risk of eye irritation related to drying of the corneal surface following PRK. All of

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the cornea procedures used to correct vision are associated with increased dry eye for a period of time (e.g. 6-12 months) following the surgery. Most patients who do a lot of reading and computer work will notice the post-operative dryness and need to use lubricant drops during these activities. Patients over the age of 40 and female patients tend to have more dryness. These symptoms may be temporary or on rare occasions, permanent. Your surgeon will discuss with you the various treatments for post-operative dry eye.

- **Contact lens intolerance:** If you wear contact lenses now, there is a chance you may not be able to do so after surgery because of the changes to the shape of your eye.
- **Other Risks:** Other reported complications include corneal ulcer formation; clouding or hazing of the cornea; cornea scarring; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; blepharitis (inflammation of eyelids or scaly eyelids); rosacea (eyelid nodules), retinal detachment; new or increased floaters; hemorrhage; cataract formation; diminished depth perception; slow epithelialization (outer surface cells re-growth) which can slow the recovery process and may lead to reoccurring corneal erosions (outer surface cell detachment) with eye discomfort and blurred vision, loss of the contact lens with increased pain (usually corrected by replacing with another contact lens). If you have had previous eye surgery it is possible that during the procedure that the incisions could re-open. This could decrease the healing and lead to irregular healing. Sutures may be required to close the incisions which can induce astigmatism. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include progressive corneal thinning known as ectasia. Ectasia could necessitate the wearing of a rigid corneal or scleral contact lens for best correction. It could even lead to a need for corneal transplantation. It is also possible that the excimer laser could malfunction and the procedure stopped. If this occurs, PRK may be attempted again after several months or another procedure may be used to attempt vision correction. There are also potential complications due to anesthesia and medications that may involve other parts of your body. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.
- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies. This procedure may impair your ability to perform your job.
- **Later-Discovered Complications:** You should be aware that other complications might occur that have not yet been reported. After the procedure, you should continue to have routine examinations to assess the condition of your eyes.

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- **Risks of Not Undergoing PRK:** The risks of not having the surgery are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

You may choose to have this procedure performed on both eyes at the same time. This will reduce your total recovery time and minimize the unbalance between eyes. However, treatment of both eyes could lead to complications, as discussed above, occurring in both eyes at the same time. Also, if you have both eyes treated at the same time, your vision may be blurred, in both eyes, making it harder to drive and function for a period of time afterward.

Contraindications: The treatment should not be performed on persons:

- with uncontrolled vascular disease;
- with uncontrolled autoimmune disease;
- who are immune-compromised or on drugs or therapy that suppress the immune system;
- who are pregnant, nursing, or expecting to become pregnant within the six months following the PRK procedure;
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia with/with astigmatism, hyperopia with/without astigmatism or presbyopia in either eye;
- with active or residual disease(s) likely to affect wound-healing capability;
- with unstable or uncontrolled diabetes;
- with progressive myopia or hyperopia;
- with uncontrolled glaucoma;
- with uncontrolled dry eyes or blepharitis.

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake PRK surgery, you should discuss them with your physician.

PRE- AND POST- TREATMENT CARE**Before PRK surgery:**

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are

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pregnant, or expecting to become pregnant, you should not undergo the PRK procedure until after the pregnancy.

- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the PRK surgery and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks prior to the initial eligibility examination. (This period may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least 3 days prior to the eligibility examination. After the eligibility exam, you may wear your contacts up until 24 hours prior to surgery.

After PRK surgery:

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such nonsterile water may expose the eye to increased risks of infection. UV protection with sunglasses is very important after PRK, it is advisable to wear sunglasses outside diligently for at least the first 6 months after surgery. The eye shield should be worn nightly for 1 week. Avoid rubbing the eye. The eye may be more fragile to trauma from impact. It is advisable that you wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high.
- **Operating Motor Vehicles:** After PRK, in order to operate motor vehicles, glasses, contact lenses, eye drops, or other measures may be needed. After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and 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. On the day of the PRK procedure and for your day one postoperative appointment, you should arrange to have a driver.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the PRK procedure varies with the individual. You should expect that the eye will be sore to some extent after the surgery. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensation of a foreign object in the eye, tearing, light sensitivity, itching, or dryness of the eye.

PATIENT STATEMENT

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- I have read this Informed Consent form (or it has been read to me). The PRK procedure has been explained to me in terms that I understand.
- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with PRK. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.
- My decision to undertake the PRK procedure was made without duress of any kind. I understand that PRK is an elective procedure, and my myopia or hyperopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that PRK will reduce or possibly eliminate my dependence on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.
- I authorize the physicians and other health care personnel involved in performing my PRK procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my PRK procedure that they deem relevant to providing me with care.
- I understand that my surgical measurements will be entered into a database (without any personally identifiable information) for the purposes of surgical planning, research, marketing and publication and that this non-identifiable data will be accessible to parties outside of UCLA.
- I have had sufficient time review this consent form. A physician or an associate has adequately addressed my questions and concerns. By signing below, I am making an informed decision to undergo the PRK procedure. I have received (or been offered) a copy of this consent for my own records.
- I authorize the release of my medical records in order to process medical claims or requests for further information from insurance companies.
- I understand that I have had an interpreter or legal guardian read this consent that they will sign under the surrogate consent area for me.

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- I understand that if I elect to have another physician and/or optometrist (outside of UCLA) follow my postoperative care that I will sign the management consent form.

I consent to have Dr. _____ perform PRK on my:
(circle one) right eye/ left eye/ both eyes.

Printed Patient Name

Patient Signature

Date

Printed Witness Name

Witness Signature

Date

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FOR SURROGATE CONSENT

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have PRK performed on the patient's right eye/ left eye/ both eyes.

Printed Name of Surrogate

Surrogate Signature

Date

Nature of Relationship to Patient

Witness Signature

MANAGEMENT CONSENT FORM

It is my desire to have Doctor _____, perform my preoperative/postoperative follow-up care for refractive surgery. I have been assured that UCLA Laser Refractive Center will be contacted immediately if I experience any complications related to my eye surgery.

Reason for Management by this doctor, is: (please check one)

- Maintain established eye care relationship.
- Difficult to return to UCLA for follow-up care because of location.
- Other (please give reason) _____

Patient Signature _____ Date _____

Witness Signature _____ Date _____