

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**MRN:
Patient Name:

(Patient Label)

INTRODUCTION

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of Peripheral Relaxing Corneal Incision (PCRI). 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 PCRI PROCEDURE

PCRI permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops on the eye). In PCRI surgery, one or two microscopic arcuate (curved) incisions are made in the steep meridian of the cornea to reduce or eliminate astigmatism. The incisions can be made using a surgical blade or a femtosecond laser.

LIMITS OF PCRI

Although the goal of PCRI is to improve vision to the point of being independent of 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. PCRI surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

PCRI 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, 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 this treatment. If you do not need reading glasses because you take off your distance glasses to read, you will likely need reading glasses after this 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

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**

decision and are extremely 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 PCRI

If you decide not to have PCRI, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses, and other refractive surgical procedures.

RISKS AND CONTRAINDICATIONS

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

- **Loss of Vision:** PCRI 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 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 PCRI.
- **Visual Side Effects:** Some patients experience light sensitivity, glare, halos or starbursts from light sources, particularly the first few months after the procedure. This may limit your ability to drive, particularly at night. These symptoms generally resolve in 3-6 months, but can persist indefinitely.
- **Residual nearsightedness, farsightedness and/or astigmatism:** It is not possible to predict how your eye will respond to this procedure. As a result, it may be that the PCRI surgery will not give you the result you desired. It is possible that you still need eyeglasses or contact lenses after this procedure to obtain good vision because of residual nearsightedness and/or astigmatism. It is also possible that you are overcorrected, resulting in farsightedness (hyperopia) with/without astigmatism. This could mean that you need glasses for distance and near vision. The results of your surgery can also regress over time. In many patients, the vision stabilizes in several months and remains stable. However, your vision can change at any time after the procedure and become either more near-sighted or more far-sighted. You may eventually need glasses even if you did not need them initially following the PCRI procedure. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision.
- **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.

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**MRN:
Patient Name:

(Patient Label)

- **Other Risks:** Rarely, a serious complication may occur as a result of this procedure such as an infection of the eye, a corneal ulcer, inflammation of the eye, perforation of the cornea possibly requiring sutures; cornea scarring; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); blepharitis (inflammation of eyelids or scaly eyelids); rosacea (eyelid nodules); formation of new corneal blood vessels (neovascularization), diminished depth perception; double vision; corneal epithelial (skin) abrasion or defect which can slow the recovery process and may lead to reoccurring corneal erosions (outer surface cell detachment) with eye discomfort and blurred vision. While many of these complications are treatable with restoration of good vision, PCRI can result in partial or complete loss of vision in the eye. This procedure can weaken the eye, making it more susceptible to severe trauma. 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. A contact lens may need to be worn as a bandage until the incisions close. In a rare case sutures may be required to close the incisions. In a very rare case a cornea transplant may be needed to restore useful vision.
- **Later-Discovered Complications:** You should be aware that other complications might occur that have not yet been reported. Longer-term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Risks of Not Undergoing PCRI:** 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 PCRI procedure;
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia with/without astigmatism, hyperopia with/without astigmatism or presbyopia in either eye;

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**

- 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 PCRI surgery, you should discuss them with your physician.

PRE- AND POST- TREATMENT CARE**Before PCRI 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 pregnant, or expecting to become pregnant, you should not undergo the PCRI 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 PCRI 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 PCRI 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. Wear sunglasses during the first day after having surgery. The eye shield should be worn nightly for 1 week. Avoid rubbing the eye. Evidence has shown that, as with any other scar, the corneal incision will not be as strong after healing as the original cornea was at the site of the incision. Therefore, the eye is somewhat more vulnerable to all varieties of injuries, particularly if you have had other eye surgeries as well. You must 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.

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**MRN:
Patient Name:

(Patient Label)

- **Operating Motor Vehicles:** After PCRI, glasses, contact lenses, eye drops, or other measures may be needed to operate motor vehicles safely. 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 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 PCRI 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. Some patients report the sensation of a foreign object in the eye, itching, light sensitivity, tearing or dryness of the eye.

PATIENT STATEMENT

- I have read this Informed Consent form (or it has been read to me). The PCRI 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 PCRI. 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 PCRI procedure was made without duress of any kind. I understand that the procedure is an elective procedure, and my astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that the PCRI 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 PCRI 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 procedure that they deem relevant to providing me with care.
- I understand that my surgical measurements may be entered into a database (without any personally identifiable information) for the purposes of surgical planning, research,

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**

MRN:
Patient Name:

(Patient Label)

marketing and publication and that this non-identifiable data will be accessible to parties outside of UCLA.

- I have had sufficient time to 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 PCRI 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.
- 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 PCRI on my:
(circle one) right eye/ left eye/ both eyes.

Patient Printed Name

Patient Signature

Date

Witness Printed Name

Witness Signature

Date

**LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
PERIPHERAL CORNEAL RELAXING INCISION(S)
(PCRI)**

MRN:
Patient Name:

(Patient Label)

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 PCRI 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 _____