



CONSENT FORM FOR PHOTOTHERAPEUTIC KERATECTOMY (PTK)

You are entitled to be informed about the proposed Phototherapeutic Keratectomy (PTK). Including the risks of the treatment and alternatives to it. Please read this document thoroughly and discuss the content with your doctor so that all of your questions are answered to your satisfaction.

This information is provided so that you can make an informed decision regarding the use of the excimer laser to treat your irregular cornea. A laser produces an intense beam of light which can be used to remove corneal (outer layer of the eye) tissue. Phototherapeutic Keratectomy (PTK) uses a computerized laser to reshape the surface of the cornea. Removal of small amounts of tissue can produce the results you need to correct your irregular cornea.

The alternatives to Phototherapeutic Keratectomy (PTK) include eyeglasses, contact lenses, lamellar corneal surgery (surgery to remove layers of cornea) or a corneal transplant (surgery to remove the entire central cornea and replace it with donated corneal tissue).

Any questions that you have regarding Phototherapeutic Keratectomy (PTK) or other alternative therapies for your case should be directed to your doctor.

PATIENT STATEMENT

I have a corneal irregularity that interferes with my daily activities of living. I have been clearly informed of the alternatives including eyeglasses, contact lenses, medical and surgical options other than laser surgery. I have decided to undergo Phototherapeutic Keratectomy (PTK) with the excimer laser.

In giving my permission for the Phototherapeutic Keratectomy (PTK) surgery, I declare that I understand the following information.

- The goal of Phototherapeutic Keratectomy (PTK) treatment with the excimer laser is to attempt to improve my best corrected visual acuity by smoothing or removing my corneal irregularity.
- I understand that as with all forms of treatment, the results in my case cannot be guaranteed; there is no guarantee that I will completely eliminate my reliance on eyeglasses and/or contact lenses. It is possible that the treatment could result in undercorrection, where some degree of myopia may remain requiring the use of glasses or contact lenses. The treatment may also result in overcorrection causing hyperopia (farsightedness) which may or may not require the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase and reading glasses may be required at an earlier age. The treatment may also result in a change in my astigmatism that could require the use of glasses and/or contact lenses. I understand further treatment may be necessary including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional treatments.
- I understand that if I currently need reading glasses, I will likely need reading glasses after this treatment. I also understand that if I do not currently need reading glasses, I may need them at an earlier age.

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- (FEMALE ONLY) I am not pregnant or nursing. If it is possible that I am pregnant, then I will take a home pregnancy test to ascertain that I am not pregnant, since pregnancy could adversely affect my treatment result. If the results of the test are positive, I will not undergo treatment until the results are proven incorrect or I will reschedule the treatment for after the pregnancy. If I become pregnant in the 6 months following treatment, I will notify my eye doctor immediately.
 - I understand the treatment should not be performed on persons with uncontrolled vascular disease or autoimmune disease, or on patients who are immunocompromised or on drugs or therapy which suppress the immune system, so I will tell the doctor if I have any of these or other medical conditions.
 - I understand the treatment should not be performed on persons known to have a previous history of keloid formation because their corneal response is less predictable.
 - I have been informed, and I understand, that certain complications have been reported in the long term post-treatment period by patients who have had Phototherapeutic Keratectomy (PTK) which include: anterior stromal reticular haze (scarring), glare (sensation produced by bright lights that is greater than normal can cause discomfort and annoyance), halo (hazy rings surrounding bright lights may be seen particularly at night, loss of best spectacle corrected visual acuity (a decrease in best corrected visual acuity with spectacles), intraocular pressure elevation associated with long term post-operative medications, and overcorrection or farsightedness.
 - I have been informed that the following complications have been reported with Phototherapeutic Keratectomy (PTK): blurred vision, corneal epithelial defect, corneal scarring (cloudiness of the cornea severe enough to affect vision), Ulceration/infection, dryness of the eye, feeling something is in the eye, shadow images, irregularities in the cornea (corneal deposits, microcysts), inflammation of the iris, irregular astigmatism (warped corneal surface which causes distorted images), itching, double vision, patient discomfort, light sensitivity, drooping of the eyelid, reading difficulty and corneal inflammation.
 - I understand that in addition to the above listed complications, the following have been reported in the short term post-treatment period by patients who have had Phototherapeutic Keratectomy (PTK) and are associated with the normal post-treatment healing process. These include: pain (first 24 to 48 hours), tearing, corneal swelling, double vision, feeling of something is in the eye, shadow images, light sensitivity and pupil enlargement.
 - Since it is impossible to state every complication that may occur as a result of Phototherapeutic Keratectomy, I understand that the above list of complications is not complete or exhaustive.
 - I understand the doctor will prescribe certain medication as a part of the treatment. The doctor is prepared to answer any questions I may have regarding the prescribed drugs and any side effects.
 - I understand that this is an elective treatment and that I do not have to have any treatment. I understand Phototherapeutic Keratectomy (PTK) treatment is not reversible.
 - I understand that Phototherapeutic Keratectomy (PTK) will require follow up care at frequent intervals for three months after treatment and I agree to return for required examinations.

Statement of Voluntary Participation

In signing this Informed Consent Form for the use of the excimer laser for performing Phototherapeutic Keratectomy (PTK) I am stating that I have read this Informed Consent (or it has been read to me) and I fully understand it and the possible risks, complications and benefits that can result from the treatment. My doctor has discussed the procedure, risks, benefits, and alternatives to surgery. We have discussed the possibility of infection, blindness, failure of the procedure, loss of the eye, and death. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all of my questions to my satisfaction.

By signing below, I agree that:

“The Phototherapeutic Keratectomy (PTK) treatment has been explained to me in terms that I understand; I have had the opportunity to have my questions answered; I fully understand the possible risks, complications, and benefits that can result from the treatment”. My decision to undergo the PTK treatment has been my own and has been made without duress of any kind.

I wish to have Phototherapeutic Keratectomy (PTK) performed on my

- Right Eye** **Left Eye**

Patient’s Signature _____

Patient’s Name (printed) _____

Date _____ Time _____

I hereby confirm that the surgical procedures, alternative treatments and possible risks and benefits of PTK, outlined in this consent form, have been explained to the patient referred to above. The patient confirmed having received an explanation of those surgical procedure, alternative treatments and possible risks and benefits. Further, the patient confirmed his/her understand of this consent form. I hereby witness his/her consent to the procedure.

Doctor’s Signature _____

Doctor’s Name (printed) _____

Date _____