

INFORMED CONSENT FOR THE USE OF THE EXCIMER LASER FOR PERFORMING PHOTOREFRACTIVE KERATECTOMY

You are entitled to be informed about the proposed Photorefractive Keratectomy, 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 mild to moderate myopia (near-sightedness), hyperopia (farsightedness) and/or astigmatism. A laser produces an intense beam of light, which can be used to remove corneal (outer layer of the eye) tissue. Photorefractive Keratectomy uses a computerized laser to reshape the surface of the cornea. Removal of small amounts of tissue can produce the results you need to decrease or correct your myopia, hyperopia and/or astigmatism.

The alternatives to Photorefractive Keratectomy include eyeglasses, contact lenses or other refractive surgery procedures such as LASIK (Laser In-situ Keratomileusis), radial keratotomy, corneal inlays (Intacs) or intraocular lenses.

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

PATIENT STATEMENT

I have mild to moderate myopia or hyperopia between (+) 4.00 to (-) 10.00 diopters and up to 5 diopters of astigmatism, which requires me to wear corrective lenses in order to see clearly for my daily activities. I have been clearly informed of the alternatives including eyeglasses, contact lenses and refractive surgery. I have decided to undergo Photorefractive Keratectomy with the excimer laser.

In giving my permission for the Photorefractive Keratectomy surgery, I declare that I understand the following information.

1. The goal of Photorefractive Keratectomy treatment with the excimer laser is to reduce or eliminate mild to moderate myopia or hyperopia between (+) 4.00 to (-) 10.00 diopters and up to 5 diopters of astigmatism, thereby reducing my dependence or need for contact lenses and/or eyeglasses.
2. 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 under correction or over correction, where some degree of myopia or hyperopia may remain requiring the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age. The treatment may also result in an under or over correction or other change in astigmatism that could require the use of eyeglasses or contact lenses. I understand that further treatment may be necessary including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional treatments. Most patients can be fitted with a contact lens following PRK surgery if necessary; however, the fitting may be more difficult than usual. It is possible that there may be more than normal difficulty wearing contact lenses following PRK and, for some, contact lenses following PRK are not tolerable. This could occur even if you were a successful contact lens wearer prior to surgery.

3. I understand that if I currently need reading glasses I will likely still 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.
4. (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 six months following treatment, I will notify my eye doctor immediately.
5. I understand that 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.
6. I understand that the treatment should not be performed on persons with signs of keratoconus since eyes with this condition may have unstable corneas.
7. I understand that the treatment should not be performed on persons known to have a previous history of keloid formation because their corneal healing response is less predictable.
8. 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 Photorefractive Keratectomy including:
 - Anterior Stromal Reticular Haze: 63% of patients experience six months after treatment. Loss of perfect clarity of the cornea, usually not affecting vision, which resolves over time.
 - Glare: 10% of patients experience six months after treatment. Sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance.
 - Halo: 9.7% of patients experience six months after treatment. Hazy rings around surrounding bright lights may be seen particularly at night.
 - Loss of Best Spectacle Corrected Visual Acuity: 6.8% of patients experience six months after treatment; 1.2% at one year after treatment. A decrease in best-corrected visual acuity with spectacles.
 - IOP Elevation: 1.8% of patients experience six months after treatment. An increase in the inner eye pressure due to post-treatment medications is usually resolved by drug therapy or discontinuation of post-treatment medications.

The following complications have been reported in less than 1% of eyes which have had Photorefractive Keratectomy: blurred vision, cataract (cloudiness of the lens), 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 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 Photorefractive Keratectomy and are associated with the normal post-treatment healing process. These

include: pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye, shadow images, light sensitivity, tearing and pupil enlargement.

Since it is impossible to state every complication that may occur as a result of Photorefractive Keratectomy, I understand that the above list of complications is not complete or exhaustive.

9. I understand that the doctor will prescribe certain medications as part of the treatment. The doctor is prepared to answer any questions I may have regarding the prescribed drugs and any side effects.
10. I understand that this is an elective treatment and that I do not have to have this treatment. I understand that the Photorefractive Keratectomy treatment is not reversible.
11. I understand that Photorefractive Keratectomy will require follow-up care at frequent intervals for one year 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 Photorefractive Keratectomy, 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. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all my questions to my satisfaction.

I understand that if I have any questions with respect to the treatment I can call

Doctor(s) Johnson/Deitch at (317) 817-1765

By signing below, I agree that:

- The Photorefractive Keratectomy 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 treatment.

My decision to undergo the Photorefractive Keratectomy treatment has been my own and has been made without duress of any kind.

PATIENT NAME (TYPE OR PRINT)	DATE
PATIENT SIGNATURE	DATE
PHYSICIAN'S SIGNATURE	DATE
WITNESS'S SIGNATURE	DATE