



INFORMED CONSENT

For the use of the Excimer Laser for Performing PRK (Photorefractive Keratectomy)

You are entitled to be informed about the 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 (nearsightedness). 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 treat your myopia.

The alternatives to Photorefractive Keratectomy (PRK) include eyeglasses, contact lenses or a refractive surgery procedure such as radial keratotomy (an operation which a number of spoke-like incisions are made with a surgical knife in the cornea) or LASIK (Laser-In-Situ-Keratomileusis)

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

PATIENT STATEMENT

I have mild to moderate myopia of between (-1.50 to -9.0 diopters) which requires me to wear corrective lenses in order to see clearly for my daily activities. I have been 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 treatment, I declare that I understand the following information:

1. The goal of the Photorefractive Keratectomy treatment with the excimer laser is to reduce or eliminate mild to moderate myopia between -1.5 to -9.0 diopters, thereby reducing my dependence or need for contact lenses and/or eyeglasses.

Please Initial After Reading: _____

PATIENT STATEMENT (Cont...)

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, 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 or 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.
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 will likely 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 after the pregnancy. If I become pregnant in the 6-months following treatment, I will notify my eye doctor immediately.
5. I understand that treatment should not be performed on persons with uncontrolled collagen 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 the treatment should not be performed on persons with signs of Keratoconus or a history of keloid formation and that I should tell my doctor if I have either of these conditions
7. 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 PRK including:
 - a. Anterior Stromal Reticular Haze: 63% of patients experience 6 months after treatment loss of perfect clarity of the cornea, usually not affecting vision, which resolves over time.
 - b. Glare: 10% of patients experience 6-months after treatment sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance.
 - c. Halo: 9.7% of patients experience 6-months after treatment hazy rings surrounding bright lights that may be seen particularly at night.

Please Initial After Reading: _____

PATIENT STATEMENT (Cont...)

- d. Loss of Best Spectacle Corrected Visual Acuity: 6.8% of patients experience 6-months after treatment: 1.2% at 1-year after treatment a decrease in best corrected visual acuity with glasses.
 - e. IOP Elevation: 1.8% of patients experience 6-months after treatment an increase in the inner eye pressure due to post treatment medications which is usually resolved by drug therapy or discontinuation of pos treatment medications.
8. I understand that the doctor will prescribe certain medications as part of the treatment. The doctor is prepared to answer my questions I may have regarding the prescribed drugs and any side effects.
9. I understand that this is an elective treatment and that I do not have to have this treatment. I understand that the Photorefractive Keratectomy is not reversible.
10. I understand that Photorefractive Keratectomy will require follow-up care at frequent intervals for 12 months after the treatment date and I agree to return for required examinations.

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 (lesion in outer layer of the eye), corneal scarring (cloudiness of the cornea persistent enough to affect vision), corneal ulceration/infection, dryness of the eye, feeling something is in the eye, shadow images, irregularity in the cornea (corneal deposits and microcysts), inflammation of the iris, irregular astigmatism (warped corneal surface which causes distorted images), itching, lens opacity, double vision, patient discomfort, light sensitivity, drooping of the eyelid, 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 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 is not complete or exhaustive.

Please Initial After Reading: _____

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 treatment. In addition to this Informed Consent, I have read and fully understand the Patient Information Booklet. 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.

I understand that if I have any questions with respect to the treatment I can call Doctor _____ at 617-636-3360.

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 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:

Physicians Signature

Date:

Witness Signature

Date: