

PT. Name:	DOS:	Informed Consent for Photorefractive Keratotomy PRK
Procedure: PRK	OD / OS / OU	
Surgeon:	Co-Manage:	
DOB:	Age:	

This information is to help you make an informed decision about having Photorefractive Keratotomy surgery to treat your nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision about signing this form. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information, which follows.

Spectacles and contact lenses are the most common method of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are likely to be a good alternative to PRK surgery. Refractive surgery is continually evolving and other refractive procedures may be available as an alternative to PRK. You should also be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies.

The surgery is performed under a topical anesthetic (drops in the eye). PRK permanently changes the shape of the cornea as a result of removing thin layers of tissue from the surface of the cornea with the light from an excimer laser. This causes the center of the cornea to flatten in the case of nearsightedness, or steepen in the case of farsightedness or become more rounded in the case of astigmatism, which changes the focusing power of the cornea. 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 (or weaker) glasses, this result is not guaranteed.

You should understand that PRK surgery would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. PRK does not correct the condition known as presbyopia (or aging of the eye), which occurs to most people around age 40 and may require reading glasses for close-up work. People over 40 that have their nearsightedness corrected may find that they need reading glasses for close vision.

During pregnancy your degree of myopia can fluctuate which could influence your results. If you know you are pregnant, plan to or become pregnant within the next 6 months, it is important that you notify your doctor immediately. You should also advise your doctor of any drug therapy you are on or any vascular or autoimmune diseases you may have.

POTENTIAL RISKS OF PRK INCLUDE:

- 1. LOSS OF VISION:** PRK surgery can cause loss of vision or loss of best-corrected vision. This can be due to infection or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids or other necessary treatment, could even cause loss of the infected eye. Vision loss can be due to the cornea healing irregularly, which could add astigmatism and make wearing glasses or contact lenses necessary and useful vision could be lost.
- 2. VISUAL SIDE EFFECTS:** Other complications and conditions that can occur with PRK surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in image size between the two eyes); double vision; hazy vision; fluctuating vision during the day and from day to day; increased sensitivity to light which may be incapacitating for some time and may not completely go away; glare and halos around lights which may not completely go away. Some of these conditions may affect your ability to read, drive and judge distances and driving should only be done when you are certain your vision is adequate. You may also feel like you have something in your eye or experience dryness of the eye for a period of time after the surgery.
- 3. OVERCORRECTION AND UNDERCORRECTION:** It may be that PRK surgery will not give you the result you desired. Many procedures result in the eye being undercorrected in which case, it may be possible or necessary to have additional surgery to fine tune or enhance the initial result. These results cannot be guaranteed. It is also possible that your eye may be overcorrected to the point of remaining farsighted. It is also possible that your initial results could regress over time. In some, but not all cases, re-treatment could be considered.
- 4. CORNEAL HAZE:** It is common for PRK patients to develop some degree of corneal haze, which in some cases, may not go away completely. If the haze is severe, re-treatment may be necessary. Corneal haze could cause loss of best-corrected vision and rarely, the need for a partial or full thickness corneal transplant using a donor

cornea. Topical corticosteroid drops may also be required to reduce the development of haze for a couple of months. However, if steroids are used for a number of months in multiple doses per day, some individuals will develop a condition called glaucoma, which could permanently damage the optic nerve. Cataracts can also be the result of using topical steroids for too long.

5. **OTHER RISKS:** Additional reported complications include: corneal ulcer formation, endothelial cell loss, epithelial healing defects, and ptosis (droopy eyelid). There are also potential complications due to anesthesia and medications, which may involve other parts of your body. Since it is impossible to state all potential risks of any surgery, this form is incomplete.

6. **FUTURE COMPLICATIONS:** You should also be aware that there are other complications that could occur that have not been reported before the creation of this consent form as PRK surgery has been performed only since the late 1980's and longer-term results may reveal additional risks and complications.

POST-OPERATIVE INSTRUCTIONS: After your surgery you will be given medications and instructions to help prevent infection and control healing. It is imperative that you follow ALL instructions exactly as they are given to you. It is also imperative that all follow-up visits be kept as directed.

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 surrounding bright lights: may be seen particularly at night.

- Loss of Best 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, which 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 PRK: blurred vision, cataract (cloudiness of the lens), corneal epithelial defect, corneal scarring (cloudiness of the cornea severe enough to affect vision), ulceration/infections, 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, 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 PRK and are associated with the normal post-treatment healing process. These include pain (first 4 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 PRK, I understand that the above list of complications is not complete or exhaustive.

In signing this form, you are stating that you have read this consent form and although it contains medical terms, which you may not completely understand, you have had the opportunity to ask questions and have them answered to your satisfaction. You also give your permission for medical data concerning your operation and related treatment and any video recordings of your surgery to be released to physicians and others demonstrating a "need to know" for clinical study.

I am making an informed decision in giving my permission to have Photorefractive Keratectomy (PRK) surgery performed on my ___right eye ___left eye.

Additional consent: _____

Signature of Patient: _____ Date: _____

Signature of Witness: _____ Date: _____

Signature of Surgeon: _____ Date: _____