



PRK Consent Form

This information is to help you make an informed decision about having a Photorefractive Keratectomy vision correction procedure performed 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 the procedure. Every medical procedure has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information with 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. Refractive vision correction procedures are 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. PRK permanently changes the shape 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. The procedure is performed under a topical anesthetic (drops in the eye). The pupil may be dilated during the procedure. After the procedure, it is common to take as few as three hours to as many as two days for the pupil to return to its normal state. You should understand that PRK will 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 them to wear 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 or attempting to become pregnant within the next three months, it is important that you advise your doctor immediately.

Potential risks and other considerations include:

1. Discomfort: Many patients experience mild discomfort for a few days following PRK. Patient reactions range from no discomfort at all to moderate pain.
2. Visual side-effects: Other complications and conditions that can occur with PRK 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 drive and judge distances, and driving should only be done when you are certain your vision is adequate.
3. Overcorrection and undercorrection: It may be that PRK 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 treatment 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. Loss of vision: There is a remote possibility that the procedure can result in 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.
6. Other risks: Additional reported complications include: corneal ulcer formation: endothelial cell loss, epithelial healing defects; and ptosis (droopy eye lid). There are also potential complications due to anesthesia and medications which may involve other parts of your body. It is impossible to state in this form all potential risks of any medical procedure.
7. Future complications: You should also be aware that other complications could occur that have not been reported prior to the delivery of this consent form as PRK has been performed only since the late 1980's, and longer term results may reveal additional risks and complications.
8. Off-label: Use of the excimer laser to correct astigmatism above 4 diopters, and/or to correct myopia in excess of FDA-approved parameters is considered an "off-label" use of an approved medical device. Off-label usage of FDA approved devices and drugs is commonly practiced by physicians without interference from the FDA and allows physicians to practice medicine in a manner they feel most beneficial to their patients.
9. Procedure instructions: It is imperative that you follow the physician's instructions to stare at the fixating light during the procedure. Minor involuntary eye movements, however, will not affect the outcome of the procedure.
10. Postoperative instructions: After your PRK procedure, 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.
11. Exclusion from TLC's Lifetime Commitment Program: Dr. Rotkis' use of a TLC facility and machinery for your procedure does not qualify you for this program.

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 had them answered to your satisfaction. You also give your permission for medical data concerning your operation and related treatment and any video recording of your procedure to be released to physicians and others demonstrating a "need to know" for clinical study. To assure that you have understood the information presented, please copy the following statement in your own handwriting: **"I understand the information presented and am willing to accept the fact that I may need glasses or contact lenses or further vision corrections procedures following PRK to achieve my best possible level of vision."**

I am making an informed decision in giving my permission to have Photorefractive Keratectomy (PRK) performed on my:

Right eye Left eye Both eyes

Patient signature: _____

Date: _____

Witness signature: _____

Date: _____

Surgeon signature: _____

Date: _____

Questions on Photo-Refractive Keratectomy Informed Consent

The following questions cover important information. Please mark the correct answer.

1. TRUE OR FALSE: PRK will permanently change the shape of your cornea.
2. TRUE OR FALSE: There are no guarantees as to exactly how well you will see after the procedure.
3. TRUE OR FALSE: PRK is the only way to correct your vision.
4. TRUE OR FALSE: You may experience vision irregularities such as haze, halos, and glare, which in some cases could be permanent.
5. TRUE OR FALSE: After the procedure, follow-up visits are not important.
6. TRUE OR FALSE: Overcorrections and undercorrections can always be retreated.
7. TRUE OR FALSE: It is very important that I stare at the fixating light during the laser treatment.
8. TRUE OR FALSE: I may experience mild to moderate discomfort for several days after the procedure.
9. TRUE OR FALSE: PRK will eliminate my need for reading glasses when I am over 40 years of age.
10. TRUE OR FALSE: Use of the excimer laser to correct astigmatism and/or myopia in excess of FDA-approved guidelines are considered "off-label" uses of approved excimer lasers by the Food and Drug Administration.

Please check your answers with the correct answers below. Mark any that you missed. If you are still unsure as to why you missed any of these questions, take the form to the doctor or staff member for an explanation.

Answers:

1. True. The purpose of PRK is to permanently change the shape of your cornea.
2. True. There are no guarantees as to how well you will see after PRK.
3. False. PRK is an alternative to glasses and contact lenses. There may also be other refractive vision correction procedures that could treat your refractive error.
4. True. These side effects are commonly experienced to some degree following PRK. It is also possible they may not go away completely.
5. False. It is extremely important that you comply with your doctor's postoperative instructions and keep all follow-up appointments.
6. False. In many cases, undercorrections can be retreated; however, this is only possible if your doctor feels it will help.
7. True. It is important not to move your eye during the laser treatment. However, a small amount of movement will not affect the outcome of the procedure.
8. True. Many patients experience mild to moderate discomfort for a few days after PRK; however, pain medications will be made available.
9. False. PRK does not treat a condition known as presbyopia which occurs to most people above the age of 40 and requires them to wear reading glasses for close work.
10. True. The FDA considers use of the excimer laser to correct astigmatism and myopia in excess of FDA-approved guidelines to be "off-label" uses of the excimer laser in the United States.