

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

INDICATIONS

This information is being provided to you so that you can make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce your nearsightedness, farsightedness, or astigmatism. Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to Dr. Darlington.

ALTERNATIVES TO PRK SURGERY

The alternatives to PRK include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK has been explained to me.

COMPLICATIONS AND SIDE EFFECTS

I have been informed, and I understand, that certain complications and side effects have been reported in the post-treatment period by patients who have had PRK, including the following:

- Possible short-term effects of PRK surgery

The following have been reported in the short- term post treatment period and are associated with the normal post-treatment healing process:

- mild discomfort or pain (first 72 to 96 hours)
- corneal swelling
- double vision
- feeling something is in the eye
- ghost images
- light sensitivity
- tearing

- Possible long-term complications of PRK surgery

- Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
- Starbursting: **After refractive surgery, a certain number of patients experience glare, a "starbursting" or halo effect** around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.
- Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
- IOP Elevation: 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.
- Mild or severe infection: Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation.
- Keratoconus: Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

- Infrequent complications

The following complications have been reported infrequently by those who have had PRK surgery:

- Itching
- dryness of the eye or foreign body feeling in the eye
- double or ghost images



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- o patient discomfort
- o inflammation of the cornea or iris
- o persistent corneal surface defect
- o persistent corneal scarring severe enough to affect vision
- o ulceration/infection
- o irregular astigmatism (warped corneal surface which causes distorted images)
- o cataract
- o drooping of the eyelid
- o loss of bandage contact lens with increased pain (usually corrected by replacing with another contact lens)
- o a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

IN GIVING MY PERMISSION FOR PRK, I DECLARE THAT I UNDERSTAND THE FOLLOWING INFORMATION
The long-term risks and effects of PRK surgery are unknown. The goal of PRK with the excimer laser is to reduce dependence upon or need for contact lenses and/or eyeglasses; however, I understand that as with all forms of treatment, the results in my case cannot be guaranteed. For example:

1. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
2. If I currently need reading glasses, I will likely still need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have PRK surgery.
3. Further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK or other refractive surgery.
4. My best vision, even with glasses or contacts, may become worse.
5. There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.

I understand there is a remote chance of partial or complete loss of vision in the eye that has had PRK surgery.

I understand that it is not possible to state every complication that may occur as a result of PRK surgery. I also understand that complications or a poor outcome may manifest weeks, months, or even years after PRK surgery.

I understand this is an elective procedure and that PRK surgery is not reversible.

FOR WOMEN ONLY: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as PRK have been presented to me in detail in this document and explained to me by Dr. Darlington. Dr. Darlington has answered all my questions to my satisfaction. I have been offered a copy of this consent form. I therefore consent to PRK surgery.

I give permission for Dr. Darlington to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for Dr. Darlington to use data about my procedure and subsequent treatment to further understand PRK. I understand that my name will remain confidential unless I give subsequent written permission for it to be disclosed outside Dr. Darlington's office or the center where my PRK procedure will be performed.

PATIENT'S SIGNATURE

____/____/_____
DATE

WITNESS SIGNATURE

____/____/_____
DATE

I HAVE BEEN OFFERED A COPY OF THIS CONSENT FORM (Please Initial) _____