

Patient Name (printed) \_\_\_\_\_

### **INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)**

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This information and the *Patient Information* booklet must be reviewed so you can make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce or eliminate 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. Sher.

#### **IN GIVING MY PERMISSION FOR PRK SURGERY, 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 or eliminate the 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 over- or under-correction 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 over- or under-correction 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.

#### **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.

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, and tearing.

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**Possible long-term complications of PRK surgery:**

1. Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
2. Glare: Sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance.
3. Halo: Hazy rings surrounding bright lights may be seen, particularly at night.
4. Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
5. 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.
6. 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.

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

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.

**EFFECT ON FUTURE EYE SURGERY:** It is important to tell any future individual providing your eye care that you have had refractive surgery. It may not always be apparent after healing. The interpretation of intraocular pressure measurement performed in the standard way (glaucoma tests) may need to be modified. Having PRK or a related procedure can alter and make more difficult and less accurate the calculation of intraocular lens power if you were to need cataract surgery at some future time. Having access to the preoperative measurements of your eye before PRK was performed might make these calculations easier.

**USE OF MITOMYCIN:** I understand that an application of diluted mitomycin, applied to the treated area of the cornea for short duration, usually less than 30 seconds, may be used at the time of my surgery.

Mitomycin may be used at the discretion of the surgeon in an attempt to reduce or eliminate the incidence of post-operative healing and/or corneal haze. It is more likely to be used in the case of higher corrections, or of prior corneal surgery, including prior LASIK or PRK. Studies on the use of mitomycin for this purpose indicate very good effect and no measurable side effects, however long term studies have not been done as the use of this medication in PRK is only 3-4 years old. This is an "off label" or non FDA approved use of mitomycin. This has been fully explained to me.

**WAVEFRONT PRK:** I understand that Wavefront measurements of my eyes may be used to perform Wavefront-guided PRK. Further, I understand that data from these measurements may be used to determine my treatment, but that this decision may not be made until the day of my surgery, at the discretion of my doctor.

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

My personal reasons for choosing to have PRK surgery are as follows:\_\_\_\_\_

I have spoken with my physician, who has explained PRK, its risks and alternatives, and answered my questions about PRK surgery. I therefore consent to having PRK surgery.

Patient name (printed) \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness signature

\_\_\_\_\_  
Date

I have been offered a copy of this consent form (please initial)\_\_\_\_\_