

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

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 your doctor.

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 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 eyedrops, 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.

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.

Revised 12/2002

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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.

OFF-LABEL PROCEDURES:

Some of the procedures that are performed as part of modern LASER Vision Correction operations may not be approved by the FDA and are considered to be “off-label” uses of a particular device, drug or technique. For example, if you and your surgeon have decided to have a Wavefront (Custom) LASER Vision Correction procedure performed as part of your epi-LASIK procedure, that is an “off-label” (non-FDA-approved) procedure. The FDA has only approved Wavefront (Custom) treatments as part of a LASIK procedure. However, your doctor may be of the opinion that combining the Wavefront (Custom) LASER technology with the epi-LASIK procedure may be the best procedure for certain situations.

Mitomycin: The drug Mitomycin was originally approved by the FDA for the treatment of certain types of cancer. However, eye surgeons have been using the drug Mitomycin for years as part of certain eye surgeries for the purpose of preventing and/or treating unwanted scarring. The use of Mitomycin for this purpose can be highly effective, but this particular use of the drug is not FDA-approved for this purpose, and is considered to be an “off-label” use. The long-term safety of this drug has not been established.

Revised 12/2002

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