

INFORMED CONSENT FOR CORNEAL SURFACE LASER TREATMENT
(PRK, LASEK, Epi-LASIK)

This information must be reviewed so you can make an informed decision regarding laser vision correction to reduce or eliminate your nearsightedness, farsightedness or astigmatism. Only you and your doctor can determine if you should have surgery based upon your own visual needs and medical considerations. Any questions you have regarding laser eye surgery or other alternative therapies for your case should be directed to your doctor.

In General most people choose to have LASIK for laser vision correction since it is a more comfortable procedure, with quicker recovery of vision. PRK, LASEK, and Epi-LASIK are similar “surface treatment” procedures that do not involve a microkeratome cutting a corneal flap. In the case of the latter two, the corneal epithelium is carefully separated and used as a flap. In all these procedures more corneal tissue is spared (since there is no actual flap), and flap complications of LASIK are eliminated.

IMPORTANT NOTE: We recommend surface treatment when the cornea is too thin for LASIK, or when the cornea is irregular or weakened. In these situations cutting a flap in the cornea could weaken the cornea even more and lead to instability or progressive thinning(ectasia). This complication may have to be corrected with contact lenses or possibly a corneal transplant. Surface laser ablation over these abnormal corneas may rarely lead to deformity of the cornea, but this is much less likely to happen than with LASIK. The treatment of these eye falls outside of the usual FDA guidelines, and may be considered “off-label”. Most refractive surgeons currently feel that PRK, LASEK, and Epi-LASIK are safe for many patients whose eyes make them non-candidates for LASIK. Every elective procedure, however, may have risks and side-effects as explained below.

IN GIVING MY PERMISSION FOR PRK SURGERY, I DECLARE THAT I UNDERSTAND THE FOLLOWING INFORMATION:

The long-term risks and effects of surgery are unknown. The goal of surface treatment 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 laser surgery.
3. Further treatment may be necessary, including a variety of eyedrops, the wearing of eyeglasses or contact lenses (hard or soft), or additional laser 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 LASER EYE SURGERY:

The alternatives to laser eye surgery include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives 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 laser vision correction, including the following:

Possible short-term effects of laser eye 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 surface laser surgery:

1. Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time. In some cases haze can be significant and further treatments may be needed. We may apply a drug on the cornea to prevent haze for very high prescriptions. Long-term safety of these drugs has not been established.
2. 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.
3. Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
4. 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.
5. 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.

Infrequent complications

The following complications have been reported infrequently by those who have had laser eye 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 laser eye surgery.

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

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

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

PRESBYOPIC PATIENTS (those requiring a separate prescription for reading): The option of monovision has been discussed with my ophthalmologist.

ENHANCEMENTS Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue or corneal distortion or instability, it may not be possible to perform an enhancement. In this situation glasses or contact lenses may be recommended. Perfect vision is rarely achieved with eye surgery. Even after an enhancement, the vision may regress again, and repeat enhancements may not be advisable. The risks and side-effects of surface laser treatment explained in this document also apply to enhancement procedures. Some, such as haze, occur more frequently with enhancements.

BILATERAL PROCEDURE. Most Patients choose to have laser eye surgery done on both eyes simultaneously for reasons of cost, convenience, and faster recovery. Complications and side-effects described herein can occur as a result of surgery. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, one may experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have surgery performed on separate days, one may avoid the risk of having these complications in both eyes at the same time. I understand that I have this option and that I may have to pay a somewhat higher fee if I choose to have surgery on different days.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The risks and benefits of the procedure have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my

satisfaction. I therefore consent to:

_____ PRK/LASEK _____ PRK/LASEK ENHANCEMENT

surgery on my:

_____ Right eye _____ Left eye _____ Both eyes

I give permission for my ophthalmologist 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 my ophthalmologist to use data about my procedure and subsequent treatment to further understand LASIK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my LASIK procedure will be performed.

Patient Name Date Witness Name Date

I have been offered a copy of this consent form and have read and understood all 4 pages.
(initial please) _____