



Addendum: Consent for Bilateral Simultaneous PRK

While many patients choose to have both eyes treated at the same surgical setting, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. **If you elect to have PRK surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.**

Safety: The risk of infection and other healing complications is applicable to both eyes simultaneously. Therefore, if an infection occurs in one eye, it may also occur in the other eye. Although rare, a serious infection in both eyes can cause significant loss of vision and even legal blindness. By choosing to have PRK performed on separate days, you will avoid the risk of having one or more of these complications in both eyes at the same time.

Accuracy: If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye if necessary. In some patients, this may improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Visual Recovery: Some patients may experience symptoms such as blurred vision, night glare or ghost images that may delay recovery of normal vision. Blurred vision may continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with your fellow eye while the first eye is healing. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes may be restored more rapidly if they are operated on the same day.

Satisfaction: Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the PRK procedure has produced satisfactory visual results without loss of vision or other undesirable side effects. If you are over age 40, you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or

farsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

Convenience: It may be inconvenient for you to have each eye treated at separate visits because it would necessitate two periods of recovery from the laser surgery and might require additional time away from work.

Cost: Professional and facility fees may be greater if the eyes are operated on different days, and the additional time off work can be costly.

Initial

Consent Statement:

“I have read and understand the above risks and benefits of bilateral simultaneous PRK, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous PRK. Dr. Olkowski, Dr. Makin and/or Dr. Gapsis answered all of my questions about the PRK procedure. I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.

Initial

The reason(s) I wish to have both eyes treated at the same time are:

- Greater convenience
- Possible faster recovery
- Less time away from work
- Contact lens intolerance and/or difficulty wearing contacts
- Elimination of possible vision imbalance between treated and untreated eyes

Other: _____

Patient Name (Print)

Date

Patient signature

Witness Name (Print)

Date

Witness signature



INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

This information must be reviewed so 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 your doctor.

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, and 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; 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.

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 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.

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

_____ (initial) 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.

_____ (initial) I understand this is an elective procedure and that PRK surgery is not reversible.

FOR WOMEN ONLY:

_____ (initial) I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result.

_____ (initial) **N/A**

FOR PRESBYOPIC PATIENTS (those requiring a separate prescription for reading): The option of monovision has been discussed with Dr. Olkowski, Dr. Makin, and/or Dr. Gapsis.

I: ___ Do / ___ Do Not CHOOSE MONOVISION

THE EYE I CHOOSE TO BE MY READING EYE IS MY:

_____ Right eye _____ Left eye _____ N/A

_____ (INITIAL)

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

I have spoken with Dr. Olkowski, Dr. Makin and/or Dr. Gapsis, who has explained PRK, its risks and alternatives, and answered my questions about PRK surgery. I therefore consent to having PRK surgery on:

_____ **Right eye** _____ **Left eye** _____ **Both eyes**

Patient Name (Print)

Date

Patient signature

Witness Name (Print)

Date

Witness signature