



BERG·FEINFIELD
VISION CORRECTION

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 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 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 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.
6. I understand that there may be a "balance" problem between my two eyes after PRK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.
7. I understand that the correction that I can expect to gain from PRK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
8. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

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:

Please initial this page after reading _____

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. **Corneal Haze:** It is common for PRK patients to develop some degree of corneal haze which in some cases, may not go away completely. If the haze is severe, re-treatment may be necessary. Corneal haze could cause loss of best corrected vision and rarely, the need for a partial or full thickness corneal transplant using a donor cornea. Topical corticosteroid drops may also be required to reduce the development of haze for a couple of months. However, if steroids are used for a number of months in multiple doses per day, some individuals will develop a condition called glaucoma which could permanently damage the optic nerve. Cataracts can also be the result of using topical steroids for too long.
2. **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.
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.
6. **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.
7. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

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.

Please initial this page after reading _____

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.

**MITOMYCIN-C TREATMENT IN CONJUNCTION WITH PRK LASER TREATMENT
TO DECREASE THE POTENTIAL RISK OF CORNEAL HAZE**

Indications

Mitomycin-C was originally developed for the treatment of various types of cancer. It has also been found to be of value in the treatment of certain conjunctival and corneal disorders. It is applied topically as a drop or may be applied during the time of surgery. Definitive criteria for using or not using Mitomycin-C have yet to be established in conjunctival and corneal disorders, although there is an evolving consensus when these agents are of most value.

Reasons to use Mitomycin-C in PRK is to decrease the risk of corneal haze which can occur after the PRK procedure is performed.

FDA Status of Mitomycin-C in Ocular Treatment and Surgery

This medication was approved by the Food and Drug Administration (FDA) for the treatment of various types of cancer. Upon approval, the drug manufacturer produces a “label” that explains its use. Once a drug is approved by the FDA, physicians can use it for other purposes “off-label” as part of the practice of medicine if they are well-informed about the product. Its use is based on firm scientific method and sound medical evidence, and maintains records of its use and effects. My ophthalmologist has informed me that this medication will be used “off-label” as part of the PRK procedure. Mitomycin-C is routinely used and accepted in the US and worldwide to prevent post-operative haze.

Patient Consent

I understand that Mitomycin-C was approved by the FDA for the treatment of various types of cancer. Nevertheless, I wish to have Mitomycin-C applied to my eye and I am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term side effects and risks of Mitomycin-C are not known.

I have read the above information and have discussed it with my physician and agree that the doctor’s decision to use Mitomycin-C “off-label” as may be found indicated during my PRK laser procedure.

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:

Please initial this page after reading _____

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 on:

_____ **Right Eye**

_____ **Left Eye**

_____ **Both Eyes**

SIGNATURE OF PATIENT: _____

DATE: _____

SIGNATURE OF WITNESS: _____

DATE: _____

(Berg-Feinfield Staff Member only)

INFORMED CONSENT FOR OBSERVATION OF SURGICAL PROCEDURE

I GRANT MY PERMISSION TO BE OBSERVED DURING MY SURGICAL PROCEDURE

I DECLINE TO BE OBSERVED DURING MY SURGICAL PROCEDURE

SIGNATURE OF PATIENT: _____

PRINT PATIENT NAME: _____

SIGNATURE OF WITNESS: _____

(Berg-Feinfield Staff Member only)

MANAGEMENT CONSENT FORM

Dr. Alan Berg has informed me that an optometrist may lawfully provide postoperative care under applicable state law. I understand that my ophthalmologist/optometrist will contact **Dr. Berg** immediately if I experience any complications related to my eye surgery. I understand that I may also contact **Dr. Berg** at any time after the surgery.

It is my desire to have Doctor _____ *(Name of Optometrist)* perform my pre-operative/post-operative care for refractive surgery. I have been assured that **Dr. Berg** will be contacted immediately if I experience any complications related to my eye surgery.

For providing your pre-operative evaluation and/or post-operative care, your optometrist, Dr. _____, will be reimbursed for these services out of your total paid surgery fees.

Reason for Management by this doctor: (please check one)

Maintain established eye care relationship

Difficult to return to Berg-Feinfield Vision Correction for follow-up care because of location

Other (please give reason): _____

SIGNATURE OF PATIENT: _____

DATE: _____

SIGNATURE OF WITNESS: _____

DATE: _____

(Berg-Feinfield Staff Member only)

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

Please initial this page after reading _____