



1550 Oak St., Suite 5
Eugene, OR 97401
(541) 687-2110



1515 Oak St., St
Eugene, OR 97401
(541) 344-2010

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

This information is to help you make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce or eliminate your nearsightedness, farsightedness and/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:

I understand that an overcorrection 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 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.

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.

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.

My best vision, even with glasses or contacts, may become worse.

I have read and understood this page. Patient initials .

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:

Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.

Glare: Sensation produced by bright lights that are greater than normal and can cause discomfort and annoyance.

Halo: Hazy rings surrounding bright lights may be seen, particularly at night.

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.

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 have read and understood this page. Patient initials .

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.

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

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.

I consent to have PRK performed on my right eye / left eye / both eyes.

Patient signature

Date

Witness signature

Date

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

Version 4-2013

I have read and understood this page. Patient initials .

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

I have read and understood this page. Patient initials .

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. My doctor has 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.

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 signature

Date

Witness

Date

Version 4-2013

I have read and understood this page. Patient initials _____.

MITOMYCIN-C (MMC) WITH REFRACTIVE SURGERY

INDICATIONS AND ALTERNATIVES

The correction of high degrees of nearsightedness (or myopia) using the excimer laser is associated with a higher chance of developing corneal scarring or “haze.” This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), and Advanced Surface Ablation (ASA) have been associated with corneal haze in some individuals.

Since 1997, a medication called Mitomycin-C (MMC) has been used to treat patients who develop corneal haze. Several studies have shown that the use of MMC decreases the likelihood of developing haze after PRK, LASEK, and ASA. For this reason, ophthalmologists are also using MMC prophylactically, as a preventive measure.

MMC is an antitumor antibiotic that has been used in the medical field for a number of decades. It is used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells, such as those seen in tumors. It also stops cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980’s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgery. The use of MMC for the treatment and prevention of corneal haze is a newer use of this medication.

COMPLICATIONS

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

Although the complications listed above have been seen in various types of eye surgeries, **no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery.** This technique uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for one to two minutes. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

I have read and understood this page. Patient initials .

