

# TAILORED EYES

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### **INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)**

#### **INTRODUCTION**

This information is provided so that you can make an informed decision about having elective refractive surgery to improve your vision. PRK is one of a number of options for correcting or improving blurry vision caused by nearsightedness, farsightedness and astigmatism.

#### Indications for Alcon WaveLight EX500 Laser:

The WaveLight Excimer Laser Systems are approved for the following specific PRK treatments and ranges: Reduction or elimination of nearsightedness of up to - 12.00 diopters of sphere and up to 6.00 diopters of astigmatism. Reduction or elimination of farsightedness up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism, with a maximum manifest refraction spherical equivalent of + 6.00 diopters. Reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 diopters.

The WaveLight Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism), who have documented evidence that their refraction did not change by more than 0.50 diopters during the year before their preoperative examination.

#### **PROCEDURE STEPS**

Photorefractive Keratectomy (PRK) is a two-step refractive surgery. In PRK, the corneal epithelium is removed (typically with a brush, spatula, or by alcohol) leaving the protective Bowman's membrane of the cornea exposed. Next a laser called an excimer laser is then used to reshape the cornea by removing Bowman's membrane and portions of the cornea stroma (deeper tissue). This process of removing corneal tissue to reshape and change the power of the cornea is called ablation. If your eye is nearsighted (myopia) then the laser will remove tissue to flatten your cornea to improve your vision. If you are farsighted (hyperopia) then the laser remove tissue to steepen your cornea to improve your vision. After the ablation excimer laser treatment, a drug called mitomycin-C is applied to the cornea for a few seconds and then irrigated off the eye (please see Addendum Consent on Mitomycin-C). A bandage contact lens is then placed and the procedure is complete.

PRK is an elective procedure: There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate vision. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, your vision result might be affected or you could end up with worse vision.

## **ALTERNATIVES TO PRK**

If you decide not to have PRK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures (for example Laser Assisted In-Situ Keratomileusis, Implantable Collamer Lens, Small Incision Lenticule Extraction, and Refractive Lens Exchange).

## **VISION THREATENING COMPLICATIONS**

1. I understand that the excimer laser used to ablate the cornea could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. I understand that my cornea could heal with or develop scarring or haze. Corneal haze and scarring represents a loss of perfect clarity of the cornea and the changes may be permanent. Regular glasses or soft contact lenses may not correct my vision, though often specialty contact lenses such as rigid gas permeable, hybrid, or scleral lenses can.
3. I understand that mild or severe infection is possible. 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 or, if very severe, perforation of the eye, corneal transplantation, or even loss of the eye.
4. I understand that I could develop keratoconus. I understand that rubbing my eyes (especially after PRK) can increase my risk of Keratoconus. Keratoconus is 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 after laser vision correction surgery. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
5. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning or warping (ectasia), new floaters or a change in floaters, and retinal tear or detachment, hemorrhage, venous and arterial

blockage, damage to the optic nerve, cataract formation. I understand that after the surgery I may have decreased vision or loss of vision that may not improve with glasses or contact lenses, total blindness, and even loss of my eye.

### **NON-VISION THREATENING SIDE EFFECTS**

1. I understand that there may be increased eye irritation or eye pain initially after the surgery. This may last a few days or weeks. I understand I may be sensitive to light, have glare or halos, and have fluctuations in the sharpness of vision. I understand these changes typically last a few months during the normal stabilization period after PRK but they may also be permanent.
2. I understand that there is an increased risk of eye irritation and vision fluctuation and dry eye after PRK. These symptoms may be temporary (lasting roughly 6 months) or may be permanent. Dry eye after PRK may require frequent application of artificial tears, closure of the tear duct openings in the eyelid, or other dry eye treatments.
3. I understand that an overcorrection or undercorrection of my vision 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.
4. After refractive surgery, a certain number of patients experience glare, starbursting, a halo effect around lights, or difficulty with night vision that may interfere with the ability to drive at night or see well in dim light. For most patients, this is a temporary condition that slowly resolves over several months 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.
5. I understand that I may not get a full correction from my PRK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.
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 there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

8. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
9. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
10. I understand that unforeseen complications or side effects from PRK could possibly occur.
11. I understand that the visual acuity I initially gain from PRK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.
12. 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.
13. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.
14. I understand that if I currently need reading glasses, I will still likely 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 this surgery.
15. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. I understand that with PRK it is customary to wait 6 months before considering re-treatment as there may still be healing and vision fluctuation. In order to perform an enhancement surgery, there must be adequate corneal tissue thickness remaining. If there is not enough tissue, it may not be possible to perform an enhancement as removing additional tissue could destabilize the cornea.
16. For women only: I am not pregnant or nursing. I understand that pregnancy and breast feeding could adversely affect my treatment result.
17. 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.

### **FOR PRESBYOPIC PATIENTS – THOSE REQUIRING READING GLASSES**

The option of monovision, setting one eye for distance vision and one eye for near vision to reduce my dependency on reading glasses, has been discussed with my ophthalmologist.

## **PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

I understand that during PRK surgery, a flap is cut in the cornea and corneal tissue is vaporized.

- Corneal tissues and nerves cut during this process must heal following surgery. Corneal nerves may not fully recover resulting in dry eyes and/or chronic pain.

Patient Initials: \_\_\_\_\_

## **CONSIDERATIONS FOR A GOOD PRK CANDIDATE**

I understand that I should not have PRK surgery while I have an active eye inflammation or infection.

I understand that I am NOT a good candidate for PRK if:

- I have severe dry eyes.
- My cornea(s) is not thick enough.
- My doctor has told me that I have a condition that causes thinning or bulging of the cornea, such as keratoconus or pellucid marginal degeneration.
- I have problems resulting from a past herpes eye infection.
- I have an autoimmune disease or connective tissue disease (like lupus or rheumatoid arthritis), glaucoma, or diabetes.

Patient Initials: \_\_\_\_\_

## **WHAT TO EXPECT IN THE FIRST 6 MONTHS**

I understand that dry eye following surgery is common, and the symptoms of dry eye, including blurred vision, can vary from mild to severe. Based on the estimates below, I am prepared to regularly use lubricating eyedrops to manage dry eye symptoms. I understand that, following PRK surgery, estimates of certain common risks are as follows:

- One (1) week following surgery, up to 85% of patients experience dry eye symptoms.
- At six (6) months following surgery:
  - Up to 27% of patients experience dry eye symptoms.
  - About 41% of patients may experience visual symptoms such as glare, halos, starbursts, and double images (with or without glasses or contact lenses).
  - Around 4% of patients may have “very” or “extremely” bothersome symptoms.
  - Around 2% may have “a lot of difficulty” or “so much difficulty that I can no longer do some of my usual activities” when not wearing glasses or contact lenses.

Patient Initials: \_\_\_\_\_

## **LONG TERM RISKS**

• I understand that, although rare, there have been reports that some patients who have had PRK have experienced severe depression or suicidality that they believe to be a result of complications following the procedure. A definitive causal link between PRK and these reported psychological harms has not been established.

- I understand that dry eye may persist beyond six (6) months.

- I acknowledge the following estimates of the percentage of patients experiencing the persistence of certain symptoms five (5) years after surgery:
  - o Around 17% of patients may still need to use eye drops daily for dry eye.
  - o Less than 2% of patients notice some visual disturbance, such as glare, halos, starbursts, and double vision.
  - o A decreased ability to see under low light conditions; around 8% of patients may have moderate difficulty or a lot of difficulty driving at night.
  - o Very rare reports (estimated rate of less than 0.8%) of severe, constant pain that may prevent normal activities.

Patient Initials: \_\_\_\_\_

**CONFIRMATION OF DISCUSSION OF RISKS**

Patient: I acknowledge that I have received and read information about the specific PRK laser that will be used during my PRK surgery and that I have had time to discuss the items in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of PRK surgery for me, given my specific health conditions. I have considered alternatives to PRK, such as contact lenses, eyeglasses, and LASIK, SMILE, and their risks and benefits

The details of the procedure known as PRK 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 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 PRK. 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 PRK procedure will be performed.

\_\_\_\_\_Patient Initial: I have been offered a copy of this consent form.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Witness Signature

### **Addendum: Consent for Bilateral Simultaneous PRK**

While many patients choose to have both eyes treated during the same surgery, 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 surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.**

**Safety:** The risks of infection, severe inflammation, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have PRK performed on separate days, you 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. In some patients, this might 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:** Most PRK patients experience visual recovery over 1-2 weeks, but some may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged 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 the fellow eye while the first eye fully recovers. 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 will usually 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 uncommon 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 that may also be needed can be costly.

**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

**ADDENDUM: USE OF MITOMYCIN-C (MMC) IN 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 Phototherapeutic Keratectomy (PTK) 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 at the time of refractive surgery decreases the chance of developing haze after PRK, LASEK, and PTK. For this reason, ophthalmologists use MMC as a preventive measure during refractive surgery.

MMC is an antitumor chemotherapy drug used because it can stop the proliferation or growth of certain types of cancer cells. It also stops a form of noncancer cells that can cause scarring or haze in the cornea (fibroblasts). 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 and today we use of MMC for the treatment and prevention of corneal haze.

### **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 techniques uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for a few seconds up to two minutes. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

Patients who received preventive MMC treatments have shown improvement in visual acuity and a decrease in corneal haze. No corneal haze developed during an average follow-up period of one year. However, there is no guarantee that you will obtain a similar result. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

### **SUNGLASSES RECOMMENDATION**

It is recommended that you protect your cornea from harmful UV rays by wearing sunglasses at all times when outside (even on cloudy days) to reduce your risk of corneal haze or scarring after surgery.

### **PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

My surgeon has indicated to me that I either have corneal haze, or that I may be more likely to develop corneal haze following PRK, LASEK, or PTK. I have read and understood the information presented above about the risks, benefits, and alternatives to using MMC for both treatment and prevention of corneal haze. I have had the opportunity to ask questions and have them answered to my satisfaction.

I understand that administering MMC for treatment and prevention of corneal haze is considered an "off-label" use of an FDA-approved medication. When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a "label" to

explain its use. Once a medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

I understand that there are no guarantees as to the success of the procedure for removing or preventing haze and that toxic side effects may develop.

I give my informed consent to my surgeon, Steven Kane, MD and/or his or her assistants to use MMC on my

\_\_\_\_\_RIGHT EYE \_\_\_\_\_LEFT EYE \_\_\_\_\_BOTH EYES

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Patient's signature

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Witness signature