

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK) OR EPI-LASEK WITH OR WITHOUT MITOMYCIN FOR THE CORRECTION OF NEARSIGHTEDNESS (MYOPIA), FARSIGHTEDNESS (HYPEROPIA), ASTIGMATISM, OR MIXED ASTIGMATISM

V7, May 2008

Introduction

This information is being provided to you so that you can make an informed decision about the use of a device known as an excimer laser along with lifting or removing surface cells to reshape the eye to reduce or eliminate refractive errors. The various versions of this procedure will simply be referred to as PRK in the remainder of this document. 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 visual acuity.

This procedure, like all surgery, presents some risks, many of which are listed below. The first important message to understand is that it is impossible to perform any type of surgery without the patient accepting a certain degree of risk and responsibility. You should also understand that there might 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, the result might make your vision worse.

Despite all our efforts, if a complication occurs, patients sometimes feel they did not fully comprehend the risks outlined. For this reason we have put together this consent form. Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing PRK laser surgery, as most of our patients will never encounter any complications, and the vast majority are pleased with the improvement they achieve. It is our intention, however, to accurately outline the associated risks to all candidates so that they may either elect not to accept the associated risks by declining surgery or be better prepared to deal with any unexpected complications or side effects. The only way in which a patient can avoid all surgical risks is by not proceeding with the surgery. No surgery is always 100% successful or 100% risk free.

PATIENT CONSENT

In giving my permission for the use of the excimer laser for PRK, I have received no disclaimers from any person, advertisement, or other educational materials that are contrary to this document and have received no guarantee as to my final outcome. I understand the following about this procedure:

Alternatives to PRK

I understand that if I decide not to have PRK, there are other methods of correcting my refractive error. These alternatives include, among others, eyeglasses, contact lenses, LASIK, Corneal Rings, clear lensectomy, laser thermokeratoplasty, phakic implant lenses (Visian), or waiting for future improvements or new technology.

Contraindications, Warnings, and Precautions to PRK

CONTRAINDICATIONS: I understand that PRK surgery is contraindicated in patients who: are pregnant or nursing; show signs of keratoconus; are taking the medications isotretinoin (Accutane®) or amiodarone hydrochloride (Cordarone®); or have an autoimmune disease, collagen vascular disease (Rheumatoid arthritis, lupus, Wegener's, others), or an immunodeficiency disease.

WARNINGS: PRK is not recommended in patients who have: insulin-dependent diabetes; severe allergies; a history of herpes simplex or herpes zoster keratitis; a history of infectious diseases (HIV, hepatitis, TB, others); severe dry eyes; cataracts or other significant eye disease; or who have a prescription that is changing a lot.

PRECAUTIONS: The safety and effectiveness of PRK has not been established in patients with: progressive myopia; ocular disease; corneal abnormality; previous corneal or intraocular surgery; trauma in the ablation zone; history of glaucoma; or history of keloid formation (excessive scarring); patients who are taking the medication Sumatriptin (Imitrex®); patients under 21 years of age; patients with implant lenses after cataract surgery; individuals suffering from significant depression or anxiety disorders; or patients with exceptionally high prescriptions or low prescriptions.

I understand that I should notify my ophthalmologist if any of these apply to me. If I elect to proceed with PRK surgery after discussion with my ophthalmologist then there may be extra risks involved and I understand the accuracy and final outcome may not be as good and there may be unknown risks or side effects that have not been adequately studied.

Vision Threatening Complications

1. I understand that irregular healing of the surface of the eye could result in a distorted cornea. This would mean that glasses or contact lenses might not correct my vision to the level possible before undergoing PRK. This may necessitate having further procedures or wearing contact lenses, may prevent safe treatment of the other eye, or prevent having later enhancement surgery. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
2. Problems can also be caused by an eye infection (corneal ulcers) that might not be controlled with antibiotics or other means, or by severe inflammation (corneal haze, corneal scarring, corneal "melting") that might not be controlled with eyedrops or other means. I understand that other very rare complications threatening vision include, but are not limited to: corneal swelling, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness and even loss of my eye.
3. I understand that further eye problems related or unrelated to the surgery may arise at a later date including, but not limited to: keratoconus (irregular cornea), cataracts, retinal detachments or hemorrhages, glaucoma, irregular or loose epithelium or severe dry eyes.

Non-Vision Threatening Side Effects and General Information

1. I understand that each person responds and heals after PRK somewhat differently. I understand that because of this unpredictable variability, no guarantees as to my final vision or speed of recovery can be given. I understand that I may have a slower recovery with blurred vision or need additional treatments or visits at a later time. This can require more time off work, may cause delay in other plans, and can cause emotional stress.
2. I understand that at night there may be a "starbursting" or halo effect around lights. I understand that this condition is common right after surgery and usually diminishes with time, but could be 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. I understand that I should not drive until my vision is adequate both during the day and at night. I understand that conditions that increase the likelihood of night vision problems include, but are not limited to: large pupils, age less than 30, high prescriptions, high astigmatism, thin corneas, or occupations requiring a lot of night driving.
3. I understand that my eyes may be drier than usual after surgery causing some discomfort and blurred vision and requiring the use of moisturizing eye drops. I understand that this condition is common right after surgery and usually diminishes with time, but could be permanent. I understand that conditions that increase the likelihood of dry eye problems include, but are not limited to: prior problems with dry eyes, arthritis, being post-menopausal, age greater than 50 years old, medications that dry the eyes, thyroid related eye problems, or doing a lot of near work or computer work.
4. I understand that some occupations (e.g. pilots, police officers, military occupations, etc.) may require a certain level of vision for that occupation, and that refractive surgery may not offer that level of vision, and/or that refractive surgery may limit qualifying for some occupations. Guidelines change frequently, and you should check your particular situation before proceeding.
5. I understand that if I am prone to depression/anxiety, or I am prone to difficulties handling and adapting to stress, or I am very critical of my vision, that I am more likely to experience visual and emotional problems adapting to a slow recovery, visual side effects, or unexpected complications. I understand that if I am taking anti-depressants or anti-anxiety agents that I am more likely to experience dryness, fluctuating vision, and focusing difficulties possibly as a side effect of the medications. I understand that some people should elect not to pursue PRK surgery if they feel they are at risk for handling the added stress.
6. **For nearsightedness w/wo astigmatism:** I understand that if my nearsightedness is greater than 6 diopters, or my astigmatism is greater than 2 diopters, or if my age is greater than 45 that my recovery will be longer, the ultimate accuracy may not be as good, and I am more likely to require second treatments (enhancements).
For farsightedness w/wo astigmatism & mixed astigmatism: I understand that if my farsightedness is greater than 4 diopters, or my astigmatism is greater than 2 diopters, or if my age is greater than 45 that my recovery will be longer, the ultimate accuracy may not be as good, and I am more likely to require second treatments (enhancements). I understand that for all levels of farsightedness the recovery period is substantially longer, and the final clarity often not quite as good as that for equivalent amounts of nearsightedness.
7. I understand that my surgeon may choose to use a medicine called Mitomycin applied to the surface of the eye immediately after the laser treatment to decrease the likelihood of excessive healing, corneal hazing, or scarring. The use of Mitomycin presents some extra risks of poor healing or corneal thinning. This use of Mitomycin is FDA "off-label".
8. I understand that there may be increased sensitivity to light, glare, halos, a difference in the size of images (aniseikonia), and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period from one to three months, but they may also be permanent.

9. I understand that an overcorrection or undercorrection could occur causing me to be nearsighted, farsighted, or to have astigmatism (even if I didn't have any before). This could be either permanent or treatable. I understand that overcorrections and undercorrections are more likely in people over the age of 40 years and may require the use of glasses or contacts for reading, intermediate, or for distance vision some or all of the time.
10. I understand that I may not get a full correction from my PRK procedure and this may require future enhancement procedures, other surgeries, or the use of glasses or contact lenses. I understand that I may not be able to achieve a full correction even with further enhancement procedures.
11. 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. I understand this could cause eyestrain and make judging distance or depth perception more difficult and may require the use of contact lenses. I understand that if my first eye takes longer to heal than is usual, this may prolong the time of "imbalance" between the two eyes.
12. I understand that after PRK the eye may be more fragile to trauma from impact. Evidence has shown that, as with any surgery, the cornea may not be as strong as the cornea originally was. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following PRK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high.
13. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this.
14. I understand that cataracts (clouding of the lens of the eye) occur in most people as they get older, and that my eyes will change with the formation of cataracts, affecting some of the benefit of my PRK surgery. This may cause my vision to change, requiring a return to lens wear, and usually requires surgical correction at some point. I understand that I should tell my cataract surgeon that I have had PRK surgery done, as the power of my implant lens used with cataract surgery will need to be modified.
15. I understand that there may be pain or a foreign body sensation, particularly during the first 3 to 4 days after surgery.
16. 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.
17. I understand that the long term effects of PRK are not known, and that unforeseen complications or side effects could occur. PRK has been studied for more than 15 years.
18. I understand that visual acuity I initially gain from PRK could regress, and that my vision may go partially or completely back to the level it was immediately prior to having the procedure.
19. 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 or contacts to refine my vision at some point later my life, and that this might occur soon after surgery or years later. I understand that nearly everyone needs reading glasses as we grow older.
20. I understand that I will be given medication (eye drops) in conjunction with the procedure and that my eye may be patched afterward. I understand that using these medications and following all directions are vital to achieving a good outcome. I understand that I must not drive for at least one day following the procedure and not until I am certain that my vision is adequate for driving. I understand that there may be other activity restrictions as well.
21. I understand that if I currently need reading glasses or am more than 40 years old, I will likely need reading glasses after this treatment. I understand that if I am used to taking my glasses off for reading or intermediate distance, this will not be possible after my surgery. 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. If I am more than 40, I understand that I may choose to have monovision done (one eye left near-sighted for upclose) and have discussed this with my ophthalmologist.
22. I understand that some uses of equipment may not have been fully considered or evaluated by the FDA. These are known as off label uses. Advances sometimes outpace the FDA process and studies sometimes have insufficient numbers to adequately evaluate some options. Examples of this may include: treating larger zones (areas); treating higher ranges of prescription and astigmatism; treating very low ranges of prescriptions; treating patients less than 21 years old; treating patients with lesser contraindications, warnings, or precautions; use of Mitomycin C, or others not listed here.
23. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. Typically, if 1.00 diopter or greater correction remains or vision is 20/40 or worse, an enhancement may be performed. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
24. 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.

Please initial here to signify that you have read this page_____

CONSENT FOR BILATERAL SIMULTANEOUS PRK

Introduction

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.

The advantages of having PRK performed on each eye at a separate time are:

- **Safety:** You will not experience the risk of developing an infection or other severe complication in both eyes at the same time, which although very rare, could lead to significant decrease in vision in both eyes. Should this occur in both eyes at the same time, carrying out normal activities could be difficult.
- **Accuracy:** 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, increasing the likelihood of a better outcome in the second eye.
- **Visual Recovery:** Most PRK patients experience blurred vision for just a few days but the recovery can at times be delayed. If the eyes are operated on separately, you can function with the fellow eye while the first eye fully recovers. This is especially true if you are able to wear a contact lens in the unoperated eye.
- **Satisfaction:** You will be given the opportunity to determine whether the PRK procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects such as glare, ghost images or increased light sensitivity. If you are nearsighted and over age 40, you will have an opportunity to experience the change in your close vision resulting from the correction of your nearsightedness. This could influence your decision whether to fully correct your other eye or only partially correct the other eye to maintain some degree of close vision without the need for glasses (monovision).

The disadvantages of having PRK performed on each eye at a separate time are:

- **Convenience:** It may be inconvenient for you to have each eye treated at separate visits. This will necessitate two periods of recovery from the laser surgery and may require additional time away from work.
- **Visual Recovery:** There will be a potential period of imbalance in vision between your two eyes. This is especially important if you are unable to wear a contact lens in your unoperated eye. It is not usually possible to use the operated eye without a corrective lens along with a strong corrective lens in the unoperated eye because it produces a strong sense of imbalance, dizziness and a form of double vision.

The advantages of having PRK performed on both eyes at the same time are:

- **Convenience:** It may be more convenient to have both eyes treated during the same visit and you may be able to take less time off work.
- **Visual Recovery:** The balance in vision between your two eyes will usually be restored more rapidly. This is especially true if you are unable to wear a contact lens in your unoperated eye.

The risks of having PRK performed on both eyes at the same time are:

- **Safety:** The risk of infection, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage is very rare but potentially devastating. If these serious but rare complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant decrease in vision or even temporary or permanent legal blindness.
- **Accuracy:** By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye. Therefore, if there is an over-correction or under-correction in one eye, chances are it will happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye also will require a retreatment.
- **Visual Recovery:** PRK patients generally experience some blurring for just a few days to a week. Some patients, however, experience delayed visual recovery and symptoms such as blurred vision, night glare or ghost images. There is no way to predict how long your eyes will take to heal, and some of these side effects can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks in both eyes, which could make driving difficult or dangerous and could interfere with your ability to work. The healing cornea epithelium is most susceptible to trauma during the first several weeks after surgery. Should both eyes become accidentally injured, significant decrease in vision in both eyes may result.
- **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, or to wait until the side effects lessen or resolve.

Implied Consent for Special Circumstances

I understand that special circumstances may arise where I give my implied consent for my surgeon to act in my best interest. I understand that I will be only minimally sedated, and my ophthalmologist will attempt to explain and discuss any special circumstances with me as the situation allows, and nothing will be done against my objections. Examples of special circumstances include: A minor problem with one eye may require judgement on whether to proceed with the second eye that day or postpone treatment. An unexpected problem may need other procedures done immediately for repair. Other circumstances not listed here might also arise.

Care Commitment, Financial Consent, & Comanagement Option

I understand that my fees for surgery include my pre-operative exam, measurements of my eye(s) and reporting done for outcome analysis, my surgery, and my post-operative exams with my co-managing doctor (if any) or us for one year from the date of your surgery. Additionally, any PRK enhancements I may need within the first year will be done at no additional charge.

Items **NOT** covered in my fees include, but are not limited to: prescription medications, artificial tear drops, material costs for glasses or contact lenses, fees for second opinions or surgeries, extra fees for wavefront treatments, fees for other surgeries other than PRK enhancements within the first year, travel expenses, missed work expenses, and any other expenses not specifically included above.

I may optionally choose, by initialing here, to have some part of my post-operative care done with my own eye doctor if it is more convenient for me (e.g. travel, office hours, and familiarity). My PRK surgeon will perform my surgery and see me the first few visits, afterwards I can see my own optometrist/ophthalmologist for some of the post-operative visits. There is NO extra charge to do this, and payment can be forwarded directly to your own optometrist/ophthalmologist by our office by giving your permission here. I give my permission to forward medical and health information to my comanaging doctor. Even though my other eye doctor may provide some of my post-operative care, I understand that my PRK surgeon will continue to be available to me if I should develop a complication or have any questions about my care. I understand that my PRK surgeon cannot, however, assume any risk or liability involved in my choosing to see my own eye doctor for some portion of my post-operative care.

___ I elect to see Dr. _____ for part of my post-operative care.

___ I elect to see only my surgeon and his staff for my post-operative care.
(initial one)

PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as PRK have been presented to me in detail in this document, explained to me by my ophthalmologist, and I have reviewed the advantages, disadvantages, possible risks, and alternatives at my leisure. Although it is impossible for the doctor to inform me of every possible complication that may occur, my ophthalmologist has answered all my questions to my satisfaction. I have received no disclaimers from any person, advertisement, or other educational materials that are contrary to this document and have received no guarantee as to my final outcome. I therefore consent to PRK surgery. I give permission for my ophthalmologist to record my procedure and use data about my procedure for purposes of education, research or training of other health care professionals. 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 office where my PRK procedure will be performed. In signing this document, I do so knowingly, voluntarily and intelligently.

Patient signature _____ Date _____

Witness signature _____ Date _____
(the patient has confirmed to me that they have read and understand this consent)

I have been offered a copy of this consent form (patient initials) _____