

INFORMED CONSENT FOR PRK SURGERY

Please read the following consent form carefully. Please initial each page where indicated.

Do not sign this form unless you read and understand each page.

Patient's Name: _____

Surgeon's Name: Mark I Golden, MD, FACS, FICS

Date of Procedure: _____

Operative Eye: Right Left Both

Introduction:

The following information is intended to help you make an informed decision about having Photorefractive Keratectomy (PRK) surgery to correct your vision. It is our hope to fully inform you concerning the side effects, limitations, and complications of laser surgery. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. The first important message to understand is that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. Risks considered unforeseeable or remote are not discussed but that does not mean they do not exist. In addition, there may be long-term effects not yet known or anticipated at the present time.

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 laser surgery, as the vast majority of patients will never encounter any serious complications and are very pleased with the improvement they achieve. It is our intention, however, to accurately outline the associated risks to all candidates so that they either may elect not to accept the associated risks or be 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 surgery.

Background:

The Excimer Laser reshapes the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness) and hyperopia (farsightedness). The curvature of the eye must be reshaped. There are two ways it can be accomplished with the laser, on the surface with PRK (Photorefractive Keratectomy) or beneath the surface with LASIK. The surface cells of the eye (epithelium) are more reactive; they may produce more pain, infection, and scarring. The intraoperative risks (risks related to the surgery itself), however, are greater with LASIK than with PRK alone. This is due to the use of the microkeratome (a surgical instrument much like a carpenter's plane) in LASIK, which is not used in PRK.

Photorefractive Keratectomy (PRK) is a procedure that is approved by the FDA to treat nearsightedness and farsightedness. Laser Assisted In Situ Keratomileusis (LASIK) is a procedure using the Excimer laser and the microkeratome which also treats nearsightedness and astigmatism.

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Overview of the PRK Procedure:

Diagnosis:

You have been diagnosed with myopia (nearsightedness) with or without astigmatism or hyperopia (farsightedness) with or without astigmatism.

PRK Surgery Described:

PRK permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops in the eye). The surface layer of tissue called the epithelium is removed. The cornea is then reshaped using the extraordinary precision of the cool light of the Excimer laser. You will hear a clicking noise during the ablation (the removal of corneal tissue with the excimer laser). The removal of tissue (ablation) causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea.

Limits of PRK:

Although the goal of PRK is to improve vision to the point of not being dependant on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision.

PRK does not correct the condition known as presbyopia (aging of the eye) which occurs in people around the age of 40 and usually requires them to wear reading glasses for close-up work. If you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses, you will probably need them at a later age (40-45). Some patients over 40 who have a low degree of myopia are able to read but only by removing their distance glasses, something they did not have to do before the age of 40. This is because presbyopia has set in and they are relying on their natural nearsightedness to read, but they must remove their corrective lenses to do so. If you elect to have surgery to correct your myopia, this “second mechanism” to read up close will be lost and you may need reading glasses, right after the surgery.

Refractive surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, macular degeneration or retinal detachment. Decreasing or eliminating your need for corrective eyewear does not eliminate your risk for developing eye problems in the future. Therefore, it is highly recommended that you continue to see your eye care professional at regular intervals as you did prior to surgery.

Risk of Not Undergoing PRK:

The risks of not having the surgery are limited to those associated with your current visual condition. These include, but are not limited to, the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks or trauma to the eye caused by breakage of spectacles or contact lenses in the eye.

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Contraindications:

The treatment should not be performed on persons:

- with uncontrolled vascular disease
- with active autoimmune or collagen vascular diseases (e.g. lupus, scleroderma, rheumatoid arthritis, etc.)
- who are immunocompromised or on drugs or therapy that suppresses the immune system
- with signs of keratoconus (progressive steepening of the cornea)
- who are pregnant or nursing
- with residual, recurrent or active eye disease(s) or abnormality
- with active or residual disease(s) likely to affect wound healing capability (keloid formers)
- with unstable or uncontrolled diabetes
- with progressive myopia or hyperopia
- with uncontrolled glaucoma
- with previous herpes infection of the eye

If you know that you have any of these conditions, you should inform us. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake PRK surgery, you should discuss them with our doctors.

Alternatives to PRK:

PRK is purely an elective procedure. Among the alternatives to having surgery are the following:

- Eyeglasses/spectacles
- Contact lenses
- Laser in situ Keratomileusis (LASIK)
- Radial Keratectomy (RK)
- Orthokeratology
- Hexagonal keratotomy (Abandoned)
- Corneal relaxing incision
- Intracorneal ring (Intacs)
- Lens extraction with Intraocular lens implantation

If you have any questions about these options, please discuss them with our doctors.

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Recovery/Risks:

- 1) The risk of serious infection is less than 1/1000 with PRK.
- 2) The risk of PAIN is approximately 1/10 with PRK. With PRK, it is common to feel a scratchy sensation, like sand in the eyes, for 3-4 days. Patients may be light sensitive, with tearing, but this is usually short-lived. The eye may be red and the lids may be swollen following the procedure, but this resolves over the next few days.
- 3) The risk of scar formation with PRK ranges from 1% to 5%, increasing in incidence with the degree of attempted correction. Scar tissue is composed of collagen proteins, which develop on the surface of the eye with PRK. It presents usually as a dirty windshield type of appearance to your vision. We limit the chance of haze or scarring by the use of medications (mitomycin) placed at the time of surgery. HAZE is not the initial blurriness that is commonly experienced, as scarring develops over time. It is very rare to have clinically significant haze.
- 4) The two side effects that are similar between the LASIK and PRK procedures are NIGHT GLARE and BLURRINESS. They are very common early in the healing process, and are observed by most patients. The risk of night glare is higher with astigmatic corrections. Both night glare and blurriness typically, but not always, improve over several months.
- 5) NIGHT GLARE is common in nearsighted individuals even before any refractive procedure is performed, but increases almost immediately in the healing process and is more common when only one eye is treated. Typically, six months after both eyes have been treated, only 2% of patients still experience significant night glare that interferes with their night driving. Severe night glare can reduce vision in all reduced lighting conditions producing blurriness, ghosting, or halos. Patients with large pupils and severe myopia and/or significant astigmatism are at greater risk for night glare.
- 6) Almost all patients describe BLURRINESS immediately following the surgery. Blurriness to one degree or another is common. Approximately 80% of the visual recovery occurs within the first several days, with the last 20% of vision improving over 3-6 months. Patients experience a large quantitative jump in vision within days, with the qualitative fine-tuning or sharpness of vision taking much longer, on the order of several weeks. Approximately 1% to 2% of the patients independent of the procedure performed will develop corneal irregularities reducing the sharpness, crispness and clarity to their vision preventing them from reading the bottom two or more lines on an eye chart that glasses, contact lenses, or another surgery cannot restore. That is, the initial blurriness resolves in 98% to 99% of patients over 6 to 12 months, however, it may be permanent in 1% to 2% of treated patients. There is no way of predicting or predetermining who will be in this 1% to 2%. A patient who loses sharpness, will have vision that is permanently worse than the vision the patient enjoyed with glasses or contact lenses prior to the surgery. Each patient heals differently and this may cause differential results in seemingly similar patients. The recovery from blurriness after PRK is typically slower than with LASIK.
- 7) LOSS OF VISION: Refractive surgery can possibly cause loss of vision or loss of best corrected vision. This can be due to infection (internal or external) or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids or other treatment, could even cause loss of the infected eye. Vision loss can be due to the cornea healing irregularly, which could add astigmatism, and make wearing glasses or contact lenses necessary or lead to loss of useful vision. Irregular corneal healing could result in a distorted corneal surface so that distorted vision or “ghosting” occurs. This may or may not be correctable by spectacles, contact lenses or further surgery.

- 8) **VISUAL SIDE EFFECTS:** Other complications and conditions that can occur with refractive surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light that usually gets better but may not; glare and halos around lights which usually diminish with time but may not.
- 9) **OVERCORRECTION OR UNDERCORRECTION:** It may be that PRK surgery will not give you the result you desired. It could be that the eye is undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It will be up to our surgeon to determine the appropriate time to pursue such options. It is also possible that your sight may be overcorrected to the point of being farsighted. At this point, this can also be corrected with the laser. Significant overcorrections are treated with glasses or contact lenses, and sometimes an enhancement is possible. It is also possible that your initial results may regress over time. The regression is usually not severe but may be treated with an enhancement, glasses or contact lenses.
- 10) **OTHER RISKS:** Other reported complications include: corneal ulcer formation; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include: dense or persistent corneal haze, progressive corneal thinning (ectasia). There are also potential complications due to anesthesia and medications that may involve other parts of your body.
- 11) **LATER-DISCOVERED COMPLICATIONS:** PRK is a relatively recent technique. You should be aware that other complications may occur in the future that have not yet been reported. Longer-term results may reveal additional risks and complications.

PREOPERATIVE CONSIDERATIONS:

PREGNANCY AND BREAST-FEEDING: Pregnancy and breast-feeding could adversely affect your treatment results since your refractive error (glasses prescription) can fluctuate during this time. In addition, pregnancy and breast-feeding may affect your healing process, and some medications may pose risk to the unborn or nursing child. Therefore, if you are pregnant or nursing, you should not undertake the PRK procedure until after the pregnancy and breast-feeding period, usually about four months, or three months after the resumption of your normal menstruation cycles.

TAKING MEDICATIONS AND ALLERGIES: You should inform your physician of any medications you may be taking, so as to avoid allergic reactions, drug reactions, and other potential complications during the LASIK surgery and subsequent treatment.

CONTACT LENS WEARERS: Patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks prior to the pre-op examination (this period may be longer in some patients). Patients who wear soft lenses must completely stop wearing these lenses at least 7 days prior to the pre-op examination. Following the examination, you must leave the contact lenses out of the eye to be treated.

POST-TREATMENT PRECAUTIONS:

EYE PROTECTION: Avoid exposing the eye to tap water in the bath or shower, as such non-sterile water may expose the eye to increased risk of infection. Eye shields should be worn at bedtime and any other time while

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sleeping for a week after surgery. Avoid rubbing the eye. The eye may be more fragile to trauma from impact for about 2 months. As a general precaution, it is advisable to wear protective eyewear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high.

OPERATING MOTOR VEHICLES: After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of your procedure, you should arrange to be driven home after the procedure.

PAIN AND DISCOMFORT: The amount of pain and discomfort that can be expected soon after the PRK procedures varies with the individual. You should expect that the eye may burn and be irritated to some extent after the surgery. These sensations usually last 3-4 days after the procedure. Vision may be blurry and you may have the feeling of a foreign object in the eye.

EXPECTATIONS:

The goal of the procedure is to achieve the best visual result in the safest way. The goal is to dramatically reduce the dependence on glasses or contact lenses in an attempt to help improve the quality of life. Night driving glasses and readers may be necessary.

The degree of correction required determines both the rate of recovery and the initial accuracy of the procedure. Severe prescriptions may require more than one procedure. Patient differences in healing will also greatly affect visual recovery and final visual outcome and is impossible to predict.

Even 90% clarity of vision is 10% blurry. Enhancement surgeries can be performed when stable UNLESS unwise or unsafe. Typically, if vision is 20/40 or worse, an enhancement may be performed. Enhancement surgeries are generally performed no sooner than 3 months after the first surgery.

In order to perform an enhancement surgery, there must be adequate corneal tissue remaining from the original surgery. 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 will be discussed.

REASONS TO CANCEL OR POSTPONE PROCEDURES:

At the time of the consultation for candidacy, it is not possible to rule out all possible contraindications for Laser Vision Correction. In a minority of cases, contraindications are found at the pre-operative exam which make it necessary to cancel Laser Vision Correction.

At the time of surgery, cases can be postponed for the following reasons: 1) problems with the laser; 2) storms that may affect the laser’s ability to perform. In this rare circumstance, the vision in most cases returns to pre-operative levels with corrective glasses or contact lenses.

Patient’s initials

PATIENT STATEMENT:

- I have read this Informed Consent Form. The PRK procedure has been explained to me in terms that I understand.
- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with PRK.
- I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that, because PRK is a relatively recent procedure, there may be unforeseen risks.
- I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked.
- I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.
- My decision to undertake in the PRK procedure was made without duress of any kind.
- My decision to participate in the consent process was made without duress of any kind.
- I understand that PRK is an elective procedure, and my myopia, hyperopia, and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery.
- It is hoped that PRK will reduce or possibly eliminate my dependence on glasses and contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.
- I authorize my physicians and other health care personnel involved in performing my refractive procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my PRK procedure that they deem relevant to providing me with care.
- I understand the great importance of keeping all of my required post-procedure visits and I agree to follow up at proper intervals as recommended by my physician. I understand, further, that by not complying with these recommended visits, I might jeopardize the ultimate outcome of my surgery.
- I understand that the decision to have surgery on both eyes at the same time versus one eye at a time is my choice and I have discussed the risks and benefits of these choices with my physician.

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INFORMED CONSENT FOR BILATERAL PRK PROCEDURE

I have consented to have refractive surgery performed on my eyes at Doctors For Visual Freedom. I have discussed and considered the risks and benefits associated with bilateral simultaneous surgery (surgery performed on both eyes on the same day) versus unilateral sequential surgery (surgery performed on one eye at a time on different days). I realize that complications that may occur in one eye could possibly occur in both eyes by having the procedure done simultaneously. I understand that these risks are low statistically but there still is a small possibility that they may occur in either one eye or both eyes.

I understand that if visual recovery is delayed in both eyes, it could prevent or delay my return to work and other normal activities (e.g. driving).

Please answer the following:

1) I consent to have PRK surgery performed on my (choose one) Right eye Left eye Both eyes.

2) I consent to having PRK surgery performed on both eyes on the same day. Yes No

3) I consent to have my surgeon try for Monovision results. Yes No

Patient Name: _____ Date: _____

Patient Signature: _____

Technician Name: _____ Date: _____

Technician Signature _____

Physician Name: Mark Golden, MD

Physician Signature _____ Date: _____

Doctor's Notes:

