

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

This information is to help you make an informed decision about having Photorefractive Keratectomy (PRK) a laser vision correction procedure to treat your nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision about signing this form. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery. Every procedure has risks as well as benefits and each person must evaluate his/her risk/benefit ratio for himself/herself in light of the information that follows. It should be understood that it is impossible to give anyone every piece of information or a complete understanding of the issues that relate to a specific procedure just as it is impossible to convey all information about any complex subject. With this realization, we have attempted to give you the information you need to make an intelligent, informed decision.

Spectacles and contact lenses are the most common method of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are likely to be a good alternative to refractive surgery. Other alternative forms of vision correction are: Ortho Keratology, Radial Keratotomy (RK), Intra Corneal Ring Segments (ICRS), Automated Lamellar Keratoplasty (ALK), Holmium Laser Thermokeratoplasty (LTK), Conductive Keratoplasty (CK), Clear Lensectomy (CLE), Phakic Intraocular Lens implant (PIOL) or Implantable Contact Lens (ICL), and Laser In Situ Keratomileusis (LASIK). Refractive surgery is continually evolving and other procedures may be available as an alternative to PRK.

PRK permanently changes the shape of the cornea. The procedure is performed under a topical anesthetic (drops in the eye). The procedure involves removing the protective layer on the surface of your eye, which is called the epithelium. There are various ways the epithelium can be removed. The ophthalmologist can either remove the epithelium 1) exclusively with the laser, or 2) partially with the laser and wiping the remainder away with a special instrument, or 3) by exclusively wiping with a special instrument, or 4) with a small rotating brush or 5) with alcohol or 6) with the assistance of an instrument called Epi-K. Then a thin layer of corneal tissue is vaporized with an excimer laser. A protective bandage contact lens is inserted for three to five days.

A variation of PRK is Epi-Lasik. Corneal epithelium is separated from cornea via Epi-K that allows it to be rolled back into a thin flap, which can then be repositioned over the cornea following excimer laser.

The result of removing these layers of tissue 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. This changes the focusing power of the cornea. Although the goal of PRK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed.

You should understand that PRK would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment. Also, PRK does not correct the condition known as presbyopia (or aging of the eye) which occurs to most people around age 40 and may require them to wear reading glasses for close-up work. People over 40 that have their nearsightedness or farsightedness corrected may find that they need reading glasses for clear, close vision.

You should be aware that some agencies and organizations that have physical or visual requirements for participation might have or may decide to impose limitations on various physical conditions including having PRK or other refractive surgeries. If there is a particular group that you are either a member of or anticipate the possibility of joining, it is your responsibility to verify the requirements before having such surgery.

Intended Benefits

- ❖ In many cases, PRK results in a person's reduced dependence on glasses and contact lenses.

- ❖ Studies performed at the Bochner Eye Institute show that 98% of patients achieve 20/40 or better distance vision, which is satisfactory for driving without corrective lenses.
- ❖ Some patients may elect to correct their distance vision in one eye while leaving the other eye slightly nearsighted. This technique, called monovision, may allow improved distance vision with one eye and may allow the other eye to be effective for reading, forestalling the effect of presbyopia and the need for reading glasses.
- ❖ There may also be psychological, professional and social benefits for patients who feel that they look better or can function better, without glasses or contact lenses.

Risks, possible complications and Other Considerations...

No vision correction procedure is risk free. Although there have been millions of PRK procedures performed worldwide, this is a relatively new procedure introduced in the early 1990's and there may be some risks, which are unknown at this time.

Discomfort. Many patients experience mild discomfort for a few days following PRK, although patient reactions range from no discomfort at all to moderate pain. Some patients may experience a burning sensation for a few moments when instilling the eye drops in the first two to three days following the procedure. Most patients who have discomfort describe it as the sensation of having grains of sand or an eyelash in their eyes or having a torn contact lens. Some sensitivity to light exists among patients during the period in which the epithelium is healing.

Dry eyes: After almost any type of eye surgery this condition may become worse but usually only slightly and temporary. However, it is possible for it to be a problem for a long time. The symptoms rarely can be very marked, affecting comfort and clarity of vision even with treatment.

Blurry Vision. During the period in which the protective tissue on the surface of the eye, the epithelium, is healing (generally two to four days), vision is blurry for most patients because of the presence of the protective lens and because the healing edges of the epithelium distort the clarity of light rays entering the eye. This condition clears for most people in a week or two as the surface of the eye heals and again becomes smooth. However, complete smoothing of the surface tissue of the treated eye may take as much as six months. During this period, some fluctuation in vision may exist. The healing process is very much individualized and varies from patient to patient.

Reading Difficulty. Most patients will find it difficult to read the first few days following PRK. People with greater levels of correction and those over forty who are experiencing the effects of presbyopia may have greater difficulty reading without the use of corrective lenses for longer periods immediately following the procedure. PRK cannot currently be used to correct this condition, which occurs naturally as one ages.

Undercorrection. There is no guarantee that, for a particular patient, PRK will be successful in providing the desired level of vision correction. The chance of being undercorrected increases in cases where higher grades of nearsightedness are being treated. If the desired level of vision correction is not achieved, corrective lenses may still be necessary for good vision. Corrective lenses may also continue to be necessary for certain activities (such as reading or night driving). In some, but not all cases, undercorrections can be retreated with an enhancement procedure. Retreatment is usually not performed until vision has totally stabilized, typically about six months after the original procedure.

Overcorrection. In some cases, PRK can result in overcorrection. In such circumstances, nearsighted patients will be farsighted, will not be able to clearly distinguish "near" objects and will have difficulty reading. Farsighted patients will be nearsighted and will not be able to clearly distinguish "distant" objects. Corrective lenses may be required. Alternatively, enhancement procedures can be performed to treat overcorrections once vision and refraction have totally stabilized, typically about six months after the original procedure.

Regression In some patients, vision correction deteriorates after the procedure. This complication is more common among patients who are either hyperopic or very nearsighted. In many cases, an enhancement procedure helps to remedy the effect if corneal thickness allows.

Sensitivity. Some patients experience increased sensitivity to any contact with the surface of the eye following PRK. The condition tends to diminish over time, but increased sensitivity could be a concern in some professions.

Corneal Haze. Corneal haze, which in most cases can only be detected by an eye care professional using a microscope, is typical following PRK. Corneal haze, if present, is most noticeable in the period two to four months following the laser procedure. Haze generally has little or no effect on vision and is usually not present after six months. A few patients, however, do experience excessive corneal haze and require treatment. Additional treatments with the excimer laser can generally correct problems of excessive haze; thus haze has rarely caused permanent vision impairment.

Reduced Night Vision/Glare/Halo/Starburst: This 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 has been treated. Typically, 6 months after both eyes have been treated, only 1% of patients still experience significant night glare which seriously interferes with their night driving. Night glare can reduce vision in all reduced lighting conditions producing blurring, ghosting or haloes. Patients with large pupils or severe myopia are at a greater risk for night glare.

Raised Eye Pressure. Increased intraocular pressure can occur in patients who use topical steroid eye drops following the PRK procedure. Typically, intraocular pressure returns to normal, with no long term ill effects, once the use of steroid eye drops has been discontinued. However, if intraocular eye pressure is elevated on a long term basis, permanent loss of vision can result. Since raised intraocular eye pressure is often painless, periodic evaluation by an eye doctor is imperative. Monitoring intraocular pressure is an important part of the follow-up care provided by your eye care professional,

Slow Healing of the Epithelium. The epithelium is removed just before the laser procedure begins. The epithelium usually heals in two to four days, but occasionally, it heals at a slower rate than expected. In such cases, there may be increased pain and risk of infection.

Loss of Best-Corrected Visual Acuity. Some patients can lose the ability to read one to two lines on the eye chart in comparison to their previous best corrected vision. This loss of acuity can occur as a result of microscopic corneal surface irregularities. Loss of acuity can also occur as a result of decentration. One cause of decentration is significant eye movement on the part of the patient when the laser is pulsing. A small amount of eye movement will typically not affect the outcome of the procedure, however.

Inconvenience Between Procedures. In the event that a patient has PRK performed on just one eye at a time, the two eyes may not work well together in the time between the performance of the procedure on the first eye and the performance of the procedure in the second eye. A patient's ability to work and drive may be impaired unless the patient procures a temporary use of corrective lenses. Glasses may not adequately compensate for the difference in refraction between the eyes. Contact lenses are more likely to provide acceptable vision correction in cases of significant differences in the refractive capabilities of one's eyes.

Infection. Is an extremely rare occurrence. However, to help prevent infection, it is critical that you follow the prescribed post operative medication regimen and post operative PRK instructions precisely.

Remote Risks. As with any procedure of this type, there is a remote possibility of severe drug reaction, corneal ectasia, corneal ulcers, or other rare complication which could cause partial loss of vision.

Long Term Effects. Because PhotoRefractive Keratectomy, or PRK, is a relatively new procedure, the long term effects and consequences of the procedure have not been fully determined.

Consent to PRK...

1. I have read this consent form.
2. I have discussed it with my eye doctor and have been given the opportunity to ask questions. All of the questions which I had have been answered to my satisfaction. I understand how PRK is performed and acknowledged its possible risks and complications.
3. I understand that:
 - A. The manufacture and use of the excimer laser for refractive surgery is regulated by the US Food and Drug Administration (FDA) and by Health Canada. Regulation of use of the excimer laser may allow for differing treatment in Canada versus the United States.
 - B. The doctor may use whichever laser is in my best interest.
 - C. PRK is an elective procedure. There is no health or medical reason why I need to have PRK.
 - D. Alternative treatments to PRK, including eyeglasses and contact lenses, are available.
 - E. The results of the PRK procedure cannot always be predicted. The safety and efficacy of PRK cannot be guaranteed. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.
 - F. PRK is not risk free. Complications from the procedure, as described in this consent form, are possible. Retreatments may be necessary, but there is no guarantee that Retreatments will be successful. As with any procedure of this type, there are remote risks, such as partial loss of best-corrected visual acuity.
 - G. Adherence to recommended eye drop regimen and periodic follow-up visits with an eye doctor after the PRK procedure are required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.
 - H. If I have a restriction on my driver's license that indicates I require corrective lenses, it is my responsibility to apply in person to the licensing office to have the restriction removed. I may also be required to undergo a vision test as required by the ministry.
4. I confirm that I am neither pregnant nor a nursing mother and that I will notify my doctor if I become pregnant in the period following PRK treatment. I understand that pregnancy may affect my healing response. I also understand that some medications may pose a risk to an unborn or nursing child.
5. My decision to undergo PRK has been my own and has been made without duress of any kind. I understand that, if at any time prior to my procedure, I decide that I do not want to go forward with PRK, I may withdraw my consent.
6. I authorize the eye doctors involved in performing my PRK procedure and in providing my pre- and post-procedure care to share with one another any medical information relating to my health, my vision, or my PRK procedure, which they deem relevant to providing me with care.
7. I understand that information gathered about my procedure and my post-procedure care may be used to study the PRK procedure. I give permission for my medical records to be released to persons involved in such studies and for my case to be presented at professional or scientific meetings or published journals, as long as I am not identified by name. I also give permission for my PRK procedure to be observed and for the procedure to be photographed by a still camera, movie camera, or videotape, and for these photographs, films, or tapes to be shown at professional, scientific, educational, promotional, or similar meetings or published in journals, as long as my name is not revealed.

8. I agree to accept personal financial responsibility for the payment of all charges and fees related to my PRK procedure, including charges for the procedure itself, for medications I may need, for pre-and post-procedure care, for any eyeglasses or contact lenses required after the procedure, and for the expenses connected with my travel to the Bochner Eye Institute. I understand that, if at any time prior to my procedure I decide that I do not want to go forward with PRK, I may withdraw my consent.
9. I understand the risk in undergoing photorefractive keratectomy, or PRK performed and hereby consent to the procedure and to any pre- or post-procedure care, which my eye doctors deem necessary or advisable.
10. I verify that I will not wear/have not worn gas permeable or hard contact lenses at any time in the three-week period prior to undergoing PRK, and I will not wear/have not worn soft contact lenses at any time in the three-day period prior to undergoing Laser-PRK.
11. I understand that should I need additional PRK vision correction, such an enhancement treatment will be performed by an ophthalmologist of the Bochner Eye Institute. I also understand that I will be required to return to the laser center in which the prior procedure was performed and that expenses for transportation and lodging will be my responsibility.

I hereby agree that the relationship and the resolution of any and all disputes arising therefrom between myself and Dr. Harold Stein, Dr. Albert Cheskes and Dr. Raymond Stein shall be governed by and construed in accordance with the laws of the Province of Ontario.

I hereby acknowledge that the treatment will be performed in the Province of Ontario and that the Courts of the Province of Ontario shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of the treatment. I hereby agree that if I commence any such legal proceedings they will be only in the Province of Ontario, and hereby irrevocably submit to the exclusive jurisdiction of the Courts of the Province of Ontario.

I consent to undergo photorefractive keratectomy (PRK) for correction of (circle one):

- | | | |
|--|--------------------|-----------|
| a) Nearsightedness/ and or astigmatism | Eye being treated: | Right eye |
| b) Farsightedness/ and or astigmatism | (circle one) | Both eyes |
| | | Left eye |

I elect to have PRK performed to create monovision.

- NO
 YES

Patient's Signature: _____ Date _____

Patient's Name: (Print) _____

Witness Signature: _____

Witness Name: (Print) _____

I am a duly licensed eye care professional in good standing. I am knowledgeable about laser eye surgery and its risks and benefits. I have personally discussed the risks with the patient, have given the patient the opportunity to ask questions, and have answered those questions to the best of my ability.

Surgeon's signature: _____ Date _____

Surgeon's Name: (Print) _____