

INFORMED CONSENT FOR LASER IN SITU KERATOMILEUSIS (LASIK)

This information is to help you make an informed decision about having Laser In Situ Keratomileusis (LASIK), 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), Refractive Lens Exchange (RLE), Phakic Intraocular Lens Implant or Implantable Contact Lens (ICL), and Photorefractive Keratectomy (PRK). Refractive surgery is continually evolving and other procedures may be available as an alternative to LASIK.

LASIK permanently changes the shape of the cornea. The procedure is performed under a topical anesthetic (drops in the eye). The procedure involves creating a thin layer of corneal tissue (corneal flap) with a laser called IntraLase® or an instrument called microkeratome. The corneal flap (approximately three human hairs thick) is folded back and then a thin layer of corneal tissue is vaporized with an excimer laser. After the laser treatment, the flap is replaced and bonds back into place without the need for stitches. 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 LASIK 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 LASIK would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment. Also, LASIK 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 LASIK surgery 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, LASIK 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 and Other Considerations

No vision correction procedure is risk free. Although there have been millions of LASIK 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.

To make the flap of the cornea, some risks are associated with that part of the procedure, which are not related to the use of the laser. While these risks are uncommon, complications may occur and include:

- (a) During the process defects on the flap surface (epithelial layer) may be created. These generally respond well to temporary bandage contact lens wear. They may however take several days or weeks to fully heal and could, while active, reduce vision.
- (b) The flap may not heal well after surgery, have loose edges, wrinkles, folds, melting and cause astigmatism, or other effects which could result in decreased vision. In the case of wrinkles and folds, the flap may need to be lifted and smoothed. More than one procedure may be required to correct this. (Incidence 1 in 500)
- (c) The flap may be incomplete, torn, not centered properly or not smooth resulting in the laser surgery procedure being cancelled and rescheduled. (Incidence at the Bochner Eye Institute 1 in 10,000)
- (d) The flap could become separated or displaced, and may need sutures to keep it in place after the laser surgery which may result in misalignment and poor refractive outcome. (Incidence 1 in 20,000)

Possible complications associated with LASIK surgery in general include:

1. **Discomfort:** Many patients experience mild discomfort, tearing and light sensitivity for 24-48 hours following LASIK, 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 some grit or an eyelash in their eyes or having a torn contact lens. Mild, transient light sensitivity following LASIK is quite common. It is possible that a very mild degree will persist for prolonged periods after the procedure. Your eyes may remain slightly more sensitive to light than they were before surgery.
2. **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.
3. **Blurry Vision:** Almost all patients experience blurring immediately following surgery due to microscopic swelling of the flap. With LASIK, there is considerable improvement in vision within the first 24-48 hours. Approximately 80% of the visual recovery occurs within the first several days, with the last 20% of vision improving over 3-6 months. Many patients do experience a profound and dramatic visual improvement and become able to read half or more of the eye chart the next day, but most state it is still not clear and crisp. It may take several weeks before clear, crisp vision is achieved.
4. **Reading Difficulty:** Most patients will find it difficult to read the first few days following LASIK. People with greater levels of correction and those over forty who are experiencing the effects of aging may have

greater difficulty reading without the use of corrective lenses for longer periods immediately following the procedure. LASIK cannot currently be used to correct this condition, which occurs naturally as one ages.

5. **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.
6. **Undercorrection:** There is no guarantee that, for a particular patient LASIK will be successful in providing the desired level of vision correction. The chance of being undercorrected increases in cases where higher grades of nearsightedness or farsightedness 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 most, but not all cases, undercorrections can be retreated with an enhancement procedure. Retreatment is usually not performed until vision and refraction have totally stabilized, typically about three to six months after the original procedure.
7. **Overcorrection:** In some cases, LASIK 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 LASIK procedures can be performed to treat overcorrections once vision and refraction have totally stabilized, typically about three to six months after the original procedure.
8. **Regression:** In some patients, vision correction deteriorates after the procedure. This complication is more common among patients who are either farsighted or very nearsighted. In many cases, an enhancement LASIK procedure helps to remedy the effect if corneal thickness allows.

RARE COMPLICATIONS:

9. **Corneal Haze:** An area of the cornea may become unclear, possibly resulting from the new epithelium growing after surgery or other effects of the laser treatment. This complication is rare with LASIK.
10. **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 LASIK instructions precisely.
11. **Epithelial Ingrowth:** During the first 24 hours, the epithelial protective layer grows to seal the edge of the corneal flap. There is a 1 in 5000 risk that epithelial cells may grow underneath the flap. This is more common in people with weak protective layers, which bond poorly to the eye surface, for which age is a factor. Treatment involves lifting the flap and clearing the cells. Untreated epithelial ingrowth may distort vision and may actually damage the flap if severe and progressive. Small ingrowths do not usually present any visual problems and need only be monitored.
12. **Diffuse Lamellar Keratitis (also known as Sand of Sahara):** The cause is unknown. The incidence at the Bochner Eye Institute is 1 in 10,000. This inflammatory reaction presents haziness in the flap-bed interface that typically shows up 1-3 days after LASIK. In the majority of cases it does not affect the vision and clears up within a few days. The treatment is intensive use of steroid eye drops and occasionally, if severe enough, lifting the flap and irrigating the cornea.
13. **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.

14. **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 following laser vision correction. Mild keratoconus can be corrected by glasses or contact lenses while severe keratoconus may require surgery.
15. **Retinal detachment:** Although retinal detachment, retinal tears and retinal holes are not usually considered a specific complication of LASIK surgery, they are a possibility. It seems conceivable that manipulation and pressure changes in the eye during the procedure could contribute to a retinal problem.
16. **Additional risk factors:** There are a few situations in which your risks of serious complications might be higher. They may include a history of vascular, collagen or autoimmune disease, glaucoma with optic nerve damage, uncontrolled diabetes, keloid, certain medication, cornea disease, a retinal detachment or prior retinal laser treatment.
17. **Remote Risks:** As with any procedure of this type, there is a remote possibility of severe drug reaction, steroid induced glaucoma, corneal ectasia/keratoconus, corneal ulcers, ptosis (droopy eyelids), loss of corneal flap, retinal venous or arterial blockage, or other rare complication, which could cause partial or total loss of vision. Since it is impossible to state every complication that may occur as a result of any surgery, the list of complication in this form is incomplete.

Questions on LASIK informed consent

The following questions cover important information. Please mark the correct answer.

1. TRUE or FALSE: LASIK is the only way to correct your refractive error(s).
2. TRUE or FALSE: It is possible that enhancements may be necessary after LASIK to obtain the best level of vision correction.
3. TRUE or FALSE: After the surgery, follow-up visits are not important.
4. TRUE or FALSE: There are no guarantees as to exactly how well you will see after the procedure.
5. TRUE or FALSE: You may experience vision irregularities such as reduced night vision, double vision, ghosting, halos and glare after your surgery. In addition, you may be more sensitive to light, which in some cases could be permanent.
6. TRUE or FALSE: LASIK will eliminate the need for reading glasses when you are over 40 years of age
7. TRUE or FALSE: You may experience mild to moderate discomfort for several days after the procedure.
8. TRUE or FALSE: There are possibilities that the LASIK procedure could cause loss of vision.
9. TRUE or FALSE: It is very important that you look at the fixating light during the laser treatment.
10. TRUE or FALSE: Your eyes may feel dryer after the procedure and you may need to use lubrication eye drops or punctum plugs after the procedure for several weeks to months. This condition may persist.

Please check your answers with the correct answers below. Mark any that you missed. If you are still unsure why you missed any of these questions, take the form to the doctor or staff member for an explanation.

Answers:

1. FALSE: In addition to glasses and contact lenses, there may be other surgical procedures to treat your refractive error(s).
2. TRUE. Re-treatment may be required to obtain the best level of corrected vision.
3. FALSE: Follow up visits are extremely important to monitor your healing process.
4. TRUE: There are no guarantees as to how well you will see after LASIK.
5. TRUE: Reduced night vision, halos, double vision, ghosting, glare and light sensitivity can be experienced and may not go away completely.
6. FALSE: LASIK does not treat "presbyopia" which occurs to most people above the age of 40 and requires them to wear reading glasses for close work.
7. TRUE: Some patients report mild to moderate pain for a short time after the procedure.
8. TRUE: Some patients have had their vision made worse.
9. TRUE: Not looking at the fixation light during treatment with the Excimer laser could cause poor results.
10. TRUE: This condition may become worse, only slightly and usually temporarily, but it is possible for it to be a problem indefinitely.

Patient Consent to LASIK

1. I have read this consent form.
2. I have been given the opportunity to ask questions. All of the questions I have asked have been answered to my satisfaction. I understand how LASIK is performed. I also acknowledge 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 U.S. Food and Drug Administration (FDA) and by Health Canada. (For U.S. and international patients: Regulation of the 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) LASIK is an elective procedure. There is no health or medical reason why I need to have LASIK.
 - (d) Alternative treatments to LASIK, including eyeglasses and contact lenses, are available.
 - (e) The results of the LASIK procedure cannot always be predicted. The safety and efficacy of LASIK cannot be guaranteed. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.
 - (f) LASIK is not risk free. Complications from the procedure, as described in this consent form, are possible. Re-treatment may be necessary, but there is no guarantee that re-treatment 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 LASIK are required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.
 - (h) I understand that 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 LASIK treatment so he/she may modify my 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 LASIK has been my own and has not been made under duress of any kind.

6. I authorize the eye doctors involved in performing my LASIK 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 LASIK 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 LASIK 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 LASIK 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 and identity is not revealed.

8. I agree to accept personal financial responsibility for the payment of all charges and fees related to my LASIK 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 before my procedure I decide that I do not want to go forward with LASIK, I may withdraw my consent.

9. I understand the risk of undergoing laser in situ keratomileusis (LASIK) and hereby consent to the procedure and to any pre- or post-procedure care, which my eye doctors deem necessary or advisable.

10. I understand that, if recommended by the surgeon or doctor, I may be required to wear a protective contact lens during the initial 2-4 day period in which my eye is healing.

11. I understand that should I need additional LASIK 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 LASIK for correction of (circle one):

- a) Nearsightedness/ and or astigmatism
- b) Farsightedness/ and or astigmatism

Eye being treated: Right eye
(circle one) Both eyes
Left eye

I elect to have LASIK performed to create monovision.

NO

YES

Change of laser procedure:

In the unlikely event that there is a medical reason LASIK cannot be performed (e.g., the suction ring cannot be applied securely), I give my permission for the surgeon after discussing with me, to perform PRK, which is a similar surgical procedure performed with the Excimer laser but without the corneal flap.

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 in situ keratomileusis (LASIK) 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)_____