CONSENT FORM

Excimer Laser PRK and iLASIK for Myopia, Hyperopia and Astigmatism Using Wavefront-Guided Laser Vision Correction

University of Ottawa Eye Institute
The Ottawa Hospital – General Campus

INTRODUCTION

Excimer Laser Vision Correction is a widely used procedure to correct myopia (nearsightedness), hyperopia (farsightedness), and astigmatism by reshaping the surface of the eye (cornea).

PRK (Photorefractive Keratectomy) is an Advanced Surface Ablation procedure that involves the removal of the epithelial layer of the cornea. The Excimer laser is then used to correct the prescription by reshaping the corneal tissue.

iLASIK (Intralase® enabled Laser Assisted In-Situ Keratomileusis) is a procedure where the epithelial layer of the cornea is not removed. In iLASIK, an extremely precise surgical instrument called a femtosecond laser (Intralase FS™) is used to create a thin flap from the surface of the cornea. The corneal flap is 100-140 microns thick, which is approximately the thickness of two hairs while the entire cornea is normally the thickness of about seven hairs. To correct the prescription, the Excimer laser is then used to reshape the corneal tissue under the flap instead of just under the corneal epithelium as with PRK. In iLASIK, the corneal flap is always replaced following the Excimer laser procedure.

Wavefront-Guided Laser Vision Correction involves measuring your vision with a device called the WaveScan WaveFront™ System, and then treating your visual or optical errors, also called wavefront errors, with the VISX STAR S4™ IR Excimer Laser using the latest software. Wavefront errors are a combination of your prescription (refractive error) and other irregularities (called irregular astigmatism or higher order aberrations). The WaveScan uses a special sensor to measure your wavefront errors. The term 'wavefront' refers to a map of the optical defects that is measured by passing rays of light through the eye. The WaveScan measurements are then used to direct the laser during a custom treatment designed just for your eye. This procedure is intended to reduce or eliminate the need for glasses or contact lenses, and may improve your vision beyond what is anticipated with standard laser treatment.

ELIGIBILITY

Patients who are 21 years or older, who are nearsighted or farsighted (with or without astigmatism) in one or both eyes, and who will be available for follow-up, may be eligible for Excimer Laser Vision Correction. A thorough eye examination is also needed to determine your eligibility.

Excluded will be anyone with residual, recurrent, or active eye disease(s) or abnormal condition(s), which we consider likely to affect wound healing capacity.

Female patients should not be pregnant or breastfeeding at the time of treatment and for three months following treatment. The hormones related to pregnancy and breastfeeding can affect vision and possibly lead to an incorrect treatment. .

Wearing contact lenses can change the shape of your eye. If you wear soft contact lenses, you must not wear them for at least one week prior to the baseline (pre-operative) examination. If you wear hard contact lenses, you must not wear them for at least four weeks prior to the baseline examination. You must also not wear contact lenses between the baseline examination and surgery.

TREATMENT

The eye being treated will receive anesthetic eye drops and there should be little or no discomfort during this procedure. As patients often experience mild discomfort following treatment (PRK and occasionally iLASIK), appropriate pain relieving medication may be prescribed. It is important that you inform us of any allergies or intolerance you have to pain relieving medications including Tylenol with Codeine (#3).

PRK (Photorefractive keratectomy) is a procedure that involves the removal of the epithelium from the surface of the cornea using: 1) Excimer laser, 2) manual scraping, or 3) epithelial brush. Then, the Excimer laser is used to correct the prescription by reshaping the exposed underlying corneal tissue.

iLASIK (Laser Assisted In-Situ Keratomileusis) involves a suction ring that is attached to the eye securing it for the femtosecond laser which is used to create the corneal flap. When the suction is applied, the vision will appear dark. The femtosecond laser creates a thin flap in the outer layers of the cornea. You cannot see or feel the flap. The instrument will stop automatically, leaving a hinge. After the suction is turned off and the instrument is removed, the surgeon will carefully lift the attached flap out of the way, exposing the underlying cornea to be treated using the Excimer laser. The hinged flap is replaced following the Excimer laser surgery. The flap is held in position through an almost immediate suction-type action within the cornea and by the protective epithelial layer, which rapidly envelops the surface within days.

During the Excimer laser surgery, you will be lying on your back, focusing on a blinking red light from the laser. A small device will be used to keep your lids wide open during the surgery. The surgeon will control treatment pulses with a footswitch. Because of the laser energy, you may see a flash of light and hear a 'ticking' sound and may notice an ozone smell during the procedure. The laser will remove a minute amount of tissue and reshape your cornea. Most people state that they do not feel any pain during the laser procedure, but rather a slight pressure around the eye and a smell of ozone. Following the procedure, the doctor will put additional medication in your eye(s) to prevent infection.

Mild sedation is given orally prior to surgery. If you receive sedation before surgery, you must be accompanied by someone over the age of 18 when you leave and you should not drive or operate machinery for 24 to 48 hours.

PERIODIC TESTS AND FOLLOW-UP

It is essential that a medical examination of your eye occurs immediately post-operatively (iLASIK only) and every 24 hours for the first 1-6 days until your eye is healed. Because of the need to monitor your progress during and after the surgery, you will be required to undergo certain tests on a regular basis, at 1 week, 1, 2, 3, 6, and 12 months following surgery. These include vision examinations, and numerous ophthalmologic measurements at our clinic. Standard eye tests include measurements of visual performance, wavefront analysis using the WaveScan system, pachymetry (cornea thickness) and corneal mapping using topography. During both WaveScan and topography measurements, you will be asked to look at a coloured target light inside the device. Each measurement takes only a few seconds and your eyes may be measured several times.

If it is determined by one of the University of Ottawa Eye Institute Excimer Laser Clinic physicians that a retreatment is necessary and there has been a failure to attend the regularly scheduled follow-up visits, as set out above, you acknowledge the forfeit of any potential special pricing.

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BENEFITS

The possible benefits of Wavefront-guided Laser Vision Correction may include the reduction or elimination of dependence on glasses or contact lenses.

RISKS AND COMPLICATIONS

The safety and effectiveness of Wavefront-guided Laser Vision Correction has been determined for up to -12.0 diopters of myopia (nearsightedness) and up to +6.0 diopters of hyperopia (farsightedness), both with up to +6.0 diopters of astigmatism. However unexpected complications or side effects may occur. As with any surgery or investigational procedure, all potential risks cannot be identified.

Your laser vision correction may be of little or no benefit and may be harmful, particularly if the healing of your cornea proceeds with less than usual effectiveness. There is a small possibility that this laser surgery may, in fact, make your vision worse. It is critical that you follow treatment instructions carefully.

The refractive correction by the Excimer laser may not be completely accurate or adequate, and additional correction to obtain proper vision may require glasses or contact lenses. Re-treatment may be required if an acceptable result is not obtained from the first treatment. In a small percentage of cases re-treatment with the Excimer laser is not possible.

Complications and side effects associated with the Excimer laser surgery in general may include:

Corneal haze: An area of the cornea, which may not be totally clear, resulting from a healing reaction after the surgery.

Night glare: This is common in nearsighted individuals even before any refractive procedure is performed, but increases almost immediately during the healing process and is more common when only one eye has been treated. Typically, 6 months after both eyes have been treated, only 2% of patients still experience significant night glare which seriously interferes with their night driving. Severe night glare can reduce vision in all reduced lighting conditions producing blurring, ghosting or haloes. Patients with large pupils and severe myopia are at the greatest risk for night glare. Modifications to the laser treatments have reduced the incidence of these symptoms.

Blurring: Almost all patients describe blurring immediately following surgery. With the PRK procedure approximately 80% of the visual recovery occurs within the first seven days, with the last 20% of vision improving over 3-6 months. With iLASIK approximately 80% of the visual recovery occurs within the first 48 hours, with the last 20% of vision improving over the next week to couple of months.

Under/Over Correction: It is possible that the procedure could result in under correction, and it may be necessary to have a second procedure. Over correction may also occur which may or may not require the continued wear of corrective lenses, or a second procedure. It is possible that the altered correction may increase dependence on reading glasses or may require the use of reading glasses depending on the age of the patient.

Regression: In some patients, the vision correction effects of the procedure diminish several months after the procedure. This complication is more common in patients who are very nearsighted. In some but not all cases of significant regression, another surgery (PRK or iLASIK) may help to remedy this effect.

Presbyopia: Patients with presbyopia or who are approaching presbyopia (the need for reading glasses, prevalent over 40 years of age) must understand that current laser vision correction techniques do not treat this age-related process.

Re-epithelialization: Prolonged use of a contact lens or patch may be required if re-epithelialization of the cornea is delayed. (Not applicable for iLASIK)

Dry Eyes: In some patients, especially those that have worn contact lenses for years or previously have had dry eyes, decreased tears and a dry eye sensation may follow the procedure. This usually resolves over 6-12 months but some patients may require long-term use of artificial tears or some other form of treatment, such as punctal plugs or prescribed eye drops.

Remote risks: These include repeated breakdown of corneal tissue, damage to the cornea, corneal perforation, corneal infection and ulcer, corneal epithelial defect, corneal swelling, corneal neuropathy (long-term sensation of pain), detachment of retina, increased pressure in your eye, inflammation inside the eye, hemorrhage (bleeding inside the eye), venous and arterial blockage or cataract formation. Although these complications are rare, if significant reduction in vision is produced because of the complications, you may require a corneal transplant or some other intervention at some time in the future.

Complications and side effects associated with the creation of a flap:

iLASIK:
The use of the femtosecond laser to cut through corneal tissue to create a flap is associated with risks, which are not related to the use of the Excimer laser. While these risks are uncommon, complications may occur and include:

- The flap may be incomplete or not be centered properly, resulting in the laser surgery being cancelled and rescheduled.

- 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 a poor refractive outcome.
- The surface epithelium may be loose and a corneal erosion could result from manipulation of the flap. A contact lens or patching may be required for healing.
- The flap may not heal well after surgery, and may have loose edges, wrinkles, folds, or melting may occur and cause astigmatism or other effects that could result in a decrease in vision.
- Cells can grow under the flap, or foreign bodies can be present, which may require re-lifting of the flap, and removal of the tissue. Additional procedures may be required to correct this.
- Infection – in order to help prevent this, we caution you not to rub your eyes, not to wear makeup or swim for 7 days following your procedure.
- Inflammation, also known as diffuse lamellar keratitis, can occur within the first few weeks of the procedure requiring frequent drops or lifting of the flap with irrigation.
- Most patients will develop sub-conjunctival hemorrhages or 'bruising' as a result of the suction ring used in the creation of the corneal flap. These gradually fade and resolve within 2-3 weeks but some may persist longer. No treatment is required for these.
- Some patients may have glare and haloes for a few days or weeks following iLASIK surgery. In rare cases it may persist.
- A few weeks following the surgery, some patients may experience a transient light sensitivity.
- There may be some risks that are unknown at this time.

ALTERNATIVE TREATMENTS

You are free to decide not to have this surgery. If you decide not to have this surgery, there are conventional methods of correcting your vision (either with or without surgery) including glasses, contact lenses, standard non-Wavefront-guided PRK or iLASIK, or a refractive intraocular lens.

FINANCIAL RESPONSIBILITY

You are financially responsible for all physicians' fees, laboratory costs and other procedures required for your treatment and follow-up. These costs are not covered by OHIP but may or may not be covered by your own medical insurance. The costs of treatment for complications related to the laser eye surgery must be met by you if they are not met by your health coverage liability.

The fee for Excimer Laser Vision Correction at the University of Ottawa Eye Institute **must be paid prior** to the surgery.

COMPENSATION

In the event of treatment-related side effects or injury, you will be provided with appropriate medical treatment. You are not waiving your legal rights by agreeing to undergo Excimer Laser Vision Correction.

WITHDRAWAL

You are free to not receive Excimer Laser Vision Correction at any time prior to the surgery and this withdrawal will not jeopardize or prevent your continued medical care by us now or in the future. If you wish to withdraw you must notify us so that we may make alternative plans for your continuing medical care.

POTENTIAL CONFLICT OF INTEREST

Dr. Jackson is a consultant to Abbott Medical Optics, Inc. on hardware and software Excimer laser development, and from time to time receives some travel expenses so that he may present at meetings. All financial support is used to support the Excimer Research Program at the Ottawa Eye Institute.

PARTICULARS PERSONAL TO ME

The following are details you have told us of any medical or physical conditions or particulars, including any known allergies or intolerance that you may have to medications, any other treatments that you have undergone, medications that you are taking and other medical or physical conditions, which may be relevant:

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DATED this _____day of _____ 20___. _____

Signature of Surgeon

VOLUNTARY CONSENT

1. **I certify that I have read this consent form, that I understand its contents and that any questions I have pertaining to it or to the proposed procedure have been answered to my satisfaction by my surgeon. My permission is freely given.**

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Initial

2. I understand that:
   - My eyes will be measured several times with the WaveScan.
   - My laser treatment will be based on one of the WaveScan measurements.
   - Wavefront-guided PRK/iLASIK is an elective procedure. There is no health or medical reason why I need to have Wavefront-guided PRK/iLASIK performed.
   - Alternate treatments to WaveScan-guided PRK/iLASIK, including traditional PRK/iLASIK, or eyeglasses and contact lenses, are available.
   - The results of the Wavefront-guided PRK/iLASIK procedure cannot always be predicted. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.
   - Wavefront-guided PRK/iLASIK 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.
   - Adherence to the recommended eye drop regime and periodic follow-up visits with an eye doctor after the PRK/iLASIK procedure is required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.

3. I confirm that I am neither pregnant nor a nursing mother. 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

4. My decision to undergo Wavefront-guided PRK/iLASIK 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 Wavefront-guided PRK/iLASIK, I may withdraw my consent.

5. I authorize the eye doctors involved in performing my WaveScan-guided PRK/iLASIK 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 Wavefront-guided PRK/iLASIK procedure, which they deem relevant to providing me with care.

6. I understand that information gathered about my procedure and my post-procedure care may be used to study the Wavefront-guided PRK/iLASIK 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 in

journals, as long as I am not identifiable. I also give permission for my Wavefront-guided PRK/iLASIK procedure to be observed and for my eye(s) to be photographed by 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 I am not identifiable.

7. I agree to accept personal financial responsibility for the payment of all charges and fees related to my Wavefront-guided PRK/iLASIK 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 Eye Institute.

8. I understand the risk in undergoing PRK/iLASIK. I wish to have Wavefront-guided PRK/iLASIK performed and hereby consent to the procedure and to any pre or post procedure care, which my eye doctors deem necessary or advisable.

9. I understand that should I need additional laser vision correction; this enhancement treatment will be performed by an ophthalmologist of the University of Ottawa Eye Institute. This enhancement treatment will only be performed at no cost up to 2 years from the date of the initial surgery, after that, a fee will apply. 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.

10. I certify that alternative conventional surgical procedures have been explained to me and that I have rejected them.

11. I have been offered a copy of the consent for my own possession.

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Patient's Name (Print)

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Date

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Patient's Signature

I was present at the explanation referred to above as well as the patient's opportunity for questions to be acceptably answered. I believe that the patient appeared to understand the risks and benefits of the excimer laser treatment and to understand the available alternative treatments. I hereby witness his/her consent to the procedure.

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Witness' Name (Print)

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Date

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Witness' Signature