



INFORMED CONSENT - LASER VISION CORRECTION

PROCEDURE:

Custom All Laser LASIK is one type of surgery used to correct refractive errors, which impact your ability to see without glasses or contact lenses. Your blurry vision is caused by a mismatch between the shape of your cornea and the length of your eye. The cornea is a part of the eye that helps focus light to create an image on the retina. It works in much the same way that the lens of a camera focuses light to create an image on film. The bending and focusing of light is also known as refraction. Usually the shape of the cornea and the eye are not perfect and the image on the retina is out-of-focus (blurred) or distorted. These imperfections in the focusing power of the eye are called refractive errors.

There are four primary types of refractive errors: myopia, hyperopia, astigmatism, and presbyopia. Persons with myopia, or nearsightedness, have more difficulty seeing distant objects as clearly as near objects. Persons with hyperopia, or farsightedness, have more difficulty seeing near objects as clearly as distant objects. Astigmatism is a distortion of the image on the retina caused by irregularities in the cornea or lens of the eye. Combinations of myopia and astigmatism or hyperopia and astigmatism are common. Presbyopia is a condition that occurs generally in your 40's where the eye muscles lose their ability to focus on close objects. Glasses or contact lenses are designed to compensate for the eye's imperfections. Surgical procedures aimed at improving the focusing power of the eye are called refractive surgery.

In LASIK surgery, precise and controlled removal of corneal tissue by a special laser reshapes the cornea, changing its focusing power. This can correct for your nearsightedness, farsightedness, or astigmatism.

Custom All Laser LASIK consists of two steps. In step one, your surgeon will create an ultra-thin flap in the cornea by using computer controlled laser pulses, which pass through the top layers of the cornea, to form microscopic bubbles at specific locations beneath the corneal surface. These bubbles then gently separate the outer layer of the cornea, referred to as the corneal flap, from the inner layer that requires reshaping. The inner layer is called the stromal bed. Once the corneal flap is made, the surgeon will gently lift the flap back and perform step two, which is to apply laser pulses to the stromal bed to re-shape these inner layers of the cornea. The reshaping portion of the surgery usually takes less than a minute. Once complete, the surgeon will fold the flap back into its normal position on the cornea, and smooth the flap.

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RISKS:

Custom All Laser LASIK is able to correct a range of prescriptions, but we do not want you to feel we are making the procedure sound too easy, or simple, or that the procedure is perfect, or guaranteed. No surgery can be guaranteed to be 100% successful. As with any procedure, there is the risk of complications. The possible complications you may suffer include: (1) problems during the surgery, (2) problems during the first three months after surgery, and/or (3) problems more than three months after the surgery.

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Possible Problems during the Surgery:

Corneal Flap Complications: Any corneal flap that is not of good quality results in the LASIK procedure being stopped, without any laser prescription treatment being performed. The surgeon in these cases will fold the flap tissue back on the eye, allowing it to heal for several weeks or months. In addition, irregular healing of the flap may occur and could result in a distorted cornea, and glasses or soft contact lenses may not correct your vision to its previous level before LASIK.

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Laser Reshaping in the Wrong Location: Although Custom All Laser Lasik is performed with advanced eye tracking systems, it is possible that the laser treatment pattern may not be centered correctly on the pupil and visual axis. Such decentration typically results in night glare symptoms, and induced astigmatism, often reducing the patient's quality of vision.

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Possible Problems During the First Three Months After the Surgery:

Foreign Body Sensation, Glare, Haziness of Vision, and Bruising: It is very common for patients to experience pain or a foreign body sensation, particularly during the first few hours following LASIK, but occasionally this may last for 2-3 days. Some patients may also experience increased sensitivity to light, or vision fluctuations, or haziness of their vision. These conditions may persist during the normal stabilization period of 1 to 3 months, but in rare cases, may be permanent. Patients may also note some red blotches, or bruising on the whites of their eyes for 2-3 weeks.

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Infections: Mild or severe infection is possible. Mild infection can usually be treated with topical antibiotics, and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring of the cornea and blurred vision. Very severe cases may result in the need for a corneal transplant, or result in the loss of the eye.**Initial** ____

Diffuse Lamellar Keratitis: Diffuse Lamellar Keratitis, or DLK (also known as "sands"), is a type of allergic reaction, which occurs at the layer of the cornea where the laser correction was performed. It usually

occurs within the first few days following LASIK, with patients complaining of glare and blurred vision, but no pain or discharge. Topical steroid drops are often used to reduce the inflammation, but if unresponsive, the corneal flap is lifted and the corneal layer is cleaned.

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Corneal Flap Striae (Wrinkles): The corneal flap is usually hinged at the top, beneath the upper eyelid, and any injury, even a minor one, during the first few days following surgery can displace it. Even a patient squeezing their eyes very tightly can occasionally move the corneal flap and produce wrinkles. If wrinkles do occur, treatment usually involves the surgeon lifting the flap and smoothing it back into alignment, sometimes sutures may be required to smooth the cornea.

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Epithelial Ingrowth: Epithelial Ingrowth is a condition where the cells on the surface of the eye, known as the epithelium, start to grow beneath the flap after the surgery. This condition may require that the corneal flap be lifted, and the area be cleaned if significant. Usually, there is no long term risk associated if managed early. If left untreated, however, the corneal flap can be damaged permanently and impair your vision.

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Reading Vision, Vision Aids, Muscles Imbalance: While healing occurs, temporary glasses may be required, either for distance, or for near vision. It is possible that dependence on reading glasses may increase, or that reading glasses may be required at an earlier age. If the procedure is performed on only one eye, balance problems between the two eyes may occur after surgery. This may cause eyestrain and make judging distance, or depth perception, more difficult.

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Possible Problems More than Three Months After the Surgery:

Refractive Error Not Treated Completely: Not every patient treated achieves 20/20 vision, primarily due to differences in the way people heal. Some patients find it necessary to wear glasses after the surgery. While this can be treated with an additional laser application, the ideal time for the second procedure is between 3 and 6 months after the first procedure. **Irregular Astigmatism:** Irregular Astigmatism following LASIK is the term used to describe corneal irregularity that is not correctable with glasses. When the cornea has a significant degree of irregular astigmatism, there is a loss of sharpness, crispness and clarity. In these cases, a gas permeable contact lens is needed in order to restore vision.

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Corneal Ectasia: One of the most serious complications is the development of corneal ectasia. This occurs when there is a loss of corneal stability or strength, resulting in thinning and bulging of the cornea. This is believed to usually be caused by a genetic condition known as Keratoconus that was

undetected and accelerated by LASIK. If a patient develops Corneal Ectasia, they may need to wear a gas permeable contact lens to correct vision, have collagen crosslinking or may even require a corneal transplant.

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Dry Eye: A common complaint following LASIK surgery is the increased risk of eye irritation related to drying of the corneal surface, known as “dry eye”. These symptoms may be temporary, lasting 1-6 months, or, on rare occasions, permanent, and may require frequent use of artificial tears or ointment, prescription medication, or other dry eye treatment methods. Although Dry Eye sounds rather innocuous, it can be quite debilitating, affecting both vision and comfort, and patients with significant dry eye symptoms prior to surgery should avoid having LASIK.

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Night Glare and other Night Visual Disturbances: Immediately after refractive surgery, most patients experience night glare around headlights or other similar situations, usually described as “starbursting” or a “halo” effect around lights. Others may simply experience a general reduction in the sharpness of their vision under low-light situations, affecting their general ability to drive at night, or see well in dim light. This is usually a temporary condition that improves over 3-6 months. Patients with very high prescriptions and pre-operative night vision difficulties are at greatest risk for decreased night vision.

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Recurrent Corneal Erosions: Recurrent corneal erosion is the repeated breakdown of the epithelium in a localized area. It can be related to trauma or a genetic weakness of the “cement” which binds the epithelium to the corneal surface. In patients with a genetic corneal weakness known as an epithelial dystrophy, the LASIK procedure can result in a large corneal abrasion with significant pain, and slow visual healing. This is often treated using a contact lens, which acts as a bandage, and eye drops, to reduce discomfort and risk of infection.

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ALTERNATIVE TREATMENTS

Custom All Laser LASIK is an elective procedure. It is not medically necessary for you to undergo this procedure in order for you to see. You may continue to wear glasses or contact lenses and forgo surgery altogether. Alternatively, you also might be able to have a different surgical procedure such as PRK, LASEK, or RK.

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PRESBYOPIA

When we are young, the lens inside of our eye is extremely flexible, and allows us to focus easily on close objects. Over time, the lens gradually loses its flexibility, which makes it more difficult to focus on

close objects. This condition is called presbyopia, and it is a normal part of the aging process that happens to everyone, even those who have never had a vision problem before. As the condition progresses, most patients begin to hold things farther away, and require brighter light to see them clearly. At this stage, most patients will require reading glasses, bifocals, or a progressive multifocal, to help focus objects that are close. Keep in mind, though, that if you need reading glasses now, you will need them after refractive surgery, unless you and your physician discuss other options in advance.

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Monovision is another option to aid reading vision and manage Presbyopia, and involves leaving one eye still slightly nearsighted after surgery. The goal of Monovision treatment is to allow one eye to focus for distance, and the other eye to focus for reading. Patients may feel less balanced unless they have used Monovision contact lenses in the past, and they definitely will notice that their monovision eye is blurry for distance.

Monovision will not eliminate the need for reading glasses for all near tasks in all lighting conditions, but may greatly reduce your dependence on them.

You may notice an increase in night vision disturbances with the Monovision eye. The majority of patients do not notice this when using both eyes together.

(Please circle the appropriate term) **DISTANCE VISION OR MONOVISION**

TREATMENT OF ONE OR BOTH EYES

Today, the vast majority of all refractive surgeries are performed on both eyes on the same day. Many patients prefer having both eyes done at once as it is more convenient. Further, operating on both eyes means that you avoid having an imbalance between the corrected eye and the uncorrected eye, making it far easier to drive. Many patients note improved depth perception, and faster resolution of night glare. Naturally, there are definite risks with having surgery performed on both eyes on the same day. There may be unrecognized surgical or healing complications, for example. Whether you choose to have the surgery on both eyes on the same day, or on separate days, visual recovery from laser vision correction may be as brief as one day, or take several weeks or longer, depending on your healing pattern and the development of any unforeseen problems.

I ELECT TO HAVE:

(Please circle the appropriate term)

BOTH EYES TREATED ON THE SAME DAY OR ONE EYE TREATED PER DAY

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I CONFIRM THAT EACH OF THE FOLLOWING STATEMENTS IS TRUE AND ACCURATE:

I understand that Custom All Laser LASIK is an elective procedure. There are alternatives to these surgeries. I could continue wearing contact lenses or glasses and have adequate visual acuity. I also could choose a different type of refractive surgery.

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I have received no guarantee of a successful outcome of my particular surgery. I understand the possible short- and long-term risks associated with Custom All Laser LASIK, and that there may be risks that are unknown at this time.

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I understand that the correction that I can expect to gain from Custom All Laser LASIK 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 that I may need glasses to refine my vision for some tasks requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

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I understand that if I currently need reading glasses I will still need reading glasses after this treatment. 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. I understand that if I am over 40 years of age and have both eyes corrected for clear distance vision, I will need reading glasses for many close tasks.

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I verify that I am at least 18 years of age that I am not pregnant or nursing, and that I must abstain from using any contact lens prior to my LASIK procedure, as directed by my eye surgeon.

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I confirm that I have disclosed my eye and general health history, including medications and allergies, to my eye doctor and eye surgeon. I confirm that I have told my eye doctor and eye surgeon if I have or have had any of the following eye conditions: glaucoma, cataracts, keratoconus, retinal or optic nerve disease, herpes simplex or herpes zoster (shingles) of the eye, lazy eye, strabismus (muscle imbalance), or prior refractive surgery.

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LEGAL RESPONSIBILITIES AND DISCLOSURES:

CONFIDENTIALITY

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Clarity Refractive Centre and its affiliates, the Excimer laser manufacturer and the governmental regulatory authorities. The data will be utilized for statistical analysis, record keeping, marketing, and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

GOVERNING LAW/JURISDICTION

By initialing below, you agree that the relationship and resolution of any and all disputes between yourself, the surgeon and the Clarity Refractive Centre shall be governed by and construed in accordance with the laws of the Province of Ontario. You also acknowledge with your initials that the procedure was 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 treatment. You hereby agree that you will commence any such legal proceedings in the Province of Ontario and you irrevocably submit to the exclusive jurisdiction of the Province of Ontario.

Initials_____

Please write in the box with your own handwriting the following statement to confirm that you have understood and accept that laser vision correction is an elective surgical procedure and as with all surgical procedures, the result cannot be guaranteed.

“I have read and understand the above. There are risks and no guarantees and I may still need to wear glasses.”

I give the below named surgeon permission to perform Custom All Laser LASIK on me in accordance with my instructions above.

PATIENT NAME (Please print): _____

PATIENT SIGNATURE: _____ **DATE:** _____

WITNESS NAME: _____

WITNESS SIGNATURE: _____ **DATE:** _____

SURGEON NAME: _____

SURGEON SIGNATURE: _____ **DATE:** _____