

Informed Consent Lasik and PRK Surgery

Please read this consent form carefully and initial and sign where indicated.
Please do not sign any section that you have not read or do not understand.

Section 1. General Information

It is our hope to fully inform you concerning the side effects, limitations and complications of Excimer laser surgery. We continually strive to balance the benefits of the laser surgery with the known and unknown risks. It is important to understand that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent form in combination with the extensive educational materials provided and the entire consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both the procedure and the healing process.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential complications. It is not our intention to frighten or dissuade someone from pursuing laser surgery, as most of our patients will never encounter any serious complications, and the vast majorities are thrilled with the improvement they achieve. It is our intention to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated or be better prepared to deal with any unexpected complication or side effects which may arise. LASIK AND PRK are purely elective procedures and you may decide not to have this operation at all. The only way to avoid all surgical risk is by not proceeding with the surgery.

I have read and understand the information in Section 1.

Patient Initials: _____

Section 2: Laser Vision Correction Background Summary:

Laser in situ Keratomileusis (LASIK) and Photorefractive Keratectomy (PRK), forms of laser vision correction, reshape the part of the eye known as the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of Myopia (nearsightedness), Hyperopia (Farsightedness), or Astigmatism (oval-ness). There are two primary techniques for reshaping the cornea with laser surgery, PRK and LASIK. Both procedures are able to treat myopia, hyperopia, and astigmatism but have benefits, limitations and risks. In both forms of laser vision correction, the transparent cornea at the front of the eye is reshaped with your prescription. PRK reshapes the surface layers of the cornea while LASIK fine-tunes the inner corneal layers with the Excimer laser. The Excimer laser produces a cool beam of ultraviolet light energy, capable of removing very precise amounts of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision. The LASIK procedure is a newer more advanced form of keratomileusis, a procedure that has been practiced in South America and Europe for over 30 years.

Both PRK and LASIK are performed on an outpatient basis and take only 15 - 20 minutes to complete. Although patients often feel some pressure sensation, both procedures are generally painless. In both the PRK and LASIK procedures, topical anesthetic drops are used to thoroughly numb the eye and an eyelid holder is used to prevent blinking. The patient focuses on a red target light throughout both procedures. In the PRK procedure, the surgeon first removes the corneal epithelium or protective



surface layer of the cornea. The Excimer Laser then applies computer-controlled pulses of light energy to the corneal surface to reshape the eye. A bandage contact lens is typically inserted or the surgeon may patch the eye closed following PRK for a few days. The epithelium grows back over 3-4 days and the vision gradually improves once the protective layer is healed.

In the LASIK procedure, a protective corneal flap is created using a very sophisticated surgical instrument known as the Intralase femtosecond laser. A small ring like device holds the eye in position while the Intralase femtosecond laser creates the corneal flap. The Intralase utilizes a beam of light to create many tiny gas bubbles in the Stroma (inner layer of the cornea), the bubbles expand and separates the layers of tissue gently and without a blade or knife. Patients are unable to see the corneal flap being made as the vision becomes gray when the suction is applied and the red target light dims as the flap is completed. Most patients sense some pressure, but the laser flap creation is completely painless. The surgeon then lifts the flap and the VISX laser pulses are completed, the corneal flap is replaced and the natural suction within the cornea seals the corneal flap within 1-5 minutes. No sutures are needed as the flap seals rapidly. A clear protective eye shield is used after surgery. Although the vision is blurry immediately, patients are able to blink normally and there is rapid overnight visual improvement.

In PRK, the removal of the surface protective layer increases the risk of pain, infection and corneal scarring or haze. The creation of the corneal flap with LASIK allows the protective layer to be preserved and provides for a more rapid and comfortable visual recovery. The surface corneal layers are more sensitive than the inner corneal layers treated with LASIK; therefore healing time is reduced compared to PRK. The intra-operative risks with LASIK however may be greater than PRK, primarily because of possible complications with the creation of the protective corneal flap with the Intralase. For patients with higher degrees of Myopia, Hyperopia and Astigmatism where more healing complications are encountered, or for patients who desire a more rapid visual recovery, LASIK may be the treatment of choice if the patient qualifies.

I have read and understand the information in Section 2.

Patient Initials: _____

Section 3. PRK/ LASIK Indications, Contraindications and Peri-Operative Care

PRK or LASIK is indicated for the treatment of Myopia (nearsightedness), Hyperopia (farsightedness), and Astigmatism (irregular curvature of the cornea).

Candidates should be over 18 years of age, though some exceptions may apply.

Candidates must have a stable refraction with no more than 0.50 diopter change within the previous year as the procedure will not change the natural growth or aging of the eye.

Candidates must be aware that this is an elective procedure and that there are alternative forms of vision including glasses, and or contact lenses.

Candidates must be free of certain eye diseases including keratoconus, cataracts, uncontrolled glaucoma, and certain retinal and optic nerve diseases.

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Candidates must be free of certain eye viruses including herpes simplex and herpes zoster. *** IF YOU ROUTINELY HAVE HERPES BREAKOUTS i.e. cold sores, shingles, etc. YOU MUST BE ON ORAL ANTIVIRAL MEDICATIONS PRIOR TO SURGERY.***

Candidates must make their surgeon aware of certain eye problems including amblyopia (lazy eye), strabismus (muscle imbalance), severe dry eyes, or any recurrent, residual or active eye condition, which may affect healing.

Candidates must be free of certain health problems including uncontrolled diabetes, autoimmune or collagen vascular disease, any medication or condition which renders the patient immunocompromised.

Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgical healing, back problems, claustrophobia or psychological problems, which may affect the surgery or recovery.

Candidates must make their surgeon aware of any implants including a cardiac pacemaker, insulin implant or other electronic implanted device.

Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid potential drug interactions and allergic reactions.

The FDA considers pregnancy and nursing contraindications, although their effects on PRK/LASIK have not been studied. Female patients agree to disclose to their surgeon if they are pregnant, could possibly be pregnant or plan to become pregnant within 6 months.

Pre Procedure and Post Procedure Care:

The screening examination performed by your eye doctor is intended to assess candidacy for refractive surgery based upon the corneal shape, prescription and other ocular and visual findings. Ocular disease may be present prior to refractive surgery or may develop after surgery, but it is unrelated to laser surgery. Refractive surgery will not treat ocular disease. Your preoperative examination is a comprehensive examination and you should continue to have annual eye examinations. In general, patients with higher degrees of myopia have a higher risk of retinal problems and reducing the degree of myopia with laser vision correction DOES NOT LOWER THE RISK. Patients who wear contact lenses must discontinue their use prior to LASIK/PRK to allow the cornea to return to its natural contour. Soft contact lenses must be removed at least 2 weeks prior to your eye examination and at least 3 days prior to your surgery. Candidates who wear gas permeable contacts must discontinue their use 1-3 months prior to any refractive surgery. Postoperative care with an eye care professional is required for 6 months to monitor your vision. If an enhancement surgery is required, the patient is required to return to Advanced Laser Vision for further surgery. The final clinical results are dependent upon properly following your postoperative care instructions.

I have read and understand the information in Section 3.

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Section 4. Keratoconus Risk

I understand that I could develop keratoconus. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several test 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 measurements). 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. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

I have read and understand the information in Section 4.

Patient Initials: _____

Section 5: Presbyopia and the Mono Vision Option: For Patients Over Age 40

Mono vision may allow for improved reading ability in both nearsighted and farsighted patients after age 40. Many people around the age of 40 begin to have trouble reading up close due to the natural weakening of their focusing muscles, which is known as Presbyopia. LASIK will not prevent the natural aging of the eyes or the need for reading glasses as you age, even if you do not require them now. Although farsighted patients usually improve their reading ability with LASIK, it is possible that nearsighted patients may need reading glasses sooner. The mono vision option is usually only selected by candidates over 40 years of age, and simply means that we leave one eye a little nearsighted after LASIK. For nearsighted patients your myopia is undercorrected in one eye, and for farsighted patients, your hyperopia is a little overcorrected to provide you with some reading ability as you age. We call this social reading vision. Mono vision will not eliminate your need for reading glasses for fine print, but is useful for reading your watch, opening your mail or reading price tags at the store. The disadvantage is that your distance vision will not be as precise and you may need glasses for night driving or when you need your most critical vision. The decision for mono vision is yours and you need to discuss this with your eye care specialist prior to LASIK or PRK surgery. Many people prefer to have both eyes corrected for the best possible distance vision, but need to understand that after age 40 reading correction will most likely be required EVEN IF YOU DID NOT NEED READING GLASSES PRIOR TO SURGERY.

I have read and understand the information in Section 5.

Patient Initials: _____

I AM OVER AGE 40 AND WISH TO HAVE MONO VISION _____

I WISH TO HAVE DISTANCE VISION ONLY IN BOTH EYES _____



Section 6: Legal Responsibilities and Disclosures

Confidentiality

I give permission for the medical data concerning my surgery and subsequent treatment to be submitted to the VISX Corporation (the laser manufacturer) and government regulatory authorities. This data will be used for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Governing Law/Jurisdiction

I agree that the relationship and resolution of any and all disputes between the surgeon and myself shall be governed by and construed in accordance with the laws of the State of Texas. I also acknowledge that the courts of the State of Texas 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. I agree that I will commence any such legal proceedings in the County of Harris in the State of Texas and I irrevocably submit to the exclusive jurisdiction of the courts of the State of Texas.

Financial Interest of Some Doctors

I acknowledge that I am aware that some Advanced Laser Vision medical doctors have a financial interest in this facility and may indirectly benefit financially from the laser vision correction service performed at this facility.

I have read and understand the information in Section 6.

Patient Initials: _____

Section 7: Risks and Complications

The Risk of LASIK or PRK Surgery Revolves Around 4 Primary Areas:

T. Post Operative Side Effects, Adverse Effects and Complications

- Foreign body sensation, pain or discomfort
- Photophobia or sensitivity to bright lights EARLY OR LATE POST OPERATIVE CARE
- Blurred vision
- Dryness
- Tearing
- Fluctuation in vision
- Glare - worse with night driving

I have read and understand the list of possible postoperative side effects and understand the information.

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2. Refractive Complications

- Over correction which may require further surgery.
- Under correction which may require further surgery
- Need for contacts and or glasses to obtain the best possible vision
- Anisometropia - a difference in eye prescription which may cause decreased vision and or reduced depth perception
- Inability to obtain the goal correction because of corneal thickness.
- Need for enhancement surgery to obtain the desired correction
- Loss of best corrected vision

I have read and understand the list of possible refractive side effects and understand the information.

Patient Initials: _____

3. Corneal Flap Complications

- Flap of inadequate size, typically too short - Surgery will be canceled and repeated in 3 to 6 months, usually without complications.
- Flap too thin - Surgery may be canceled and repeated in 3 to 6 months and this may cause blurred vision for several months.
- Irregular flap -inadequate orbital size, suction pressure, or patient cooperation. The surgery will be canceled and repeated in 3-6 months and this may cause blurred vision.
- Free cap or flap - usually the flap is hinged, but extremely infrequently a cap is totally free, this can be replaced and usually the patient recovers as well as a patient with a normal hinged flap. If the flap cannot be replaced, further surgery may be necessary.
- Corneal Perforation - the most serious LASIK complication. This is an extremely rare occurrence and every effort is made to prevent this problem. If for any reason the cornea is perforated, the surgery is canceled and the patient will need further extensive surgery to repair the eye. No guarantee of outcome can be made with this complication.
- Corneal Flap displacement, partial or complete - This usually occurs within the first 24 hours but can occur up to weeks later with severe trauma. The cap can usually be replaced but may need sutures for severe displacement. If repaired as soon as the displacement happens usually the cap heals normally.

Epithelial ingrowth usually occurs during the first month following LASIK. This happens when the corneal surface cells (epithelium) grow underneath the flap as well as on top of the incision. Gently lifting the area of the flap involved and irrigating removes these cells. Many times a few cells will be left within the flap zone and vision will remain stable.

I have read the possible Corneal Flap complications and understand the information.

Patient Initials: _____

4. Corneal Healing Complications

The cornea may heal more slowly in people with higher degrees of prescription. This may increase the need for enhancement surgery.

The cornea may not heal smooth and vision may be blurred or distorted.

Corneal irregularity can occur and can produce central islands, a central raised area or microscopic bump in the central cornea. This can cause doubling or shadowing of the vision. Many times this swelling will resolve in 3 to 6 months and if the swelling does not resolve, enhancement surgery will alleviate the problem.

Irregular astigmatism from healing and surgical complications may result in a loss of best-corrected vision.

Patients with a previous history of ocular disease or decreased vision may have a higher risk of impairment or decreased vision following LASIK surgery. You need to discuss this risk to benefit ratio very thoroughly with your surgeon BEFORE SURGERY.

I have read the risks of Corneal Healing complications and understand the information.

Patient Initials: _____

Section 8. Expectations of the Procedure

The goal of LASIK is to achieve the best visual result the safest way. The goal is not to eliminate glasses and contacts completely but to dramatically reduce your dependence upon them in an attempt to help improve your quality of life.

Enhancement procedures will not be performed until 3 months after the initial procedure. Many times any residual correction will have dissipated and no surgery will be necessary.

Enhancements

Enhancement surgery is done after your initial 3-month healing time is complete. Your cornea must heal completely and the refraction must remain stable for one month before the enhancement surgery.



If your prescription fluctuates it is impossible to determine what prescription to operate for and your outcome will be less than successful. You and your doctor need to discuss the benefits and risks of enhancement surgery.

I have read the risks and benefits of Enhancement Surgery and understand the information.

Patient Initials: _____

TREATMENT OF ONE OR BOTH EYES

Advantages of Surgery on Both Eyes:

- Less time lost from work and personal activities
- Vision is balanced when both eyes are done at the same time
- Improved depth perception

DISADVANTAGES OF SURGERY ON BOTH EYES

- Decreased vision with surgical complications
- Need for glasses or contact lens correction during the healing phase to obtain the best possible correction

I have read the advantages and disadvantages of having one or both eyes surgically corrected on the same day.

Patient Initials: _____

Section 9. Post Operative Care

Postoperative care is a necessary part of your surgical plan. Your postoperative visits are scheduled at one day, one week, one month and three months. Even if you see well the day after surgery, it is necessary to continue your follow up visits to prevent postoperative complications. You may be released at your three-month visit from further visits, but your surgery is covered for one year from the date of surgery.

If you do not continue your post operative care as stated above your post operative coverage will be discontinued and you will be released from care for non compliance. It is very important that you continue your visits to ensure that your surgery has the most successful outcome.

I have read and understand the information in Section 9.

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Please Complete the Following and Sign at the Laser Center

Circle One of the Choices Below

I wish to have **my Right Eye** **my Left Eye** or **Both of my eyes** treated today.

**Please Write the Following Paragraph in
Your Own Handwriting and Sign.**

I have read this consent form and all of my questions pertaining to either LASIK surgery or PRK surgery have been answered to my satisfaction. I understand that all surgery has risks and benefits and no guarantee can be made as to the outcome of this surgery.

Handwriting area with six horizontal lines.

Signed by _____ Date _____

Patient Name Printed _____ ID# _____

Witnessed by _____ Date _____

Comments: _____

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