CONSENT FOR LASIK (LASER IN SITU KERATOMILEUSIS) RETREATMENT
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INTRODUCTION

It is our hope to fully inform you about the indications, side effects, limitations, and complications of repeat LASIK surgery, or retreatment. This consent form in combination with the 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. It is important to realize that even if you did not experience any difficulties with your original LASIK procedure, that does not mean that you will not have any complications with the retreatment. The only way in which a patient can avoid all surgical risks is by not proceeding with surgery. Each patient must balance the risks and benefits to determine whether to proceed with further surgery.

INDICATIONS AND ALTERNATIVES

As you were informed before your first LASIK procedure, retreatments are at times indicated to correct remaining or induced myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. There is no guarantee that repeat LASIK will correct these problems. Alternative forms of vision correction exist, including eyeglasses, contact lenses, orthokeratology (ortho-K), radial keratotomy (RK), intracorneal ring segments (ICRS), holmium laser thermokeratoplasty (LTK), or photorefractive keratectomy (PRK).

ELIGIBILITY FOR RETREATMENTS

The ophthalmologist alone can determine whether or not you are a candidate for retreatment. Several factors determine eligibility. LASIK retreatment procedures are performed by lifting the corneal flap and applying additional laser to the corneal bed, or by repeating the original LASIK procedure and creating a new corneal flap. Eligibility and the choice of technique are determined primarily by the amount of time that has passed since the original corneal flap was created, the amount of corneal flap healing that has taken place, and the corneal thickness. An enhancement can be performed once the vision and prescription (refraction) stabilize after the original LASIK procedure, which takes between one to four months for most patients. Typically, the higher the attempted correction for the original procedure, the longer it takes for the cornea to heal. Many surgeons wait three months before retreating any patient, others treat those with low prescriptions after one to two months. The corneal flap can usually be easily lifted during the first two years, and in many cases, it can even be lifted after several years. Sometimes, however, even after a few months, the corneal flap is sealed and cannot be lifted again. If the flap cannot be lifted, the surgeon and patient must decide either to abandon the surgery, apply the laser correction to the surface (PRK), or create a new flap. Creating a new flap in an eye with an existing flap is considered by many surgeons to be a more risky option and should be approached with caution. The ideal time for a retreatment is when the refraction is
stable. There must be adequate corneal tissue under the flap to safely perform the reoperation and this can be measured at the time of the surgery. The remaining corneal thickness is an important factor the surgeon considers when deciding whether a retreatment can be safely performed.

ADVANTAGES AND DISADVANTAGES OF ORIGINAL VERSUS NEW FLAP

Surgeon experience, patient preference, and corneal measurements determine the type of technique. The advantages of lifting the original corneal flap are related to safety, because no additional incision is required and the surgical risks associated with the creation of the corneal flap are avoided. The disadvantages are that the procedure is often more uncomfortable postoperatively for the first several hours, and the corneal flap edges must re-heal. The risk of epithelial ingrowth may be increased when the flap is lifted. If this occurs, additional surgery may be required to remedy the problem. As stated above, depending upon the healing of the original flap, it may or may not be possible to lift the flap. Occasionally, the flap can only be partially

lifted; if this happens, the retreatment must be cancelled for several months while the flap re-heals before making another incision.

The advantage of creating a new flap is that the procedure is much the same as the original procedure and many patients find it easier as they know what to expect. The most serious concern with creating a new corneal flap is that inadequate healing of the original flap may result in a free or loose piece of corneal tissue being formed. That is, while creating the new flap, a separate, small wedge of the original corneal flap tissue is produced either in the center or on the side of the flap. This wedge of tissue can make the center of the cornea irregular or cause scarring on the side that could lead to epithelial ingrowth, both of which can compromise vision.

During the re-treatment procedure, after the original flap is lifted, or after the microkeratome or IntraLase laser cuts a new flap, the flap is flipped over out of the way, and the laser application is performed within the corneal bed instead of on the corneal surface as with PRK. The flap is replaced immediately following the laser application. The flap is held in position through an almost immediate suction-type action within the cornea and by the protective layer of the cornea called the epithelial layer, which rapidly envelopes the surface within days. In most cases no stitch is required. If a stitch is required, it is below the surface and usually removed within several days. A soft contact lens may be applied as a bandage to protect the surface for the first day or so. Often, the surgeon may choose to perform the retreatment on the surface of the cornea without lifting the flap. This option is usually chosen to enhance the safety of the retreatment and to provide the best quality of vision.

COMPLICATIONS

The risks associated with the original LASIK procedure apply to retreatment as well. It is not possible to list every complication. Some risks and complications may not be known, including long-term risks. The most severe complications would require more invasive or repeated corneal surgery, including corneal transplantation, and could potentially cause partial or complete loss of vision.

POSTOPERATIVE SIDE EFFECTS AND COMPLICATIONS

1. Early in the postoperative period, you may experience a foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dry eyes, tearing, or fluctuations in vision. Discomfort is more common during the first few hours after surgery with retreatment than with the original LASIK procedure. Persistent pain is uncommon, and may indicate a disturbance of the epithelial protective layer, displacement of the corneal flap, or a possible infection. You should immediately notify the surgeon if you have persistent pain.
2. Corneal infection following LASIK enhancement is rare but if serious can cause corneal scarring and require a corneal transplant. In very severe cases, blindness can result.
3. Corneal inflammation can be caused by medications or healing reactions which can be allergic, toxic, or immune in nature. Diffuse interface keratitis (also known as the Sands of the Sahara) may occur with both primary and repeat LASIK. This inflammatory reaction can cause corneal haze, blurred vision, farsightedness, astigmatism, or permanent corneal irregularities. Treatment may involve topical steroids or further surgery, and treatment may or may not fully restore vision.
4. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
5. After refractive surgery, a certain number of patients experience glare, a "starbursting" or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see

well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. Retreatment often improves night glare by reducing the residual refractive problems, but it is limited by the remaining corneal thickness, treatment area, individual patient sensitivity to night glare, and corneal healing pattern. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate.

6. Some patients develop keratoconus, 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. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

REFRACTIVE COMPLICATIONS

1. Repeat LASIK may result in overcorrection and undercorrection due to the variability in patient healing patterns and other surgical variables, leaving patients nearsighted, farsighted, or with astigmatism. This may or may not require patients to wear glasses or contact lenses or undergo additional surgery. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is often obtained.
2. Patients may heal differently between eyes based upon differences in preoperative prescriptions, corneal curvature, variation in healing, or other factors. Differences in refraction between eyes is called anisometropia. This is most severe when only one eye is treated, and may result in loss of depth perception, eyestrain, headache, double vision, and the need for contact lenses. Both farsightedness and anisometropia may result in worsening of muscle balance problems, causing the eye to wander more or producing eye fatigue.
3. Depending upon the severity of the original prescription, the healing pattern of the patient, and other factors, regression may occur, causing the eyes to return to their original prescription, either partially or completely. Further retreatment surgery may be performed when the eye is stable and if adequate corneal tissue is available and no medical contraindications exist.

CORNEAL FLAP COMPLICATIONS

1. The most severe flap complication is a corneal perforation, which requires corneal stitches or sutures, and usually the need for an intraocular lens implant as the natural lens is usually lost or damaged. Corneal perforation could also lead to infection, the need for a corneal transplant, or even blindness.
2. When repeat LASIK is performed by lifting the original flap, the risk associated with the flap creation are avoided, although other risks remain. Corneal flap complications that occur after the LASIK procedure during the recovery period, such as displacement and wrinkling of the flap and epithelial ingrowth, may occur whether lifting the original flap or creating a new one.
3. The most serious concern with creating a new corneal flap is that inadequate healing of the original flap may result in a free or separate piece of corneal tissue being formed. This wedge of tissue can make the center of the cornea irregular or cause scarring on the side that could lead to epithelial ingrowth, both of which can compromise vision.

4. Partial or complete corneal flap displacement may occur either during the early postoperative period or days to weeks later after trauma. Care should be taken to protect the eye from trauma, and you should not rub your eyes or forcefully close them during the first week after repeat LASIK. Partial displacement of the corneal flap may result in corneal striae or wrinkles, which blur vision. Most striae are treatable, but some patients, such as those who are highly nearsighted, may be resistant to treatment. Complete displacement of the corneal flap is often painful and requires urgent replacement. There is a higher risk of epithelial ingrowth and infection with complete flap displacement.
5. Epithelial ingrowth occurs during the first month after LASIK and is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a risk factor. Epithelial ingrowth is produced when epithelial surface cells grow underneath the corneal flap during the healing of the corneal flap incision. Epithelial ingrowth is more common with any trauma or breakdown of the epithelium, so it is more common in LASIK retreatment procedures that lift the original corneal flap. Treatment of this condition involves lifting the flap and clearing away the cells. Although most small areas of epithelial ingrowth only need to be monitored and do not cause visual problems, untreated larger areas may distort vision and may actually damage the flap integrity if severe and progressive.

CORNEAL HEALING COMPLICATIONS

1. The protective corneal flap of LASIK reduces the healing component of LASIK compared to PRK, but significant healing is still required, which can affect visual quality and ability. Corneal healing problems are more common in patients corrected for higher prescriptions for over- and undercorrection.
2. Corneal healing may affect not only the speed of healing but the smoothness of the cornea, leading to blurry vision or rarely corneal scarring. Corneal irregularities may develop that affect the quality, crispness, and sharpness of the final result. Corneal irregularity or corneal astigmatism is produced when the cornea heals in an irregular pattern, which may or may not follow a surgical flap complication. It may also be produced by abnormalities and complications of the laser treatment, including central islands and decentrations. These are expected during the first few weeks following an uncomplicated repeat LASIK, but if they persist beyond 3-6 months, they are considered abnormal and permanent. Further surgical intervention does not guarantee better healing and may result in a further reduction of visual quality.
3. Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that you may be unable to read the bottom few lines of an eye chart even with glasses or contact lenses. The best vision you may experience after surgery, even with lens correction, may not be as good as before refractive surgery.
4. In some cases, vision may be severely impaired and affect your ability to drive legally, especially if you already have reduced vision from other causes. LASIK is not intended to improve visual potential, and many patients with high prescriptions often are unable to read 20/20 before surgery and should not expect to read 20/20 after surgery. A patient who is best corrected before surgery to 20/40 is already borderline for driving legally and any loss of best corrected vision from healing or surgical complications may prevent legal driving.
5. In general, healing after repeat LASIK is usually more rapid, but may follow the same course as the original LASIK healing pattern. The speed of the original healing pattern is usually based upon the severity of the original prescription and is typically slowest for patients treated for high degrees of farsightedness.

EXPECTATIONS

The goal of repeat LASIK is to achieve the best visual result with the safest method while dramatically **reducing** dependency on glasses or contacts. As examples, night driving glasses and reading glasses may still be needed. The degree of correction required determines both the rate of recovery and the initial accuracy of the procedure. Severe degrees of nearsightedness may require two procedures. Patient differences in healing can also greatly affect visual recovery and final visual outcome and are impossible to predict. After the initial

procedure and even if further procedures are performed, you may have some remaining nearsightedness, farsightedness, or astigmatism, If so, glasses and/or contact lenses may still be needed some or all of the time.

VOLUNTARY CONSENT

By signing this Informed Consent Form, I certify that I have read the preceding information and understand the contents. The potential advantages and disadvantages have been reviewed with me. Any questions I have concerning this consent form have been fully answered. I fully understand the possible risks, complications, and benefits that can result from repeat LASIK. I consent to repeat LASIK on my _____ (state "right" or "left") eye.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date

_____ _____

Surgeon Signature Date

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purpose of education, research, or training of other health care professionals. I also give permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand LASIK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my LASIK procedure will be performed.

Patient Initials: _____

I have been offered a copy of this consent form (please initial) _____