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Risks and Limitations of LASIK Procedure

Infection, serious injury, or even death, from known and unforeseen causes. Neither your surgeon nor the surgeon's staff can promise or guarantee that the Procedure will be effective or make your vision better than it was before the Procedure.

It is possible that the Procedure or a complication arising from the Procedure could make your vision worse or could injure your cornea or your retina, which could result in partial or total blindness, or could require a cornea transplant. Certain inflammatory conditions can cause severe post-operative complications such as cornea or flap inflammation, or thinning of the corneal flap, which could result in permanent loss of vision. In addition, because the Procedure is fairly new, very little is known about the long-term effects of the Procedure. During you pre-operative examination, the likely outcomes (e.g. uncorrected vision) will be conveyed to you based on the level of your particular refractive error. Although it is not possible to list every potential risk or complication that may result from the Procedure, many of them are described below.

Halos / Starbursts

Some patients do not see as clearly at night or in dim light and may notice an optical effect called a "halo" or a "starburst" around lights and illuminated objects after the Procedure. Patients who notice these effects may need to wear glasses to drive at night. These effects are for the most part temporary, but could be permanent and uncorrectable. Further, these conditions are more likely to occur in patients with high levels of nearsightedness or farsightedness and for patients with larger-than-average pupil size.

Equipment Malfunction

The microkeratome and excimer laser are maintained according to manufacturer specifications. Despite this maintenance, the microkeratome or the excimer laser could malfunction, requiring the Procedure to be stopped before completion. In some instances, this could result in a loss of vision, or rescheduling of the Procedure.

Under-correction or Over-correction

The exact removal of tissue performed by the laser is overridden in some cases by the healing response of the eye. While the treatment of your refractive error is designed to completely neutralize your refractive error (unless otherwise discussed with your surgeon) this treatment is aimed at the "average" eye. If your eye tends to heal in a different way from the "average," your refraction may result in an over- or under-correction. In the majority of instances, the over or under-correction can be corrected with glasses, contact lenses or additional surgery. In other instances, it can be permanent and not amenable to surgery because of structural stability issues or the presence of an irregular corneal surface.

Increased Light Sensitivity of the Eye / Fluctuating Vision

Patients may be extremely sensitive to light and glare or find that their visual acuity fluctuates after the Procedure. These conditions are generally temporary and usually go away within one (1) to three (3) months after the Procedure; however, in some cases they could be permanent.

Optical Imbalance

There will be a potential period of imbalance in vision between the two eyes if surgery is performed on each eye on separate days. This is especially important if a contact lens in the unoperated eye cannot be worn. You may experience a sense of imbalance, dizziness and a form of double vision.

Infection, Hemorrhage, Blockage, Drug Reactions and Other Complications

Other risks include severe infection that cannot be controlled by antibiotics, hemorrhage, corneal swelling, retinal detachment, venous or arterial blockage, cataracts, drug reaction, or other complications. These complications range from minor, temporary problems to major, permanent conditions, including but not limited to perforation of the cornea, retinal damage, loss of an eye and can cause partial or total blindness.

Regression

The cornea is living tissue. Once tissue has been removed from the cornea during the Procedure, the surface epithelium ("front surface") can thicken to compensate for the change in shape that has occurred. This happens to a variable degree among treated patients, accounting for the reason why some patients have a stable immediate result (minimal epithelial thickening) and others regress (more significant epithelial thickening). Regression is more likely to occur in very nearsighted patients. In other cases where tissue availability for safe laser retreatment is limited, the regression is corrected with glasses and/or contacts.

Increased Pressure in the Eye

The steroid drugs used during the first week after surgery may, on rare occasions, cause increased pressure in the eye. This raised pressure needs to be closely monitored and may require additional topical and/or oral medications if significantly elevated. It is important for you to return to the office for scheduled follow-up visits to monitor your eye pressure in order to modify the medication schedule as needed.

Fragility on Impact

For at least three (3) months after the Procedure, the eye should be considered fragile to direct trauma. When participating in sports or other activities involving possible contact with the eye during this period, you should wear protective eyewear. In any event, it is advisable to protect your eyes form direct trauma after the Procedure as much as possible.

Eyelid Droop

The eyelids have a natural tendency to droop with age. The eyelid speculum that is used in the Procedure may hasten this process.

Corneal Ectasia

A certain amount of corneal tissue must remain under the flap after the laser has achieved tissue removal. This is believed to relate to the long-term stability of the cornea. In rare instances, imprecision in the accuracy of the keratome cut, coupled with inaccuracy of the pre-operative corneal thickness evaluation can result in less tissue being left under the flap than intended. This can have two effects: it can either result in bulging of the cornea thus reversing the intended flattening effect of the treatment, or it can lead to progressive deformity of the cornea with thinning and increasing curvature changes, and the cornea can develop an irregular shape. In more severe instances, the condition of progressive deformation is called ectasia and the patient may need a corneal transplant in order to restore his or her vision. The probability of this occurring with currently employed modern technology is thought to be approximately one in 10,000.

Faulty or Improperly Created Flap

The corneal flap may be too thin, too thick, uneven, and too short, may wrinkle, become displaced or may not heal properly. This condition could be temporary, requiring that LASIK be postponed until the surgeon can create a new flap, or could cause permanent damage to the cornea. In addition, there is a risk that the

"hinge" of the flap may be separated from the cornea (also known as a "free flap"). In some instances, the surgeon can still perform the laser treatment, reposition the detached flap on the cornea, place a contact lens bandage on the eye to promote healing, but in some instances the surgeon may choose to wait to perform laser treatment until after the flap heals. If, however, a "fee flap" is lost, the patient could experience permanent corneal damage. If the damage or distortion in vision is severe, a partial or complete corneal transplant may be necessary to restore vision.

Debris under the Flap or Infection under the Flap

Sometimes after the surgeon creates the flap during LASIK, there may be a small amount of debris or tissue under the flap. Debris can result from the instruments used or consist of tear-film oil or floating material. The surgeon may decide in the immediate post-operative period to irrigate beneath the flap to remove this debris. Small amounts of debris can generally be monitored in the clinic without surgical intervention. In most cases, debris that is left behind is cleared in time by the body's own clearing systems.

Infection, on the surface of or beneath the flap is a rare event, estimated to occur at a rate of one in 10,000. Infection is managed by starting antibiotic eye drops and in most instances, taking cultures of the cornea. Your surgeon might even need to lift the corneal flap to culture and treat the infection. If the infection results in significant scarring of the cornea, a partial or complete corneal transplant may be necessary to restore vision.

Diffuse Lamellar Keratitis or "Sands of the Sahara"

In some cases, patients experience a temporary complication caused by an inflammatory reaction between the flap and the corneal bed of the eye. This condition has been called "Sands of the Sahara" or Diffuse Lamellar Keratitis (also known as "DLK"). The exact cause of this complication has not been determined. Patients with DLK may not show any symptoms at all or may experience blurred vision and tearing, which can last from several days, up to several weeks, which can delay the healing process. DLK can generally be treated with topical or oral steroids, with possible need for surgical intervention (the surgeon irrigates beneath the corneal flap).

Epithelial Erosion

The epithelium is the surface layer of cells that protects the cornea. If the epithelium is cut or removed, it generally grows back. In LASIK, the surgeon creates a flap, consisting of epithelium and stroma, and holds the flap back while performing the Procedure. The epithelium in some people is not as well attached to the underlying stroma: such eyes are at increased risk for epithelial scratches or epithelial sliding, especially as the flap-maker is passing over the corneal surface to create the flap. In some cases, we can identify eyes at risk and advise about the increased risks associated with surgery. There are, however, rare patients where there are no pre-operative clues. In addition, older patients are more likely to have areas that are weakened or slip during flap creation. In such instances, the surgeon places a bandage contact lens over the cornea at the end of the LASIK to assist in healing and to reduce discomfort. Patients who experience an epithelial slide or abrasion or erosion may experience a longer recovery period and may be at risk for complications including infection, inflammation, recurrent erosions, flap wrinkles or epithelial ingrowth. The surgeon may postpone and reschedule LASIK until the eye heals, or he may choose to not treat the second eye at the same session following a severe slide or erosion on the first eye.

Epithelial Ingrowth

Epithelial ingrowth is a condition in which epithelial cells from the surface of the cornea grow under the edge of the flap. If the cells continue to grow, they can effect the underlying tissue causing astigmatism, flap edge thinning and reduction of vision. Medication and observation generally treat this condition, although further surgery to remove the epithelial cells from the interface may be necessary.

Dry Eyes

Dry eye is a common, but generally temporary, complication arising from LASIK or PRK. This condition can usually be treated with lubricating eye drops and occasionally with temporary inserts or "plugs" that prevent the normal drainage of tears into the nose. Dry eye generally improves within a few months after surgery, but in some instances can continue for longer periods of time, and may require long-term use of lubricant drops and permanent plugs. Patients who have dry eyes prior to LASIK or PRK are likely to experience dry eyes after the Procedure.

Vascular Occlusion

When the suction ring is applied to the eye during the flap-making process, the pressure in the eye increases significantly and many patients will notice that the light will dim or go out completely in the eye. When the suction ring is removed, the vision is restored to the eye within a few seconds. There is a remote risk that when the suction ring interrupts the blood supply to the eye, permanent damage to the retina (like the film in a camera) and loss of vision can result. This possible occurrence has a theoretical probability of less than one in 1,000,000.

Microscopic Corneal Surface Irregularities

Microscopic irregularities on the surface of the cornea can cause slight vision loss. One to two percent (1-2%) of patients may lose up to two lines of vision on the eye chart after the Procedure.

Excessive Corneal Haze

Although corneal haze is part of the normal healing process, and gradually subsides with little or no permanent effect on vision, if the haze is excessive or does not go away, the patient may need additional treatment.

Elevated IOP (Intraocular Pressure)

Because a steroid drop is used post-operatively to control the healing response, some patients may experience a rise in their intraocular pressure (IOP). You will need to be monitored and may require an additional medication to control the pressure until you have completed your prescribed steroid medication.

Retreatment

At Drs. Fine, Hoffman and Packer, we experience an overwhelming success rate with our patients in only one refractive treatment. However, due to each individual's prescription level and unique physiology, an additional treatment or enhancement, may be required. The patient must generally wait at least three (3) months after the first LASIK and must have adequate corneal tissue and stable vision. Results cannot be predetermined or guaranteed.

There are currently two methods used for retreatment. One involves relifting the flap created from the first surgery and reshaping the underlying corneal tissue. The second involves making a new flap. Both methods involve all the risks of LASIK.

Our goal is to help you achieve a life free from the dependence on glasses or contacts. It should be noted, however, that all patients eventually require the need for reading glasses as part of the unrelated and natural aging process of the eye.

Cataracts, Amblyopia, Strabismus, Presbyopia

The LASIK procedure does not correct vision defects that do not arise from refractive errors, such as cataracts, amblyopia, strabismus or presbyopia. Patients with such conditions may be subject to additional

risks and additional side effects and should discuss their condition with the surgeon and optometrist before deciding whether to have the Procedure.

Cataracts

Cataract is a condition that, if not treated, can cause reduced vision, correctable by cataract surgery. LASIK or PRK will not prevent cataracts, nor will it reverse the effect of a cataract that is beginning to appear.

Amblyopia

Amblyopia is a medical condition that develops in early childhood in which a person who has reduced vision in one eye relies on the other eye to focus. LASIK or PRK will not reduce or eliminate amblyopia. It will not improve the vision in the amblyopic eye. If the patient experiences side effects or complications from the Procedure in the eye that is able to focus, he or she could experience a loss of vision because that eye would no longer be able to compensate for the other.

Strabismus

Strabismus is an eye disorder caused by a weakness in the eye muscles in which the eyes may not be aligned properly. LASIK or PRK will not correct, reduce, eliminate or prevent strabismus. Patients with strabismus may develop double vision as a result of or as a side effect of the Procedure.

Presbyopia

As we age, the crystalline lens of the eye may lose its ability to accommodate to near objects. This condition, known as presbyopia, usually begins around the age of 40, and can most often be comfortably corrected through the use of eyeglasses.

The significance to You of a Surgical Complication

The occurrence of a complication may or may not lead to a poor visual outcome. However, in the event a complication does occur, and it leads to an unsatisfactory visual outcome, this would mean that your vision could be blurred, doubled, distorted, or have halos or other disturbances, and these would NOT be correctable with glasses or contact lenses. In the event this should happen, your surgeon will discuss and offer you advice on further treatment, which may involve medications or more surgery. If the outcome cannot be corrected by medications or more external surface corneal surgery, the only way of restoring the vision may be a corneal transplant. It is believed that with current techniques and technology, the combined risk of all causes of a corneal transplant being necessary is approximately one in 10,000 or less.

Alternatives

Other methods of correcting vision include eyeglasses and contact lenses. Eyeglasses are safe, relatively inexpensive and most people can wear them reasonably well. However, depending on the nature of the correction, the lenses may be thick, and may reduce or increase the size of the visual image.

Contact lenses are another non-surgical alternative. Contact lenses come in a variety of materials, and comfort, effectiveness, and ease of use varies. Since contact lenses rest directly on the cornea, not everyone is able to tolerate them. If fitted and used properly, contact lenses are effective, relatively safe and easy to use. Complications arising from the use of contact lenses include allergic reactions, infections, scratches, ulcers, or other injuries to the cornea.

For those persons with mild myopia (three diopters or less), Intacs might be a possible alternative. Intacs are surgically implanted plastic half rings that changes the shape of the cornea. Intacs can be removed at a later date if so desired. Complications from Intacs may include difficulty with night vision, glare, halos,

blurry or double vision and fluctuating distance vision. The FDA approved labeling of Intacs indicates that up to 7% of these devices were removed for complications during the FDA phase III clinical trials.

Other methods of refractive surgery available include Radial Keratotomy (RK) and Automated Lamellar Keratoplasy (ALK).

RK is seldom performed at the time of writing (2000) because the excimer laser can achieve the same effect as the incisions without the need for placing incisions, which effectively lead to a weakening of the structure of the cornea to achieve the refractive surgical effect. ALK is a procedure that existed before LASIK..