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IntraLASIK Correction Of Nearsightedness, Farsightedness, and Astigmatism Using IntraLase™ Technology

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision about IntraLASIK, or “all-laser” LASIK. Traditional LASIK surgery involves two procedures: first, a microkeratome blade is used to create a flap on the cornea to expose the underlying tissue. After the flap is created, an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. Finally, the flap is returned to its original position, without sutures.

The IntraLASIK surgery also involves two procedures. First, instead of a microkeratome blade, it uses the FDA-approved IntraLase™ laser to create a flap with laser energy. The IntraLase laser is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created, an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. The flap is returned to its original position, without sutures.

ALTERNATIVES

IntraLASIK is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have adequate visual acuity. There are also other types of refractive surgery, including LASIK with a microkeratome.

RISKS AND COMPLICATIONS

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse. In giving my permission for IntraLASIK, I understand the following: The surgeon will use the FDA-approved IntraLase™ laser to create a flap, and then an FDA-approved excimer laser to reshape the eye. The long-term risks and effects of IntraLASIK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

A. VISION-THREATENING COMPLICATIONS

1. I understand that the IntraLase™ laser or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. I understand that irregular healing of the flap could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing IntraLASIK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
3. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.
4. 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 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.
5. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

B. NON-VISION-THREATENING SIDE EFFECTS

1. I understand that there is a greater chance that the whites of my eyes may temporarily appear pink or red for several days to several weeks after surgery. This redness is more common with IntraLase-created flaps than with microkeratome-created flaps.
2. I understand that my vision after surgery using the IntraLase technology may not be clear immediately and that I might not notice improvement for several days to several weeks.
3. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.

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. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. If permanent, I may need to use glasses or contact lenses. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
6. 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. Although there are several possible causes for these difficulties, 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. 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. These risks in relation to my particular pupil size and amount of correction have been discussed with me.
7. I understand that I may not get a full correction from my LASIK procedure and this may require future retreatment procedures, such as more laser treatment or the use of glasses or contact lenses.
8. I understand that there may be a “balance” problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult.
9. I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
10. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

11. I understand that there may be pain, irritation, or a foreign body sensation, particularly during the first 48 hours after surgery. I also understand that pain may be associated with complications such as infection.
12. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
13. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
14. I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require additional surgery, or require glasses or contact lens use to see clearly.
15. I understand that the correction that I can expect to gain from 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 I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
16. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I, therefore, understand that I must not drive the day of surgery and should not drive until I am certain that my vision is adequate for driving.
17. I understand that if I currently need reading glasses, I will still likely 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.
18. 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. The strength of readers I will need may vary over the course of my healing. It is possible that my dependence on near correction may increase or decrease after surgery.
19. I understand that even 90% clarity of vision is still slightly blurry. Retreatment surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. Retreatment surgery can be performed no sooner than three months after surgery, and for up to one year. Generally, the original flap can be re-lifted without creating a new flap. Rarely, a new flap may need to be created. A retreatment will only be considered if there is adequate corneal tissue. A retreatment will not be considered an option when it is deemed unwise or unsafe. In order to perform a retreatment surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform a retreatment. An assessment and consultation will be held with the surgeon at which time the benefits and risks of a retreatment surgery will be discussed.
20. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

C. FOR PRESBYOPIC PATIENTS (those requiring a separate prescription for reading): The option of monovision has been discussed with my ophthalmologist.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as IntraLASIK have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I have been offered a copy of this consent form I therefore consent to IntraLASIK surgery on:

_____ Right eye _____ Left eye _____ Both eyes

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand IntraLASIK. 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 IntraLASIK procedure will be performed.

Patient Name

Date

Witness Signature

Date