

Informed IntraLASIK Consent

For the Correction of Nearsightedness, Farsightedness, and/or Astigmatism Using Intralase Technology

Patient _____
 First name _____
 Last name _____
 D.O.B _____ SS# _____

Surgical Eye  right  left

Introduction and Alternatives

This information is being provided to you so that you can make an informed decision about IntraLase, or “all-laser” LASIK. Traditional LASIK surgery involves two procedures: first, a microkeratome blade is used to create a flap on the cornea and 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 IntraLase 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.

IntraLase 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.

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be

I have read and understand this page. Patient initials _____

Possible Side-Effects and Complications

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 Intralase, 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 IntraLase 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:

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 IntraLase. 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 other, very rare, complications that might threaten my vision, including but 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.

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.

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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 IntraLase procedure. These symptoms may be temporary or, on rare occasions, permanent, and I 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 under correction could occur, causing me to become farsighted or nearsighted or increase ray 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 under correction 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. I understand that at night there may be a "starbursting" or halo effect around lights. I understand that this condition usually diminishes with time, but could be 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. I understand that I should not drive until my vision is adequate both during the day and at night.
7. I understand that I may not get a full, correction from my IntraLase procedure and this may require future enhancement 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 IntraLase 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 IntraLase, 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 IntraLase. 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 its process

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11. I understand that there may be pain, irritation, or a foreign body sensation, particularly during the first few 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 IntraLase are unknown and that unforeseen complications or side effects could possibly occur.
14. I understand that visual acuity I initially gain from IntraLase 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 IntraLase 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, that 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. Enhancement surgeries can be performed when vision is stable **UNLESS** it is unwise or unsafe. Enhancement surgery can be performed no sooner than three months after surgery, and for up to one year. Generally, the original flap can be relifted without creating a new flap. Rarely, a new flap may need to be created. An enhancement will only be considered if there is adequate corneal tissue. An enhancement will not be considered an option when it is deemed unwise or unsafe. In order to perform an

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enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement 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.

For Presbyopic Patients (those requiring a separate prescription for reading): the option of monovision has been discussed with my ophthalmologist.

The details of the procedure known as IntraLase have been presented to me in detail in this document and explained to me by my ophthalmologist. Dr. Benjamin has answered all my questions to my satisfaction, I therefore consent to have IntraLase surgery on:

Surgical Eye  Right  Left

Patient's Statement of Acceptance and Understanding

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 IntraLase. 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 IntraLase procedure will be performed.

 Patient's Signature

 Date

 Patient's Name (please print)

 Witness' Signature

 Date

 Witness' Name (please print)

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