

PATIENT INFORMATION ON CORNEAL REFRACTIVE SURGERY

There are two types of refractive surgery utilizing the excimer laser to re-shape the cornea in order to improve vision without glasses or contacts. They are **LASIK** and the **NuSite™** procedure, the newest form of surface ablation (older surface procedures went by several different names including: PRK, LASEK, epi-LASIK, or “Supralase”). These procedures can correct near-sightedness, far-sightedness and astigmatism. This hand-out will describe the two procedures in detail to help you make an informed decision about your surgery. Most patients will be able to choose between the two procedures based on risk tolerance and need to have rapid visual rehabilitation. Some patients will not be good candidates for **LASIK** due to issues of access to the eye, corneal shape, corneal thickness, etc. Your surgeon will inform you if you are only eligible for one of the procedures. Please read this form completely, write down questions and bring the form with you to your evaluation. Do not sign the form until you are asked to do so by a staff member.

1) Description of Procedures

In **NuSite™**, the thin front layer of cells called epithelium is removed from the central cornea using an epi-keratome. The excimer laser treatment is then applied. A contact lens is placed on the eye until the epithelium heals, usually in 3 days.

In **LASIK**, a corneal flap is made with a microkeratome. This flap is usually 160 to 180 microns thick. The best way to imagine this is: pretend that the cornea is a book with 525 pages (average thickness of the cornea is 525 microns). We will “open the book” to page 180 using our microkeratome. We then apply the excimer laser treatment beneath the flap and then replace the flap (“close the book”).

2) Your experience with surgery

In both procedures you are given an oral sedative (pill) to take one hour prior to surgery. This medicine relaxes you, but does not impair your ability to co-operate with surgery. Several eye drops are placed in your eyes to numb them and prevent infection. You are then brought to the laser room where you are placed in a reclining chair. The eyelids and surrounding area are then prepped with antiseptic solution to help prevent infection. Tapes are placed on the lashes to drape them away from the eye. A shield is placed over the non-operative eye to make sure you are only looking with the operative eye during the procedure. You are rotated beneath the laser microscope. A lid speculum is placed in order to keep your eye open during the procedure. You will see a red blinking light inside the laser. This is your fixation target. You need to keep your gaze steady upon the target during the entire procedure.

NuSite™ Procedure

With **NuSite™** we then remove the epithelium with the epi-keratome. The speculum is spread open which can cause a stretching or pressure sensation on the eyelids. The suction ring of the epi-keratome device is placed on the eye. You will feel some mild-moderate pressure during the 30 seconds it takes to remove the epithelium and your vision will go dim during the procedure. The suction ring is removed. The surface of the cornea is moistened with a sterile sponge.

Laser Portion: *Once you are well fixated on the target light, the laser is commenced. The laser makes a tapping or snapping sound with each rapid laser pulse. There is no pain during the laser application. You may normally experience a slight pungent smell during the procedure, which is the vaporization of the corneal tissue by the laser. The laser portion usually takes anywhere from 10 -50 seconds. During the laser portion it is important that you keep your body, head and eye very still. We recommend that you internally (not out loud) chant a word, such as “fixate”, “focus”, “center” to yourself each second during the procedure. This will help to keep your eye on the target light. The target light may become fuzzy or blurred during the procedure, but you will still be able to see it. Concentrate on looking at the very middle of the light even if it gets blurry.*

Once the laser is completed, cold solution is placed on the eye to help prevent inflammation. Sometimes a medication called mitomycin is also applied for several seconds to prevent haze formation. The eye is rinsed thoroughly and an extended wear soft contact lens is applied along with an antibiotic drop.

LASIK Procedure

In **LASIK**, the eyelid speculum is commonly spread apart in order to place a suction ring on the outside (white part) of the eye. Some patients will experience a stretching or pressure sensation on the lids. An ink mark is then made on the cornea with a special device in order to accurately replace the corneal flap once the procedure is completed. You will feel only minor pressure. The suction ring of the microkeratome device (flap maker) is then placed on the eye and suction commenced. The microkeratome is attached to the eye via this suction. You will experience pressure similar to the feeling you have if you press on your eye through your eyelid with your finger or thumb. Try this, pressing rather hard and you will experience the pressure and mild aching in the eye that occurs during the suction portion of the procedure. Once suction is started, the surgeon checks several things to make sure suction is adequate. We check the pressure gauge on the microkeratome, measure the pressure in your eye directly with a tonometer (pressure instrument), check your pupil to make sure it has dilated (normal response to suction), and ask you directly if the microscope light has “blacked out” (normal response to suction). If all four indicators are normal, then the microkeratome is engaged and the flap created. There is no significant additional feeling to the flap making portion of the procedure, only the pressure from the suction ring. The suction is discontinued and the suction ring is removed from the eye. Your vision returns at this point. We inspect the flap to make sure it is adequate for the laser portion and flip it over to expose the inside (stromal) portion of the cornea. The ***Laser Portion*** of the procedure is then performed as noted above in the **NuSite™** section. Once the laser is completed, the flap is replaced on the cornea and the interface (space between flap and the cornea) is irrigated with sterile solution. The flap is then smoothed into place using wet sponges to stretch the flap and make sure it is adherent to the underlying tissue. We wait approximately two minutes for drying of the cornea and this adherence to occur. An antibiotic drop is applied and the speculum removed.

In **both procedures**, if you have chosen to do bilateral surgery, the second eye procedure is then performed. We do notice that some patients tend not to fixate as well during the second eye surgery, so we always encourage the patient to re-double their effort at fixating while we

are doing the second eye. After surgery, you are moved to another room to examine the flap or contact lens with the slit lamp (ophthalmic microscope). You are then given detailed instructions on care of your eyes after surgery.

3) Your experience following surgery

In both procedures your vision will be fuzzy at first following surgery. There will be irritation of your eyes which is variable among different patients, but in general is slightly worse and lasts a little longer in **NuSite™** compared with **LASIK**. It is important to keep your eyes closed as much as possible during the first day and to stay inside and limit your activity as much as possible. It is important to stay clean, not perform any activity in which dirt, dust or other contaminants get in your eyes, and avoid exposure to any potentially contaminated water such as in pools, hot tubs, lakes, salt water, etc. (shower water is fine). You should avoid eye make-up during the first week after surgery. You should avoid rubbing your eyes during the first week after surgery and when you are sleeping or napping it is important to protect your eyes with the protective eye shields. You should protect your eyes from strong sunlight by using a hat and sunglasses when outside during the first few weeks after surgery. Avoid activities where there is a chance of eye injury especially during the first few weeks after surgery and wear appropriate eye protection whenever possible.

With **NuSite™** there are several medications, both eye drops and pills, that are used in order to reduce pain and inflammation after surgery. Some medicines are used as needed for pain control and some are used on a regular basis. Usually the discomfort is the worst on the first day after surgery and averages 1-3 out of 10 (10 being the worst pain imaginable). This subsides over several days, usually 1-2 at day two, 0-1 at day three and then zero by day four. Many patients have very little, if any pain. Your vision is typically better than your vision without glasses or contacts prior to surgery, but is typically blurry until the epithelial defect heals (usually 3 days) and the contact lens is removed. You may not be able to drive during this 3 day period because of blurry vision. Your vision after the contact lens is removed is usually good enough to make you functional at your daily activities, including driving. Your vision slowly improves over several weeks to months as the epithelium molds and adjusts itself to the new corneal shape. Typically, you will be seen in the office on the first and fourth post-operative days, then at two months and six months. More visits may be required depending on your response to surgery.

With **LASIK**, eye drops are used to control pain and inflammation. Usually, the eyes are noted to be scratchy or irritated (like a “bad contact lens day”). This almost always is subsiding by the end of the day of surgery and usually there is no significant discomfort by the first post-operative day. Vision is almost always clearing towards the end of the day of surgery and is quite good by the first post-operative day. Usually, you are back to normal daily activity, including driving, the day after surgery. The post-op visits are usually at one day, one week, two months and six months. More visits may be required depending on your response to surgery.

4) NuSite™ risks and side effects

There is very little intra-operative risk during this surgery. The epithelium can almost always be removed without any problems, and the laser is almost always performed without difficulty.

After surgery, the immediate risk is delayed wound healing. Most eyes heal within 3-4 days after surgery, with younger patients healing faster than older patients. Occasionally, the eye heals more slowly and we need to continue contact lens wear longer, use ointments, put in punctal plugs to keep the eyes moisturized, patch the eye or sometimes remove redundant epithelium with forceps. Significant post-operative haze occurs rarely after this procedure, and when mild to moderate usually resolves over time without treatment. When severe (which is exceedingly rare) it can cause visual loss and must be treated, usually with repeat laser treatment and application of a medicine, mitomycin, to prevent further haze formation. We are now utilizing this medicine routinely in our **NuSite™** patients as a prophylactic treatment to prevent haze.

5) **LASIK risks and side effects**

There are rare but significant complications during the **LASIK** procedure. Occasionally during the procedure an abnormal flap is created. This can take the form of an incomplete or partial flap, an irregular flap, a free cap, a buttonhole flap, etc. When this occurs, the laser procedure sometimes can't be completed. The flap is replaced and the eye is allowed to heal without treatment. Sometimes the eye heals without visual loss in this situation, but scarring or irregularity may occur that could cause poor vision. Other procedures, (including, very rarely corneal transplant) might be needed to improve vision.

Post-operatively, the flap will sometimes develop microstriae (tiny folds) due to the mismatch of the flap curvature compared to the altered (lasered) curvature of the stromal bed. These folds can cause a decreased quality of vision or visual loss by creating an irregular curvature to the cornea (called "irregular astigmatism"). The treatment for these folds is lifting the flap in the operating room and stretching the flap out across the bed to attempt to "re-seat" the flap in a better position. Rarely, the folds are persistent and further attempts to eliminate them must be made using hypotonic solutions, repeat laser procedures or even suturing.

Another occasional problem with the flap is called epithelial in-growth, in which the edges of the epithelium grow beneath the flap. When this occurs only slightly, it is rarely a problem. But when it is more severe or progressive it can cause visual loss or even threaten the health of the flap. The therapy for this problem is to re-lift the flap and remove the epithelium. Unfortunately, recurrence of the in-growth is more common than the original in-growth and if it recurs, additional steps such as suturing may be needed.

Inadvertent trauma is also a concern after **LASIK**, and is a greater threat early in the healing process when trauma to the eye is more likely to dislodge the flap. The flap does adhere more strongly as time passes and the risk of dislodgement decreases but is probably never completely eliminated.

When the flap is created, the corneal nerves are cut, and the nerves subsequently have to grow back into the flap. This creates decreased nerve supply to the cornea resulting in a condition indistinguishable from "dry eye syndrome". Most patients only experience a temporary dry feeling in the eyes, which lasts for weeks to months and then resolves. This is treated with topical lubricants (artificial tears), punctal plugs or occasionally Restasis eye drops. Studies show that in some cases the cornea may never completely regain its full pre-operative nerve supply, and therefore dry eye problems could persist.

There are also rare problems with progressive steepening and thinning of the cornea after **LASIK**, known as “iatrogenic keratoconus”. This occurs because tissue removal in the cornea is performed at a much deeper level (compared with **NuSite™**) after making the flap, and the flap no longer contributes to the structural integrity of the cornea. This steepening and thinning leads to irregular astigmatism and poor vision which could require corneal transplantation.

6) Risks, outcomes and issues related to both procedures

Very rarely, the patient may have enough difficulty fixating during the laser portion of these procedures that we need to externally fixate the eye with the suction ring during the laser application. It is always better for the patient to “auto-fixate” voluntarily as all studies show this leads to better outcomes, fortunately the results are still good even when external fixation is necessary. Also equally infrequently, the patient may inadvertently fixate just off center of the target light and cause an oblique ablation of the cornea which could reduce vision or even cause double vision. This is virtually undetectable to the laser tracking system and the surgeon (very important to fixate on light!).

Intraocular pressure elevation does occur during placement of the suction ring and this pressure very rarely can lead to vascular problems (bleeding or occlusion) in the back of the eye or retinal detachment that could threaten vision. These problems are exceedingly rare and have never occurred at Virginia Beach Eye Center.

Infection of the cornea is very rare after these procedures (one in a few thousand cases). This can be treated with antibiotics successfully in most cases, but could potentially cause permanent corneal scarring resulting in vision loss in which case a corneal transplant might be necessary. No one has required a corneal transplant at Virginia Beach Eye Center for infection.

Irregular astigmatism is the term used to denote a mis-shapen cornea or one that is “out of round” as a result of the procedure itself or abnormal healing. In most cases the problem is small enough that the patient does not notice any ill effects. In other words, their vision has improved so much without glasses or contact lenses, that they do not notice the small decrease in their best vision with glasses or contact lenses. For instance, if the patient’s pre-operative uncorrected vision (vision without glasses or contacts) was 20/400 (big E on chart), and their post-operative uncorrected vision was 20/20, they would probably not notice if we could not improve their vision to 20/15 with glasses or contacts post-operatively, even though it was this good before surgery. That’s because their vision has improved so much without glasses or contacts that they are happy, and 20/20 vision is perfectly functional for all their visual needs. However, if your uncorrected vision was only 20/40 after surgery and we could not correct it to 20/20 with glasses or contacts, that would be a more significant problem. The small inconsequential loss of best corrected vision (1-2 lines on the eye chart) occurs approximately 1-2% of the time and again is rarely noticed by the patient, so requires no treatment. The more significant loss (>2 lines on the eye chart) occurs approximately 0.2% (1 in 500) of the time, and usually requires treatment if possible. Some cases will require re-treatment with the laser, others re-lifting the LASIK flap, and others medications or contact lenses. Rarely, the visual decrease could be permanent and treatable only by corneal transplant. No one has required a corneal transplant at Virginia Beach Eye Center for irregular astigmatism.

Night vision abnormalities can occur after these procedures. These take the form of halos, flare, starburst effect or a general decrease in vision quality at night. The VISX laser CustomVue procedure (which is used at Virginia Beach Eye Center) was the first FDA study of refractive surgery which actually showed a lower risk of night vision complaints after surgery compared with before surgery. This does not mean that you won't have problems; it just means it is rare. Patients noticing these effects generally report a decrease or elimination in the symptoms as healing occurs. At Virginia Beach Eye Center, no patient has ever wished they had not undergone refractive surgery because of night vision complaints. All patients who perform a critical night vision function (pilots, truck drivers, harbor pilots, etc.) may wish to reconsider having surgery if lowering of night vision would jeopardize their employment.

About 95% of patients will be happy with their visual results and have very low or no significant refractive error following one procedure. About 5% will have residual or induced near-sightedness, farsightedness or astigmatism following their procedure and will require a second procedure to improve the result. This "enhancement" procedure is performed at, or after, six months to insure that the eye has stabilized. In the **NuSite™** procedure, the same procedure is performed again. In **LASIK**, the original flap is lifted if possible, and the laser is again performed beneath the flap. If the flap cannot be lifted (rare), the **NuSite™** procedure can be performed over the flap with mitomycin application. Very rarely (one in hundreds), a patient will require a third procedure for residual refractive error.

These procedures can be performed either unilaterally or bilaterally. If both eyes are performed at the same surgical session, there is a very small chance of bilateral infection. If only one eye is operated, you cannot get a bilateral infection. Most patients choose bilateral surgery for convenience, which is standard of care, but the safest method would be one eye at a time. **NuSite™** patients sometimes choose one eye at a time so they always have one eye with excellent vision while the other eye is healing.

Most patients choose both eyes set for distance vision. Under age 40, your focusing ability is still intact, so each eye will be able to see both at distance and at near following your surgery. Sometime after age 40, your focusing ability will decrease to the point that if both eyes are set for distance, you will have to wear reading glasses for near. One strategy to obtain both distance and near vision following refractive surgery in patients over 40 is termed monovision. This means that one eye is set for distance (dominant eye) and the other set for near / reading vision (non-dominant eye). Approximately 50% of patients that try monovision like it and the other 50% are unable to tolerate the effect. It is therefore imperative to try this effect with contact lenses prior to surgery. Some vocations and leisure activities require excellent stereo (3 dimensional) vision, also called depth perception. These include surgeons, golfers, pilots, tailors, wood workers, tennis players, etc. Monovision reduces stereo vision and may effect your ability to do these and similar activities.

Alternatives to these therapies include continuing on with contact lenses or glasses. Some patients will do better with Refractive Lens Exchange (removal of natural crystalline lens with insertion of a plastic intraocular lens implant), especially patients with higher levels of far-sightedness, patients developing any significant cataract, and patients who desire both uncorrected near and distance vision who cannot tolerate monovision.

7) How to Choose the Procedure That is Right For You

Here at Virginia Beach Eye Center, **NuSite™** is our procedure of choice. There are less complications both pre and post-operatively and many studies show a tendency towards better visual acuity results and better visual quality results compared with **LASIK**. The **NuSite™** procedure does not significantly weaken the cornea, reducing or eliminating the possibility of long term biomechanical destabilization of the cornea (thinning and steepening). There is also less risk of eye trauma causing serious complications since there is no flap to potentially dislodge. So, at Virginia Beach Eye Center we believe that if your main criteria for choosing your procedure is long term safety and long term visual quality, **NuSite™** is your best choice.

So why would anyone choose **LASIK**? The main issue is convenience. **LASIK** patients almost always have better vision during the first few days and even weeks following the procedure. A less significant advantage is slightly better eye comfort during the first day or two following the procedure, but with the current medical regimen, this is a small difference. Therefore, if your main criteria for choosing your procedure is short term convenience and even shorter term comfort, then **LASIK** may be right for you.

8) Write Down Questions For Your Doctor

Please read and attest to the following statement by signing below:

“I have read and understand the material presented and my questions have been answered.”

Patient signature _____ Date _____

Witness _____ Date _____

Surgeon _____ Date _____