

Laser Vision Correction – Informed Consent Document Version 1-2013

Intralase LASIK (IntraLASIK, iLASIK)

Indication 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 to IntraLASIK

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 but not limited to LASEK (see below) and LASIK with a microkeratome (blade operated device).

LASIK-Specific Risks and Possible 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:

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 my surgeon may stop the procedure if my flap is not adequate (too thin/too thick/short/irregular etc...)
3. 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, blockage in the veins and arteries of the eye, cataract formation, total blindness and even loss of my eye.
4. I understand that I should keep my eyes closed for at least 4 hours after LASIK and avoid rubbing my eyes in the first week after surgery. Trauma to my eye could cause the corneal flap to dislocate either early on or even years later. Dislocation of the flap can lead to formation of flap folds, infection, scarring and loss of vision. 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, especially 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.
5. I understand that some patients may rarely experience light sensitivity after IntraLASIK that could last for months.
6. I understand that cells (inflammatory or from the surface layer) can migrate or move under the flap; the surgeon may need to lift the flap to clean the cells. Sometimes the surgeon may need to place flap stitches. I understand that cells under the flap may occur early or late after LASIK. Most small areas of epithelial ingrowth do not cause visual problems and are watched closely but that untreated larger areas may distort vision and may actually damage the flap if severe and getting worse.

LASER IN-SITU EPITHELIAL KERATOMILEUSIS (LASEK - Same applies to PRK)

LASEK or PRK refers to laser vision correction without the creation of a corneal flap. The surface epithelium is usually peeled off to allow laser reshaping of the underlying layer. A bandage contact lens is placed for a few days to help with comfort and healing. The goal of LASEK with the Excimer laser is to reduce or eliminate the need for contact lenses and/or eyeglasses;

however, I understand that as with all forms of treatment, the results in my case cannot be guaranteed and that I may need to wear glasses or contact lenses.

Alternatives to LASEK Surgery

The alternatives to LASEK include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to LASEK has been explained to me.

LASEK-Specific Risks and Possible Complications

I have been informed, and I understand, that certain complications and side effects have been reported in the post-treatment period by patients who have had LASEK, including the following:

Possible short-term effects of LASEK surgery

The following have been reported in the short-term post treatment period and are associated with the normal post-treatment healing process: moderate to severe discomfort or pain (first 72 to 96 hours), corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity, and tearing. It is impossible to predict how quickly your eye will heal. Some patients may experience delayed healing that will place them at a higher risk of infection and/or scarring. There is a possibility of loss of the bandage contact lens with increased pain (usually corrected by replacing with another contact lens); and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

Possible long-term complications of LASEK surgery

Haze (scarring): Loss of perfect clarity of the cornea, usually not affecting vision, which may or may not resolve over time. This can lead to blurry vision even with glasses or contact lenses. An anti scarring medication (Mitomycin c, see below) is recommended for patients who are at higher risk of scarring.

IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.

LASER VISION CORRECTION (LVC) RETREATMENT SURGERY

It is important to realize that even if you did not experience any difficulties with your original LASIK/LASEK/PRK (LVC) 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. Most risks associated with the original procedure still apply during the repeat procedure. This section covers some risks that occur with the retreatment.

Indications and Alternatives

As you were informed before your first LVC procedure, retreatments are at times needed to correct remaining or induced myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. There is no guarantee that repeat LVC will correct these problems. Alternative forms of vision correction exist, including eyeglasses, contact lenses, orthokeratology (ortho-K), radial keratotomy (RK), intracorneal ring segments (Intacs), and Conductive Keratoplasty (CK).

Eligibility

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. LASEK and PRK are performed by repeating the original procedure. 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. A retreatment can be performed once the vision and prescription (refraction) stabilize after the original procedure, which takes between three 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 small and stable residual prescription. 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 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.

Possible Side Effects and Complications

The risks associated with the original LVC procedure apply to retreatment as well (please read the appropriate sections). 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.

Contrary to the original procedure, a contact lens is placed after LASIK retreatment. 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.

Corneal Flap Complications

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.

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.

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.

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.

Corneal Healing Complications

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.

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.

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.

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.

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 reducing dependency on glasses or contacts. However, 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.

COMPLICATIONS ASSOCIATED WITH LASIK/LASEK AND PRK (LVC, Laser Vision Correction)

The below list of complications may be associated with LVC during the primary or the repeat procedure:

1. I understand this is an elective procedure and that LVC surgery is not reversible.
2. I understand that the long-term effects of LVC are unknown and that unforeseen complications or side effects could possibly occur.
3. I understand that I should follow alloral and written instructions related to my medications, follow up visits and postoperative care. Failure to do so may lead to loss of vision as severe as blindness.
4. I understand that there is a small chance that the whites of my eyes may temporarily appear pink or red for several days to several weeks after surgery.
5. I understand that my vision after surgery may not be clear immediately and that I might not notice improvement for several days to several weeks.
6. 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.
7. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the 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.
8. 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.
9. 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. I have discussed these risks in relation to my particular pupil size and amount of correction.
10. I understand that I may not get a full correction from my procedure and this may require future retreatment procedures, such as more laser treatment or the use of glasses or contact lenses.
11. I understand that there may be a “balance” problem between my two eyes after LVC 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.
12. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
13. I understand that there may be pain, irritation, or a foreign body sensation, particularly during the first 48 hours after the surgery. I also understand that pain may be associated with complications such as infection.
14. I understand that temporary glasses for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
15. I understand that irregular healing of the flap or the cornea itself 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 LVC. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
16. 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, flap removal, corneal transplantation or even loss of the eye.
17. 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 may be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before the 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.
18. I understand that I could lose the visual acuity I initially gain from LVC and that my vision may go partially back to a level that may require additional surgery, or require glasses or contact lenses to see clearly.
19. I understand that the correction that I can expect to gain from LVC 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 the surgery or years later. I understand that I may need to use contact lenses in the future and their fitting may not be as easy as before laser vision correction.
20. 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.
 21. 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.
 22. 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 typically 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.
 23. 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.
 24. A yearly eye exam is needed to constantly monitor my eyes after LASIK. I understand that it is best to inform my LASIK surgeon in the event of any trauma or new condition that may develop later on in life.
 25. **For Presbyopic patients** (those age 40 or above requiring a separate prescription for reading): 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. If I currently need reading glasses, I will likely still 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 Laser Vision Correction. The option of monovision has been discussed with me. (see below)

MITOMYCIN-C (MMC) WITH LASEK and PRK

Indications and Alternatives

The correction of high degrees of nearsightedness (or myopia) using the Excimer laser is associated with a higher chance of developing corneal scarring or “haze.” This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), have been associated with corneal haze in some individuals.

Since 1997, a medication called Mitomycin-C (MMC) has been used to treat patients who develop corneal haze. Several studies have shown that the use of MMC decreases the likelihood of developing haze after PRK, LASEK. For this reason, ophthalmologists are also using MMC prophylactically, as a preventive measure.

MMC is an antitumor antibiotic that has been used in the medical field for a number of decades. It is used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells, such as those seen in tumors. It also stops cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980’s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgery. The use of MMC for the treatment and prevention of corneal haze is a newer use of this medication.

Possible Complications of MMC

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corneal ectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

Although the complications listed above have been seen in various types of eye surgeries, no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery. This technique

uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for less than 90 seconds. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

Patients who received preventive MMC treatments have shown improvement in visual acuity and a decrease in corneal haze. No corneal haze developed during an average follow-up period of one year. However, there is no guarantee that you will obtain a similar result. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

My surgeon has indicated to me that I either have corneal haze, or that I may be more likely to develop corneal haze following PRK or LASEK. I have read and understood the information presented above about the risks, benefits, and alternatives to using MMC for both treatment and prevention of corneal haze. I have had the opportunity to ask questions and have them answered to my satisfaction.

I understand that administering MMC for treatment and prevention of corneal haze is considered an “off-label” use of an FDA-approved medication. When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a “label” to explain its use. Once a medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

I understand that there are no guarantees as to the success of the procedure for removing or preventing haze and that toxic side effects may develop.

I give my informed consent to my surgeon and/or his or her assistants to use MMC on the eye undergoing LASEK or PRK.

TRADITIONAL VERSUS CUSTOM TREATMENT (“Wavefront”-Guided Laser Vision Correction Surgery)

Indications and Alternatives

“Conventional” or “traditional” laser vision correction surgery refers to correction of spherical (near- or farsightedness) and cylindrical (astigmatic) refractive errors of the eye. Such treatment is rendered based upon measurements of the refraction, using lenses combined within an instrument called a phoropter.

“Wavefront”-guided treatment or “Custom” is based upon an imaging system called wavefront (aberrometer) measurement of the whole eye. In May of 2003, Visx received approval for its “CustomVue” treatments using their Wavescan aberrometer and S4 laser, with approval for hyperopia with astigmatism in December, 2004.

Wavefront measurement is relatively new to the eye care profession, having evolved around imaging and manufacturing applications in the fields of astronomy, aerospace engineering, and photography. Wavefront measurement is able to detect subtle imperfections in an optical system that contributes to imperfect focus of an image. “Sphere” and “cylinder” are referred to as “low-order aberrations,” while other optical factors comprise the “higher-order aberrations.” Higher-order aberrations include spherical aberration, coma, trefoil, and others. Most people are not at all familiar with these terms. Unfortunately, it is not easy to graphically or pictorially represent the influence that higher-order aberrations have on human vision.

A minority of patients treated with conventional laser treatment describe some visual difficulties after their treatment, including glare, haloes around lights, diminished comfort at night, and ghosting of images (among other things). Data presented to the FDA suggests that a significant amount of these adverse visual consequences may be reduced by wavefront-guided treatment. The data also suggest that with wavefront-guided treatment a higher percentage of patients achieve better visual acuity, and a lower percentage have complaints, even in reduced illumination. The research was performed in very tightly-controlled circumstances on a relatively small number of patients (several hundred) by a small group of surgeons (less than 10). These results have not yet been reproduced or confirmed in large-scale studies on thousands of patients treated by larger numbers of surgeons in diverse settings more typical of the public domain.

Candidates for Custom Correction

At present, the range of prescriptions treatable by wavefront-guided systems is narrower than the range of treatments approved for conventional treatment. The Visx Star S4 & WaveScan WaveFront System is approved for up to -11.75 D of myopia, with or without astigmatism up to -3.50 diopters, and for hyperopia with or without astigmatism up to +3.00D MRSE, with cylinder up to +2.00D.

Possible Advantages and Benefits of Custom Vision Correction

The advantages of wavefront-guided treatment may include:

A higher percentage of patients are reported to achieve better visual acuity (“20/20” and “20/15”) after wavefront ablation treatment than with conventional therapy. There is no guarantee that you will achieve these results. A lower percentage of patients report glare, halo, or discomfort with night vision after treatment.

The process eliminates some of the subjective component of the refraction measurement process (the “Which is better, one or two?” part).

Possible Disadvantages and Risks of Custom Laser Vision Correction

There are some potential disadvantages to wavefront-guided treatment. These include (but are not limited to):

Wavefront-guided treatment removes more tissue (typically 18 – 30% more) than conventional treatment.

Wavefront treatment is currently more expensive than conventional treatment, and the supposed benefit is intangible, as it cannot always be measured.

Wavefront measurements of the eye, like refraction measurements, can fluctuate somewhat from hour to hour, day to day, or week to week.

Custom or Traditional Treatment?

As with any elective surgery decision, you are well-advised to make your decision based upon multiple factors. Speak to your surgeon; do your research; consult the websites of the laser manufacturers and the FDA; and satisfy your own curiosity before making a determination.

If you are having a Custom treatment (Customvue wavefront), your treatment is considered “off-label” with LASEK or PRK. The latter means that the FDA approved custom treatments based on a Lasik (not LASEK) study and gave the physicians the discretion to decide with their patients whether Custom laser treatment with LASEK or PRK is appropriate for them.

MONOVISION (One eye corrected for distance and the other for near)

Vision-correcting surgery such as LASIK and PRK can precisely and accurately correct fixed focal errors of the eye such as nearsightedness, farsightedness, and astigmatism. These optical conditions are fundamentally different than presbyopia, the loss of adjustability of focus for near viewing. Presbyopia is the reason that reading glasses (magnifiers) become necessary, typically in the mid-40's, even for people who have excellent unaided distance vision. For those that require prescriptive correction to see clearly at distance, bifocals or separate (different prescription) reading glasses become necessary at that age to see clearly at close range.

There are several options available to those who are presbyopic, besides wearing bifocals or separate distance and reading glasses. For example, contact lenses can be worn for distance correction in both eyes, and dime-store reading glasses ("granny glasses") can be put on to read. For some individuals, wearing a contact lens in one eye for distance vision, and a contact in the other eye for reading, affords a reasonable solution. This is called monovision (mono for one; one eye for distance, one eye for near vision).

If a person enjoys and functions well with monovision in contact lenses, the same option can be created on a more permanent basis with vision-correcting surgery such as LASIK. If you are contemplating such correction for yourself, it is important to understand the advantages and drawbacks of such care.

At this time, there is no perfect treatment or cure for presbyopia. The typical solutions described above are all to some extent a compromise of one form or another. For many people, wearing eyeglasses for distance correction is troublesome enough, and wearing bifocals is even less pleasant. Many people dislike bifocals with a distinct line visible in the lenses, and are willing to sacrifice some degree of sharpness and clarity to eliminate the line (progressive, blended, or Varilux® lenses, for example). With increasing use of computers in our home and work, additional problems arise because we view computer monitors at a different distance and a different angle (from the horizontal) than typical written material.

Reduced depth perception: For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for distance. Eye care professionals refer to this as binocular vision. Monovision can impair depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is sometimes recommended that this option be tried with contact lenses (which are removable) prior to contemplating a surgical correction (which is permanent). We typically do not perform this monovision contact lens trial in near sighted patients as we found that their chance of not liking it and needing a touch up is as much as the distance eye (3%). Please inform your surgeon if you prefer to try this option with a contact lens.

Ocular dominance, and choosing the 'distance' eye correctly: This is especially important if you are contemplating monovision surgery. Ocular dominance is analogous to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant or preferred eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a particular person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near.

While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant (rather analogous to being ambidextrous), and in rare circumstances a person may actually prefer using the dominant eye for near viewing. The methods for testing and determining ocular dominance are not always 100% accurate; there is some subjective component in the measurement process; and different eye doctors may use slightly different methods of testing. It is critical to determine through use of contact lenses which combination is best for each person (right eye for distance, left for near; or vice versa) prior to undertaking any surgical intervention. You can imagine how uncomfortable it might be if monovision were to be rendered "the wrong way around". It might be compared to a right-handed person suddenly having to write, shave, apply make-up, etc. with the left hand. Be sure you understand this and have discussed with your surgeon which eye should be corrected for

distance, and which for near. If you have any doubts or uncertainty whatsoever, surgery should be delayed until a very solid comfort level is attained through use of monovision contact lenses. Please discuss with your surgeon whether a monovision contact lens trial is applicable in your situation. If you decide after discussion with your surgeon to proceed ahead with Monovision correction without a contact lens trial, there is a possibility you may have to undergo a retreatment if you are not satisfied with your vision. Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.

EXTENDED RETREATMENT AGREEMENT

The price you pay for your surgery includes the cost of repeat laser surgery if the surgeon decides it is necessary within the first year. Boston Laser provides for its patients the option of purchasing an Extended Retreatment Agreement for \$225/eye. This Extended Agreement refers to any repeat procedure performed after the one year Retreatment Agreement has been completed. If the surgeon determines that the surgery is needed, and that the patient's eye condition permits a retreatment, the laser surgery will be performed at no additional expense to the patient. I understand that I must complete the post-operative schedule for the first 12-months after my surgery with Boston Laser unless agreed differently with your surgeon.

This Agreement remains in effect as long as my surgeon or his colleagues are performing laser vision correction at Boston Laser. I understand that having yearly eye exams at Boston Laser would allow close monitoring of any patterns in my vision and will enhance the accuracy of future retreatments. Keep in mind that there is a limit on how many retreatments can be performed. In most cases 2 retreatments is the limit.

Exclusions

Annual Eye Exam- this is usually covered by your insurance.

Patients whose change in vision is a result of accident or trauma to the eye.

Patients who are diagnosed with eye disease such as diabetes, glaucoma, cataracts, diabetic retinopathy, retinal disorders or degeneration.

Patients who have had other ocular surgical procedures prior to having treatment at Boston Laser.

Patients whose repeat surgery is deemed unsafe to perform from a medical standpoint.

Patients with presbyopia leading to a natural decrease in near vision due to aging.

BILATERAL SIMULTANEOUS SURGERY

Laser Vision Correction (LVC) has become a common procedure for many refractive surgery patients. While many patients choose to have both eyes treated at the same surgical setting, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. If you elect to have surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.

Safety The risks of infection, severe inflammation, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have LVC performed on separate days, you avoid the risk of having one or more of these complications in both eyes at the same time.

Accuracy If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye. In some patients, this might improve the accuracy of the result in the second eye.

By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Visual Recovery Most LVC patients experience rapid visual recovery, but some may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the fellow eye while the first eye fully recovers. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes will usually be restored more rapidly if they are operated on the same day.

The healing LASIK corneal flap is most susceptible to trauma during the first several weeks after surgery. Should both flaps become accidentally displaced, significant visual loss in both eyes may result.

Satisfaction Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images,

increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the LVC procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects. If you are over age 40, you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

Convenience It may be inconvenient for you to have each eye treated at separate visits because it would necessitate two periods of recovery from the laser surgery and might require additional time away from work.

Cost Professional and facility fees are the same if the eyes are operated on the same or different days. Keep in mind that the additional time off work that may also be needed can be costly.

I have read and understand the above risks and benefits of bilateral simultaneous LVC, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous LVC. My doctor has answered all of my questions about the LVC procedure. I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.

PRE AND POST-OPERATIVE CO-MANAGEMENT SELECTION

Dr. Samir Melki, (or my surgeon), an ophthalmologist, will be performing laser vision correction surgery on me. Part of my preoperative testing may be performed by an optometrist or an ophthalmologist in training as deemed appropriate by my surgeon. I understand that my surgeon will review all my testing results in person and that my treatment is based on his assessment. On occasion, another ophthalmologist (Fellow) who is pursuing additional training in laser vision correction may participate in my clinical and surgical care. I understand that I have the option of requesting no fellow participation in my care. My first postoperative visit will be performed by an ophthalmologist. If I agree, either my own ophthalmologist/optometrist or an optometrist designated by my surgeon may perform part of the rest of my postoperative follow-up care. I have discussed this pre and postoperative selection with my surgeon.

I understand that my ophthalmologist/optometrist will contact Dr. Samir Melki, (or my surgeon) immediately if I experience any complications related to my eye surgery. I understand that I may also contact or see Dr. Samir Melki (or my surgeon) at any time after the surgery.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the requested procedure have been presented and explained to me by my ophthalmologist (surgeon). My ophthalmologist has answered all my questions to my satisfaction. I therefore consent to having the procedure I initialed on the first page of this document. I understand that, if I agree, some of my preoperative and postoperative care may be performed by an ophthalmologist or optometrist working in close association with my surgeon. I can request to see my surgeon at any time

during my care pathway. I also understand that on occasion a surgeon-trainee may be involved in my procedure under the direct supervision of my surgeon.

FOR WOMEN ONLY: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result.

I give permission for my ophthalmologist to record on my procedure on video or photographic equipment, 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 Refractive Surgery. 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 procedure will be performed.

My signature on the "Scheduling Consent" form indicates that I have read, understood and accept the information provided in the "Laser Vision Correction – Informed Consent Document Version 1-2013." All of my questions have been answered to my satisfaction.

Examples of Possible
Visual Side Effects

Glare



Halo



Starbursts



Hazy vision



Blurred vision



Distortion



Double vision

