

# **PRESBYLASIK INFORMED CONSENT FOR NEAR VISION MULTIFOCAL LASIK (LASER ASSISTED IN-SITU KERATOMILEUSIS)**

The intent of this document is to inform you as to the nature, risks and complications of laser assisted in-situ keratomileusis (LASIK). It is a lengthy and detailed explanation. It is not intended to frighten or dissuade you, or to imply that this surgery is dangerous. LASIK has been approved by the United States Food and Drug Administration for the correction of nearsightedness, farsightedness and astigmatism. The correction of presbyopia (difficulty reading without glasses as we age) is considered an off-label use of the excimer laser. Although rare, serious complications can occur. It is important to read this document thoroughly so that you have an understanding of unexpected complications that may arise. LASIK is an elective procedure. If you do not wish to accept any of these risks, you may elect not to have surgery.

Laser assisted in-situ keratomileusis (LASIK) is a surgical procedure that may permanently restore vision. Near Vision Multifocal LASIK combines the correction of myopia (nearsightedness) with or without astigmatism and hyperopia (farsightedness) with or without astigmatism with the correction of reading or near vision compromised by presbyopia. The information contained herein is provided to you so that you can make an informed decision about whether to undergo surgery for nearsightedness or farsightedness and presbyopia.

## **Focusing Problems**

In the normal eye, images carried by light rays enter the eye through the cornea, the crystal clear front of the eye. Passing through the lens near the center of the eye, the images are focused onto the retina at the rear of the eye. Vision occurs when these focused images are sent from the retina to the brain and are interpreted.

Presbyopia is an inevitable condition of aging. Its time of onset varies but usually occurs between the ages of 40 to 45 when individuals begin to lose their ability to see close objects with or without glasses. This occurs when the lens, the clear focusing portion of the eye, thickens and gradually becomes resistant to bending or focusing. This is not, as many people fear, a serious deterioration of the eye. It is simply part of the normal aging process.

Myopia, or nearsightedness, is a condition in which the individual can see clearly to read, but cannot see clearly in the distance without glasses or contact lenses. The cause is a combination of the curvature (power) of the cornea being too strong and/or the power of the crystalline lens being too strong and/or the eyeball being too long. These conditions focus the image in front of the retina. Glasses and contact lenses "push" the poorly focused image back towards the retina.

Myopia can be minimal, creating only slight blurring of distance vision. Patients with minimal myopia may be able to read most of the vision chart in the doctor's office without glasses. When myopia is moderate, patients are barely able to see the big E on

the chart without glasses or contact lenses. Such eyes have myopia between 2 and 6 diopters). High myopia exceeds 6 diopters.

Hyperopia, or farsightedness, is the reverse: the curvature of the cornea is too flat, causing images to focus behind the retina. As a result, in youth, most vision is clear because a young lens can add focusing power by a process we call accommodation. As the eye ages, accommodation is reduced by presbyopia. Glasses “pull” the poorly focused images forward toward the retina. For hyperopic individuals over 40 years of age, the focusing mechanism of the eye weakens. The focusing change (called accommodation) helps the farsighted person see well in the distance; but as one ages and this accommodative process deteriorates, distance and reading vision become blurred by presbyopia.

Since two-thirds of the focusing power of the eye is determined by the curvature of the cornea (the remainder is controlled by the lens), the greater the curvature of the cornea, the greater its focusing power.

In astigmatism, the curvature of the cornea, and therefore its focusing power, varies from one point of the cornea to another. In the normal eye, the corneal curvature is spherical--like the inside of a mixing bowl. With astigmatism, the cornea more closely resembles the bowl of a teaspoon--still curved, but unevenly so. The cornea and lens focus light rays at different points. In hyperopic astigmatism, both points focus behind the retina. In eyes with mixed astigmatism, one point focuses in front of the retina and the other point focuses behind the retina. The different points of focus permit only part of an image to be in focus.

When individuals can no longer tolerate contact lenses or when vocational or avocational goals demand good vision without optical devices for near and far vision, then the surgical correction of myopia, astigmatism, hyperopia and/or presbyopia can be considered.

## **Refractive Surgical Options**

Several refractive surgical procedures are currently available for the correction of refractive errors (such as myopia, hyperopia and astigmatism). Each procedure has specific benefits and risks, and different procedures correct different amounts of myopia, hyperopia and astigmatism. Some can correct astigmatism whereas others cannot. The current available procedures are **Excimer Laser Vision Correction**, or **Photorefractive Keratectomy (PRK)**, **Laser Assisted In-Situ Keratomileusis (LASIK)**, **Near Vision Multifocal LASIK**, **Near Vision Multifocal PRK**, **Toric PRK (astigmatism correcting)**, **Toric LASIK (astigmatism correcting)**, **Refractive Lens Exchange**, and **Refractive Lens Implant (Phakic IOL=s; ICLs)**.

The surgical elimination of nearsightedness will prevent an individual with presbyopia from performing every activity that requires focusing usually within arm's length or closer. If eyes are corrected for distance vision, near and intermediate vision (anything within an arm's length and closer) will be lost. Such reading activities may include focusing on a computer screen at 24 inches to reading small written material six inches

away. Other focusing activities may require focusing closer than 36 inches such as shaving, putting on make up, deskwork, cooking, painting fingernails, or threading needles, etc. Near Vision Multifocal LASIK is designed to treat both the distance and near vision so that individuals are able to perform most of their daily activities without the need for glasses or contact lenses.

Current surgical procedures available to treat presbyopia, with or without, nearsightedness, farsightedness and astigmatism, include Monovision LASIK or PRK, Near Vision LASIK or PRK, and Multi-focal or Accomodative Intraocular Lens Implants. Of these, only Accomodative and Multi-focal Lens Implants have received FDA approval to treat presbyopia. Monovision and Near Vision Multifocal LASIK are considered to be “off-label” uses of a surgical technique. The Near Vision Multifocal LASIK procedure is a combination of two currently FDA approved treatments. Many surgical techniques and medications are used in an “off-label” application. For example, until 2000, LASIK was an “off Label” use of the excimer laser. You should understand that it is the right and choice of the doctor and patient to use treatments “off label”. It is important that you be aware of and understand this FDA labeling status. For instance, the use of Aspirin on a daily basis to help prevent heart attacks is an off -label use of the medication.

## **The Near Vision Multifocal LASIK Procedure**

The information described herein is about the surgical correction of presbyopia in combination with or without, myopia (with or without astigmatism) or mild to moderate hyperopia (with or without astigmatism) using the LASIK procedure. LASIK was first performed in 1989 in Greece and was introduced to U.S. surgeons in 1990. The procedure involves two steps: first a flap is created and then an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea. LASIK involves creating a flap of corneal tissue using a microkeratome. After the flap is created, it is gently folded aside still attached to the cornea, and an excimer laser removes a special shape of tissue depending on the refractive error to be corrected. The corneal flap is then repositioned into its pre-surgical position without sutures. The excimer laser was approved by the US FDA in 1995.

The excimer laser produces a unique beam of ultraviolet light. When it comes into contact with a substance it does not produce heat or cause the substance to burn, as other types of lasers may do. Instead, the excimer light energy breaks molecular bonds and vaporizes tissue, a few molecular layers at a time without any heat damage. This special ability makes the excimer laser ideal for changing the shape of the eye’s cornea to correct focusing problems.

Near Vision Multifocal is performed using numbing (anesthetic) eye drops. Once the surgeon is certain the eye is numb, the eyelids are kept open with a small instrument to prevent blinking. While the eye is numb, the surgeon creates a flap of very precise thickness. This disk, or corneal flap, is gently folded aside. The excimer laser treatment is performed on the central cornea. The hinged corneal flap is replaced into its pre-surgical position. No sutures are used. The surface of the eye is dried with oxygen and is then flushed with antibiotic drops. The entire procedure is over in 10 -15 minutes. An eye shield is applied and is to be kept in place for 24 hours by the patient. In most instances bilateral, simultaneous surgery is performed.

## **After Surgery**

After surgery the patient may experience some mild burning and itching in the eye. It may feel as if there is something in the eye. Rarely will oral pain medications be necessary. On the evening of the surgery reading should be avoided, as it will irritate the operated eye. The shield will be removed the morning after surgery. For many patients the vision will be greatly improved after the shield is removed, whereas for others variable improvement will be noted at this time. Eye drops will be prescribed. These drops are vital in regulating the healing and ultimate surgical result. They *must* be used as instructed until the surgeon indicates otherwise.

**Vision may fluctuate up to 90 days. Vision may improve or worsen. Some patients may experience a reduction in clarity and best-corrected vision in the first week to one month. This tends to improve over time. Visual stability usually occurs within the first month.**

Once the vision is stable, for some patients whose eyes have under-responded to the treatment, thin spectacles may be needed. Further surgery to enhance the results may be indicated. The timing for enhancement correction is usually after 12 weeks or more following the initial surgery, and preferably six months. There is a small risk of losing some vision without glasses with enhancement surgery. The decision to perform enhancement surgery is made between the patient and surgeon after careful consideration of all influential factors.

## **Activities after Surgery**

Patients are able to return to work, in most cases, less than 24 hours after the procedure. Eye medications should be continued during working hours, as instructed by the surgeon. Most activities may be resumed almost immediately. The face, however, should not be placed under water for at least the first week following surgery, but showering with the eyes closed is acceptable. Care should be taken to avoid rubbing the eyes or trauma to the eyes. It is best to wear protective eye wear or an eye shield at all times. An eye shield should be placed over the eye at night for five days following the surgical procedure. Jogging, biking and aerobics are permitted. When only one eye is operated, it may be necessary to wear a contact lens in the unoperated eye or until the unoperated eye undergoes surgery.

## **Risks and Complications**

All eye surgery carries risk. It is not possible to list all risks here. Some of the most important are stated below.

**Undercorrection** - I may need to undergo additional surgery if I do not have my myopia, astigmatism or hyperopia completely corrected with the LASIK procedure.

**Overcorrection** - The procedure could create a farsighted condition in myopic patients or a nearsighted condition in hyperopic patients. In a nearsighted patient this could

create a farsighted condition where both distance and near vision are blurry. In this condition, glasses, contact lenses, conductive keratoplasty or hyperopic LASIK could be used to correct my condition.

**Presbyopia** – I understand I may need glasses to refine my vision for some purposes requiring fine detailed near vision at some point in my life and that this may occur soon after surgery or years later. I understand that if I currently need reading glasses, I may still need reading glasses for some activities after this treatment.

**Dry Eye** - I understand that following LASIK surgery, I may experience dry eye symptoms. This condition may be relieved by occlusion of my tear drainage system (punctal occlusion). LASIK does not affect tear flow, but it may temporarily decrease the ability of my cornea to detect dryness, which would make my eye feel dry.

**Keratoconus** – I understand that I could develop surgical keratoconus known as keratoectasia. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. Ectasia (corneal thinning) is a post-surgical condition resembling keratoconus. This occurs in approximately .01 to .7% of the 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. In both instances, mild keratoconus can be corrected by glasses or contact lenses. Severe keratoconus may need to be treated with intacs, collagen cross linking, or a corneal transplant.

**Infection** - I understand that infection is always a risk for any surgical procedure but that every precaution will be used to prevent the possibility of infection. Infection could lead to permanent corneal scarring and loss of vision.

**Corneal Scarring** - I understand that it is possible for scar tissue to build up underneath the top layer of my cornea in the area of the laser treatment. I understand that if scar tissue develops, it could reduce my best possible vision, even with the best glasses or contact lenses. I further understand that in this case the only possible means of improving my vision would be through additional laser surgery or possibly through corneal transplantation.

**Irregular Astigmatism** - I understand that it is possible that the top layer of my cornea may not be perfectly smooth following surgery. If this were to occur, my vision with glasses would not be as good as it possibly could be. I would either need to have the corneal flap relifted with or without additional laser surgery, I could wear a hard contact lens, or could undergo a replacement of the top layer of my cornea to treat this irregular astigmatism.

**Glare/Light Sensitivity** - I know that all surgical procedures for vision can create the condition of glare or light sensitivity, possibly even causing me to see halos around lights at night, although in most circumstances these conditions are temporary. I

understand that in a very small percentage of cases I could be permanently sensitive to light or see halos around lights at night.

**Double Vision** - I understand that if any part of the surgical procedure is not perfectly centered on the center of my vision, I could possibly have double vision. This double vision could also be caused by the natural wound healing of my eye. If I were to develop double vision I could undergo a replacement of the top layer of my cornea (the flap), additional laser surgery, wear a hard contact lens or possibly even need to undergo a corneal transplant.

**Flap Dislocation** - Once repositioned, the corneal flap does not form a seal for up to two weeks following surgery. A severe, direct blow to my cornea could dislocate this top layer, possibly necessitating suturing of the flap back into position. The suturing process carries with it all the known risks of surgery, including infection and irregular astigmatism.

**Occupational Restrictions** - I understand that vision correction surgery may disqualify me for employment in certain professions such as the military or law enforcement or from obtaining certain licenses or certifications. I accept the responsibility to learn what these restrictions may be and if they apply to me.

**Pregnancy (Females)** - I understand that I should not be pregnant or nursing at the time I undergo laser vision correction, since pregnancy could adversely affect my surgical outcome. You must let us know if you are pregnant, trying to get pregnant, or are breast feeding.

I understand that there are always rare and unforeseen complications that could occur and could permanently reduce my vision. I understand that with any surgical procedure on the eye there is always a risk of permanent loss of vision.

## **Alternatives to Near Vision Multifocal LASIK**

### **Glasses and Contact Lenses**

Presbyopic individuals may use near vision or multifocal (bifocal and progressive) glasses to improve their uncorrected vision. Spectacles may be worn and changed at any time. The only risk with glasses is potential damage to the eye following direct head trauma.

Contact lenses are another alternative for presbyopia correction and offer several choices, including contacts for distance vision used with reading glasses for close work; contacts fitted for clear close-up vision used with glasses for distance; bifocal contact lenses; or monovision contacts. Monovision contact lenses usually correct distance vision in the dominant eye and near vision in the non-dominant eye. This type of "blended" vision is generally accepted, but can inhibit depth perception. Bifocal contacts are available in both hard and soft lenses. The pros and cons should be discussed with a contact lens specialist.

Contacts may be worn and exchanged indefinitely. The risks with contact lenses are primarily infections, some of which may be permanently blinding. The risk of infection

increases significantly as one switches from daily wear to continuous or disposable wear

## **Surgical Alternatives to Near Vision Multifocal LASIK**

**Near Vision Multifocal Photorefractive Keratectomy** - PRK removes the superficial part of the center of the cornea to achieve corneal flattening for myopia and astigmatism and corneal steepening for hyperopia. This procedure does not weaken the cornea to the extent that LASIK does. Certain corneae are better treated with PRK, and your doctor will discuss this with you if applicable. Vision recovery is slower than LASIK. The major risk of PRK is scarring of the operated part of the cornea. Current PRK surgery is done using an anti-scarring agent, mitomycin, which has greatly reduced the incidence of scarring. This is an off label use of the medication. PRK is more painful in the first 24 hours than Z-LASIK.

**Lens Surgery: Refractive Lens Implants (ICLs), Refractive Lens Exchange** - These procedures operate inside the eye (they are intraocular procedures). Risks of intraocular surgery include cataract formation, retinal detachment, hemorrhage and infection. They can correct more myopia or hyperopia than LASIK or other procedures. These procedures may be combined with LASIK in certain circumstances. Intraocular Lenses are available in accommodative, multi-focal or monovision lens options.

## **Limitations of Surgery**

It is important to understand the limits of refractive surgery. Individual corneas respond differently to surgery, and each individual has a unique healing process. These factors make exact predictions of surgical results or the promise of perfect vision without corrective lenses or contact lenses after refractive surgery impossible. I understand and accept these facts.

## **Informed Consent**

It has been the purpose of this document to provide you with the information necessary to assist you in the decision to undergo the refractive surgical procedure known as Near Vision Multifocal Laser Assisted In Situ Keratomileusis (LASIK). The known benefits are to correct your presbyopia, myopia, hyperopia, and/or astigmatism and to improve your vision without corrective lenses. The alternative procedures and the risks of Near Vision Multifocal LASIK and other refractive surgical procedures have been described.

I have read this informative document about Near Vision Multifocal LASIK and understand the terminology about the procedure as it is used here. My surgeon has told me the risks, benefits and alternatives of Near Vision Multifocal LASIK and has addressed my concerns and answered my questions to my satisfaction. I am aware of the risks of the Near Vision Multifocal LASIK procedure and the known alternatives. I understand everything that has been said to me and that I have read in this informed consent. I freely sign this informed consent because it is my desire to undergo vision correction with the Near Vision Multifocal LASIK procedure.

I understand that bilateral surgery is usually done at the same time with Near Vision Multifocal LASIK treatments.

If you agree and desire the procedure done, please write the following sentences in your own handwriting:

**“My doctor and staff have answered all of my questions. I have been informed of the benefits, risks and alternatives of this procedure and I have read and I understand this informed consent document. I understand that Near Vision Multifocal LASIK is an “off label” LASIK use and am willing to accept the potential risks that my physician has discussed with me. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of Near Vision Multifocal LASIK are not known.” I also understand that, as with any medical procedure, no guarantees may be made.**

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### **Voluntary Consent**

Please sign below that you have carefully reviewed this informed consent document and that you have had opportunity to have any questions that you may have had answered. By signing below you also are aware that **PresbyLASIK** is an elective procedure, that you do not need to have this procedure, and that you understand your other surgical and non-surgical alternatives for vision correction. **You have been offered a copy of this consent form.**

\_\_\_\_ **I HAVE DISCUSSED AND ANSWERED ALL QUESTIONS ASKED BY PATIENT.**

\_\_\_\_ **I HAVE DISCUSSED ALL POTENTIAL RISKS AND COMPLICATIONS THAT APPLY TO PATIENT’S PROFESSION.**

**Surgeon Name (print):** Stanley D. Braverman M.D.

**Co-managing Doctor:** \_\_\_\_\_

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Patient Signature Date

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Surgeon Signature Date

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Witness Signature Date