

**FACTS YOU NEED TO KNOW ABOUT LASIK (LASER-ASSISTED IN SITU
KERATOMILEUSIS) FOR THE CORRECTION OF MYOPIA AND HYPEROPIA WITH
OR WITHOUT ASTIGMATISM AND MIXED ASTIGMATISM**

A Surgery to Reduce or Eliminate Myopia and Hyperopia with or without Astigmatism and Mixed
Astigmatism

PATIENT INFORMATION BOOKLET



Please read this entire booklet. If you have any questions about it, discuss them with your doctor before you agree to the surgery.

The MEL 90 is indicated for use in primary Laser-Assisted in situ Keratomileusis (LASIK) treatments for the reduction or elimination of:

- Myopia (nearsightedness) less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder (eye shaped more like a football than a basketball) up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia (farsightedness) up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older and whose nearsightedness, farsightedness, or astigmatism has changed by no more than 0.50 diopter in the year before surgery.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Contact:
Carl Zeiss Meditec USA, Inc.
5300 Central Parkway
Dublin, California 94568 USA
(925) 557-4100
Internet: www.zeiss.com/med/us

TABLE OF CONTENTS

	PAGE
GLOSSARY	5
INTRODUCTION.....	8
How the Eye Functions.....	8
Focusing with Your Eye	8
Checking Your Focus	9
The Nearsighted Eye.....	9
The Farsighted Eye	10
The Astigmatic Eye	10
WHAT IS LASIK?.....	10
How Does Lasik Reduce or Eliminate your Nearsightedness or Farsightedness with or without Astigmatism, or Mixed Astigmatism?	11
WHAT ARE THE BENEFITS OF LASIK SURGERY?.....	12
WHAT ARE THE ALTERNATIVES?	12
INDICATIONS FOR USE.....	FEHLER! TEXTMARKE NICHT DEFINIERT.
CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS.....	14
Contraindications – When You Should Definitely Not Have LASIK.....	14
Warnings – When You Should Consider Not Having LASIK	14
Precautions – Other Things That May Increase Your Risk of LASIK Complications	15
WHAT ARE THE RISKS OF LASIK SURGERY?.....	20
WHAT TO EXPECT BEFORE, DURING AND AFTER SURGERY?	23
Unrealistic Expectations about Surgery.....	23
Before the Surgery	24
The Day of LASIK Surgery.....	24
Immediately After the Surgery	25
First Days After Surgery.....	25
During the First Week Following Surgery	26
During the First Week to One Month Following Surgery	26
Three Months or Longer After Surgery.....	26
CLINICAL STUDY INFORMATION	27
Patient Characteristics	27
RESULTS TO EVALUATE RISKS	27
Distance Vision with Glasses (Best Vision) after Treatment	27
Adverse Events	29
Patient Symptoms Before and After the LASIK Procedure with MEL 90.....	31
RESULTS TO EVALUATE BENEFITS	35

Visual Acuity without Glasses Before and After LASIK.....	35
Vision without Glasses after LASIK Compared to Vision with Glasses before Treatment...	36
Accuracy of Correction.....	37
ARE YOU A GOOD CANDIDATE FOR LASIK?	38
QUESTIONS TO ASK YOUR DOCTOR	38
SELF-TEST	40
ANSWERS TO SELF-TEST QUESTIONS	41
SUMMARY OF IMPORTANT INFORMATION	42
PATIENT ASSISTANCE INFORMATION	44
PATIENT DECISION CHECKLIST.....	45

GLOSSARY

This section explains important terms in this booklet. Please discuss any related questions with your doctor.

Accommodation:	This is the process of changing the focus of the eye from distant objects to near objects.
Astigmatism:	A type of error in the focusing power of the eye caused by the eye being shaped more like a football than a basketball.
Cataract:	Cloudiness that develops (usually with the natural aging process) in the clear, natural lens of the eye that reduces vision.
Cornea:	Clear tissue located in the front of the eye covering the colored portion. Its shape determines most of the focusing power of the eye.
Cylinder:	Another term for astigmatism. A type of error in the focusing power of the eye caused by the eye being shaped more like a football than a basketball.
Diopter (D):	Unit of focusing power.
Dry Eye:	A condition in which the eye does not produce enough tears to stay moist and comfortable. Symptoms of dry eye include pain, stinging, burning, scratching, and blurring vision.
Ectasia:	A condition where the tissue of the cornea is too thin, leading to bulging in the central portion. This is a possible risk after LASIK is performed.
Excimer Laser:	A medical device used to remove tissue from the cornea with short pulses of ultraviolet light. It re-shapes the cornea to correct nearsightedness, farsightedness and mixed astigmatism.
Farsightedness or Hyperopia:	A vision condition where distant objects can be seen clearly, but ones that are up close may appear blurry. This is caused by a cornea that is too flat or an eye that is too short.
Femtosecond Laser:	A medical device used to make cuts within the cornea with short pulses of near-infrared light. It is also used to re-shape the cornea to correct nearsightedness.
Focal point:	The spot in your eye where the focused light rays come together.
Glare:	When bright light interferes with the ability to see. An example of the effect of glare would be driving at night and looking at oncoming headlights, resulting in difficulty seeing road signs or other vehicles.

Glaucoma:	A disease marked by increased pressure in the eye that may lead to damage of the optic nerve, the nerve that allows you to see.
Halos:	A fuzzy cloud or hazy ring seen around bright lights. Some patients may see halos when they do not wear their glasses or contact lenses and look at bright light.
Iris:	The colored tissue at the front of the eye that contains the pupil in the center.
Keratoconus:	Gradual thinning of the cornea resulting in a cone-shaped bulge in the center. This condition tends to run in families.
Keratectomy:	The surgical removal of corneal tissue
LASIK:	LASIK stands for “Laser Assisted <i>in situ</i> Keratomileusis.” LASIK is a type of surgery to treat nearsightedness, farsightedness, and astigmatism. A device called a microkeratome, which is like a carpenter’s plane, cuts a thin flap of tissue from the front of the cornea (clear part on the front of the eye). The same procedure can be performed with a femtosecond laser. The flap is then folded out of the way. Next, an excimer laser removes tissue from the front surface of the cornea to alter the shape and power. After the laser treatment, the flap is folded back over the cornea.
Lens:	A clear structure located behind the colored part of the eye (the iris). It helps to focus light on the thin layer of nerve cells in the back of the eye (the retina) to create a visible image.
Microkeratome:	A surgical tool that cuts a flap of tissue from the front surface of the cornea with a surgical blade or laser.
Mixed astigmatism:	A vision condition where one part of the cornea has nearsighted astigmatism and the other part has farsighted astigmatism.
Nearsightedness or Myopia:	A vision condition where objects far away appear blurry because the cornea is too steep or the eye is too long.
Ocular Hypertension:	Pressure inside the eye of more than 21 mmHg with no other signs of glaucoma.
Pellucid Marginal Degeneration:	Thinning of the lower outer edge of the cornea, where adjacent cornea may protrude.
Pupil:	The dark center of the colored part of the eye (iris) that allows light into the eye. It shrinks in bright light and enlarges in dim light.

Refractive Error:	Error in the focusing power of the eye such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.
Refractive Surgery:	A surgical procedure to reduce or eliminate an error in the focusing power of the eye.
Retina:	The thin layer of nerve cells in the back of the eye, responsible for converting light images into signals sent to the brain.
Spherical equivalent:	The average refractive power in diopters needed to correct the refractive error of the eye.
Visual acuity:	A measure of the clarity of your vision using a standard letter chart.
Vitreous:	A clear, jelly-like substance that fills the inside of the eye.

INTRODUCTION

This booklet is written to help you decide whether to have Laser Assisted in situ Keratomileusis (LASIK) surgery to eliminate or reduce your nearsightedness, farsightedness, or mixed astigmatism. Glasses and contact lenses also correct these conditions, as do other vision correction methods using lasers. This booklet refers to LASIK using the Carl Zeiss Meditec MEL 90.

If you are nearsighted (with or without astigmatism), farsighted (with or without astigmatism) or have mixed astigmatism in both eyes, both eyes may qualify for the procedure. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this whole booklet. Discuss your questions with your doctor. Your doctor can determine if you are a good candidate for LASIK, but only you can decide if the expected benefits are worth the risks. Please keep in mind that some jobs have vision requirements that may not allow for LASIK or other vision correction methods that use lasers.

How the Eye Functions

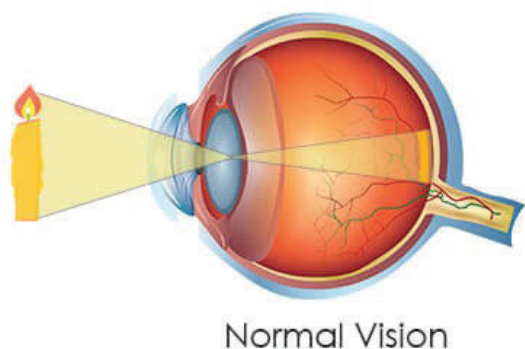
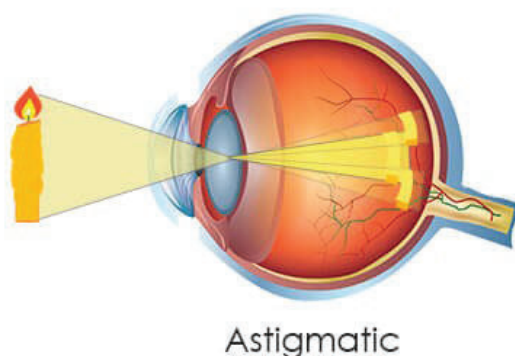
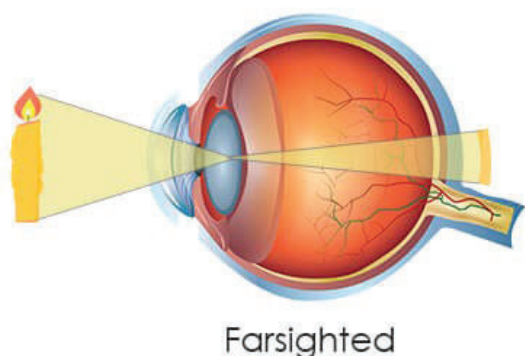
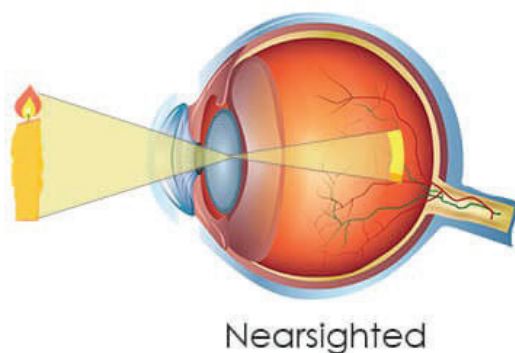
Your eye focuses light on the retina (the thin layer of nerve cells at the back of the eye) to form images, similar to how a camera creates pictures on film. Your eye takes the focused light, changes it into nerve signals, then sends it to the brain for processing. If your eye is out of focus, the image you see will also be blurred.

The cornea (clear front portion of the eye) bends the light toward your retina and accounts for two-thirds of the focusing power of the eye. The lens (a clear structure inside your eye) accounts for the other one-third of the focusing power of the eye. Together, the cornea and lens focus the light onto your retina.

Focusing with Your Eye

The eye focuses light by bending all light rays to meet at a single point. If the light focuses in front of or behind the retina, the image you see will be blurred. If you have perfect vision or are using the proper glasses or contact lenses, the object will be focused on the retina (Figure 1). If you have nearsightedness (Figure 2), the point of focus will be in front of the retina, resulting in blurry vision. If you have farsightedness (Figure 3), the point of focus will be behind the retina, resulting in blurry vision. If you have astigmatism, the light will be focused on multiple points on the retina, also resulting in blurry vision. You can have astigmatism alone or in addition to nearsightedness or farsightedness.

With the LASIK procedure, the goal is to sharpen the blurred image on the retina by removing a small amount of corneal tissue so you can see more clearly without glasses.

Figure 1-Normal Eye**Figure 2-Nearsighted Eye****Figure 3-Farsighted Eye****Figure 4-Astigmatic Eye****Checking Your Focus**

Your doctor checks where your eye focuses light. When the doctor corrects your vision, one or more lenses are added to place the focal point perfectly on your retina. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

The Nearsighted Eye

Myopia, also referred to as nearsightedness, is a common vision condition in which close objects are seen clearly but objects farther away are blurred. A common sign of myopia is difficulty seeing distant objects, like a TV or movie screen or street signs. Myopia occurs when the eye focuses light in front of the retina. This can be due to the shape of the cornea being too steep and/or the length of the eyeball being too long. Glasses or contact lenses can correct nearsightedness by correctly focusing the light right at the retina. Surgery options for changing the shape of the cornea, like LASIK and other vision correction methods that use a laser to remove a small amount of tissue to permanently reshape the cornea.

The Farsighted Eye

Hyperopia, also referred to as farsightedness, is less common than myopia (nearsightedness). Hyperopia occurs when the eye is too short for the power of its optical components. In hyperopia, the cornea is not steep enough and light rays hit the retina before they come into focus. Distant objects appear blurred, and nearby objects are even fuzzier. Most farsighted individuals need corrective eyewear to see clearly at all distances. Glasses or contact lenses can correct farsightedness by correctly focusing the light right on the retina. Surgical options for changing the shape of the cornea, like LASIK and other vision correction methods that use a laser to remove a small amount of tissue to permanently reshape the cornea.

The Astigmatic Eye

Astigmatism is a common vision condition in which the eye causes images to appear blurry and distorted. Most commonly, it occurs due to an irregular shape of the cornea, in which the cornea is not evenly curved like a basketball but shaped more like a football. This causes the eye to focus light on multiple points at the retina. Astigmatism often occurs with other vision conditions like nearsightedness and farsightedness. A special type of astigmatism called mixed astigmatism occurs when the eye has both nearsighted astigmatism and farsighted astigmatism occurring at the same time.

Glasses and contact lenses can correct astigmatism by correctly focusing the light in one point at the retina. Some types of astigmatism can also be treated by changing the shape of the cornea with procedures such as LASIK and other vision correction methods that use a laser to remove a small amount of tissue. To correct mixed astigmatism, the cornea needs to be flatter in one curve and steeper in the other curve. This will allow the eye to focus light at one spot on the retina.

WHAT IS LASIK?

LASIK is a surgical treatment for nearsightedness with or without astigmatism, farsightedness with or without astigmatism and mixed astigmatism. In a LASIK procedure, an excimer laser (a medical device used to remove tissue from the cornea) is used to reshape the cornea to improve the way the eye focuses light rays on the retina. A device called a microkeratome, which is like a carpenter's plane, cuts a thin flap of tissue from the front of the cornea. The same procedure can be performed with a femtosecond laser. The doctor then folds the flap out of the way.

Next, an excimer laser removes some tissue from the front surface of the cornea to change its shape. An excimer laser aims a strong beam of UV (ultraviolet) light at your eye. The laser is used to remove tiny amounts of tissue from the cornea of the eye using a series of small pulses each less than 1 mm (millimeter) in size, one microscopic layer at a time. This allows the excimer laser to reshape the cornea and focus visible light entering the eye correctly on the retina to provide improved vision. After the laser treatment, the doctor replaces the corneal flap back in place.

Doctors perform LASIK surgery on one eye at a time. In most cases, the doctor does the second eye on the same day. The doctor can also do it later; it depends on your case. LASIK is currently one of the most commonly performed elective procedures in the world. It is also the most popular form of refractive surgery that patients choose to correct common vision problems such as nearsightedness (myopia), farsightedness (hyperopia) and astigmatism.

How Does Lasik Reduce or Eliminate your Nearsightedness or Farsightedness with or without Astigmatism, or Mixed Astigmatism?

To correct nearsightedness with or without astigmatism, the cornea needs to be flattened in the center. The excimer laser eliminates or reduces your myopia by removing a small amount of tissue within the cornea, which is thicker in the center and thinner at the edge. When you have a significant amount of astigmatism, the tissue removed will be more round in one direction compared to the other direction (i.e. like a football), but the tissue removed is still thicker in the center compared to the edge.

To correct farsightedness with or without astigmatism, the cornea needs to be steepened in the center. The excimer laser eliminates or reduces your hyperopia by removing a small amount of tissue within the cornea, which is thinner in the center and thicker at the edge. When you have a significant amount of astigmatism, the tissue removed will be more round in one direction compared to the other direction (i.e. like a football), but the tissue removed is still thinner in the center compared to the edge.

To correct mixed astigmatism, the cornea needs to be flattened in one direction and steepened in the other direction. The excimer laser eliminates or reduces your mixed astigmatism by removing a small amount of tissue within the cornea, which is thinner in one direction and thicker in the other direction.

LASIK corrects your vision so you can see objects more clearly. It does not take away the need for reading glasses. Depending upon your age, you may need reading glasses even if you did NOT wear them before having LASIK.

INDICATIONS FOR USE

The MEL 90 is indicated for use in primary Laser-Assisted in situ Keratomileusis (LASIK) treatments for the reduction or elimination of:

- Myopia (nearsightedness) less in magnitude than -10.00 D sphere (in minus-cylinder notation), with and without cylinder (eye shaped more like a football than a basketball) up to -4.00 D, when MRSE is less in magnitude than -10.00 D;
- Hyperopia (farsightedness) up to +4.00 D sphere (in plus-cylinder notation), with and without cylinder up to +3.00 D, when MRSE is up to +5.00 D; and
- Mixed astigmatism with cylinder from >1.00 D up to 4.00 D;

in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in MRSE within +/- 0.50 D.

WHAT ARE THE BENEFITS OF LASIK SURGERY?

LASIK surgery using the MEL 90 Excimer Laser can correct nearsightedness with or without astigmatism, farsightedness with or without astigmatism and mixed astigmatism. Clarity of vision is measured using a standard letter chart (visual acuity). After the LASIK procedure, your visual acuity without glasses may improve, which means you may read smaller lines of letters on the eye chart. Your visual acuity without glasses after the LASIK procedure may be comparable or even better than your visual acuity with glasses before the procedure. It may reduce or end your need to use contact lenses or glasses.

The clinical study described at the end of this booklet found that LASIK surgery with the MEL 90 is a reasonably safe and effective way to correct nearsightedness with and without astigmatism, farsightedness with and without astigmatism and mixed astigmatism.

WHAT ARE THE ALTERNATIVES?

Alternatives to the LASIK procedure to have your nearsightedness with or without astigmatism, farsightedness with or without astigmatism and mixed astigmatism corrected might include glasses, contact lenses, surgery with another FDA approved laser using LASIK or other vision correction methods that use a laser, or a lens implant surgically placed inside the eye.

Glasses or contact lenses can correct a variety of refractive errors by correctly focusing the light right at the retina. Surgery options which correct vision using a laser procedure, permanently reshape the cornea since a laser is used to remove a small amount of tissue from your cornea.

You should consult your physician to determine if you are a candidate for these procedures and to discuss the risks/benefits of each alternative. Furthermore, important information about these alternative procedures is available at the following websites (accessed June 2023):

- FDA:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/default.htm>

- NEI: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/refractive-errors>
- AAO: <http://www.aao.org/eye-health/treatments/lasik>
- FTC: <https://www.consumer.ftc.gov/articles/0062-basics-lasik-eye-surgery#lasikbasics>

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications – When You Should Definitely Not Have LASIK

You should NOT have LASIK if you have any of the conditions described below. In these cases, the risk is greater than the benefit. You should not have LASIK if...

- Your cornea (the clear front part of the eye) is too thin to perform LASIK.
- You have any condition that causes thinning or bulging of the cornea (ectasia) including a cone-shaped cornea (keratoconus) or thinning of the bottom of the cornea (pellucid marginal degeneration).
- You have severe dry eye. LASIK may increase dryness. This may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery. It may result in poor vision after LASIK.
- You have an active eye infection or active inflammation (such as keratitis, iritis or uveitis). These may increase the risk of complications and should be cleared up before LASIK treatment.
- You have recently had a herpes eye infection or have corneal damage from a past herpes infection. These may put you at high risk for further corneal damage.
- You have an active connective tissue disease or active autoimmune disease (such as rheumatoid arthritis or lupus). If you have LASIK, there is risk of severe damage to your cornea.
- You have uncontrolled diabetes. If your blood sugar is uncontrolled, your eyeglass prescription can change, and your doctor will not be able to accurately determine what treatment is appropriate. If you have vision problems related to diabetes, the LASIK procedure may make them worse.
- You have uncontrolled glaucoma (a disease marked by increased pressure in the eye causing damage to the optic nerve, the nerve that allows you to see).
- You are pregnant or nursing, which can cause short-term changes in your cornea. Eyes of pregnant and nursing women can have changes due to hormonal changes, increased blood volume, fluid retention, and other physical shifts. These temporary changes in vision typically resolve after pregnancy or breastfeeding. Let your doctor know if you are pregnant or might be pregnant, or are nursing.

Warnings – When You Should Consider Not Having LASIK

If you have any of the following conditions, you should talk to your doctor before you decide to have LASIK, because you may be at greater risk for poor outcomes or injury related to LASIK. You should discuss your level of risk with your doctor. You and your doctor should determine whether the benefits of LASIK outweigh the risks for you.

- If you have a controlled autoimmune disease or connective tissue disease (such as rheumatoid arthritis and lupus). You may have slower healing and less predictable outcomes. Depending upon your disease, its severity, and the medication you are taking, there may be additional risks. Discuss these additional risks with your surgeon, after your surgeon has consulted with the other doctors who are treating you.
- If you have controlled diabetes. Even if your diabetes is well controlled, you may have poor healing following LASIK.

- If you have a weakened immune system due to medications such as steroids or chemotherapy, or a medical condition such as AIDS.
- A history of herpes (simplex or zoster) infection in your eyes. LASIK surgery might reactivate the herpes infection.
- If you have controlled glaucoma. There is greater difficulty in accurately monitoring eye pressure after LASIK. The steroid drops used after surgery may raise your eye pressure and cause glaucoma to worsen.
- You have been or are currently taking isotretinoin (Acutane®) as it can increase the risk of dry eye and abnormal wound healing.
- You have repeated attacks of sharp eye pain due to the outer layer of corneal cells rubbing off easily because the outer cells do not stick well to other corneal layers (epithelial basement membrane dystrophy). This procedure may worsen the condition.
- You have amblyopia, also called “lazy eye”, a condition in which vision is compromised in one or both eyes (even with glasses) due to communication problems between the eyes and the nervous system.
- Moderate or mild dry eyes. LASIK may increase the dryness causing discomfort and blurred vision. If you take certain medications, such as nasal decongestants or steroids, you are at greater risk of having dry eyes.
- You have difficulty following directions or are unable to constantly focus on a target.
- If you participate in activities that could damage the LASIK flap, including contact sports (e.g., football, hockey, etc.)

Precautions – Other Things That May Increase Your Risk of LASIK Complications

It is not known whether LASIK is safe and effective for the following conditions or situations. You should discuss possible risks with your doctor before you decide whether to have LASIK. If you have any of the conditions below, tell your doctor.

- The amount of nearsightedness, farsightedness, or astigmatism you have is greater than the amount in the approved indications for use.
- You have a difference of 0.75 D or more of total focusing power of your eye as measured by your doctor when your pupils are dilated (or enlarged) compared to when your pupils are not dilated.
- Your cornea in the middle is thinner than 480 micrometers
- If you are hyperopic (farsighted): the horizontal width of your cornea (so called white-to-white distance) is less than 11.5 mm
- If you have a family history of thinning of the cornea. Eye diseases like a cone-shaped cornea (keratoconus), thinning of the bottom of the cornea (pellucid marginal degeneration), and other conditions that may cause a thinning or bulging of the cornea can run in families. If thinning of the cornea has not been diagnosed for you but you have a family history of one of these conditions, LASIK may cause more rapid progression of the disease. You should tell your LASIK doctor about any family history of these or any other eye problems.

- If you have large pupils. Patients with large pupils may be at greater risk of experiencing visual symptoms, such as halos and glare. Ask your doctor whether you have large pupils.
- You have previously had a LASIK, or another corneal surgical procedure performed on your eye or any trauma to the area that will be treated with LASIK.
- History of “crossed eyes” (strabismus). If you are having LASIK for farsightedness and have a history of “crossed eyes” (strabismus), you may be at an increased risk of having double vision after surgery. Tell your doctor if you have ever had “crossed eyes” or double vision.
- You have problems with your iris (the colored part of the eye) including coloboma (a problem with the formation of either the eyelid or the eyeball that has been present since birth) or previous iris surgery as it may make eye tracking during your LASIK treatment more difficult.
- You have a history of keloid formation, which is a raised or thick scar after an incision has healed.
- You have active eye disease or your eyes are not normal. You have any condition leading to large amounts of eyelid debris (e.g. severe blepharitis or rosacea of the eye).
- You now have or previously had high pressure in your eyes or possibly have glaucoma.
- If you have allergies and rub your eyes. Rubbing your eyes after LASIK may dislodge the corneal “flap”. If you have severe allergies and take medicines for them, LASIK may be riskier for you, because symptoms of eye dryness, often associated with anti-allergy medication, may increase after LASIK.
- You take medicines that may affect wound healing such as antimetabolites, hormone replacement therapy and antihistamines. It is not known whether LASIK is safe and effective for you.
- Taking amiodarone hydrochloride. This medication is used to treat irregular heartbeats (ventricular arrhythmias) and can cause cloudy areas in the cornea and may cause problems with healing after LASIK. Tell your LASIK doctor about all the medications that you are taking.
- Taking sumatriptan. This medication is used to treat migraine headaches and may cause problems with healing after LASIK. Tell your LASIK doctor about all medications you are taking.
- You have had negative reactions to medicines before.
- You have a major mental illness.
- The safety and effectiveness of LASIK has not been established over the long term (more than 12 months after surgery).
- The structures of your eye in the path of vision are not completely clear. For example, corneal scars may affect the accuracy of LASIK.
- If you have a history of any eye disease (e.g., uveitis), abnormality, injury, or surgery. If you have a history of any of these conditions, you should discuss them with your LASIK doctor, as they might increase the risks of LASIK. For example, corneal scars may affect LASIK accuracy and vision following the surgery.
- Your doctor should determine if you have dry eyes, especially if you have had trouble wearing contact lenses.

- If you participate in any activities under poor lighting conditions, LASIK may cause you to have problems seeing in dim lighting, rain, snow, fog or when there is glare from bright lights, especially at night. You should discuss your activities with your doctor.
- You should be aware that the thinning of the cornea due to LASIK surgery may affect the accuracy of eye pressure measurements after LASIK, for instance when evaluating your eyes for glaucoma, and make them more difficult to interpret. For this reason, you should inform future eye care providers that you have had LASIK, so that they may be better able to interpret your eye pressure measurements.
- Future cataract surgery. Almost everyone needs cataract surgery (removal of your natural lens) later in life. LASIK may make it more difficult for the surgeon to implant the correct artificial lens.

Table 1 is a quick reference that you can use to start a conversation with your doctor about whether LASIK is right for you. If you are considering LASIK, mark those characteristics or conditions that you know apply to you.

TABLE 1. CHARACTERISTICS AND CONDITIONS CONSIDERED TO EVALUATE SUITABILITY FOR LASIK (TO BE DISCUSSED WITH YOUR DOCTOR)

	When you should not have LASIK (Contraindications)
	When you should consider not having LASIK (Warnings)
*	Other things that may increase your risk of LASIK complications (Precautions)

<u>Characteristics/Conditions</u>	<u>Check the box  if the characteristics Applies to You</u>
Dry Eyes	☐  If you have severe dry eyes ☐  If you have moderate or mild dry eyes
Cornea not thick enough	☐  If the clear front part of your eye is not thick enough
Thinning of the Cornea	☐  If you have any condition that causes thinning or bulging of the cornea, including, • Cone-shaped cornea (Keratoconus) • Thinning of the bottom part of the cornea ☐ *If you have a family history of thinning cornea
Eye Infection	☐  If you have an active eye infection
Eye Inflammation	☐  If you currently have an eye inflammation ☐ *If you have a history of any eye disease (e.g., uveitis), abnormality, injury or surgery
Herpes eye Infection	☐  If you have had a recent eye infection or problems resulting from a past infection ☐  If you have had a past eye infection
Autoimmune or Connective tissue disease (Rheumatoid Arthritis, Lupus)	☐  If you have had an active autoimmune or connective tissue disease ☐  If you have an autoimmune or connective tissue disease that is controlled
Glaucoma	☐  If you have uncontrolled glaucoma (your eye pressure is too high even with treatment) ☐  If you have controlled glaucoma ☐ * If you have elevated eye pressure, ocular hypertension) or are being followed for possible glaucoma
Pregnancy or Nursing	☐ * If you are pregnant or breast feeding
Diabetes	☐  If you have uncontrolled diabetes ☐  If you have controlled diabetes
Weakened Immune System	☐  If you have weakened immune system due to medication (such as steroids) or a medical condition (such as AIDS)

Characteristics/Conditions	Check the box ☐ if the characteristics Applies to You
Crossed eyes or Strabismus	☐ * If you had a crossed eye
Medications	☐ ⚠ If you take medication that have dry eyes as a side effect such as: • Isotretinoin • Steroids • Immunosuppressants ☐ * If you take any of the following medications: • Amiodarone hydrochloride • Sumatriptan • Antimetabolites • Hormone Replacement Therapy • Antihistamines
Large pupils	☐ *If you have large pupils
Allergies or eye rubbing	☐ *If you have allergies or rub your eyes
Having unstable prescription (Glass & Contact lens prescription has changed in the last 12 months)	☐ ⚠ If your glass or contact lens prescription has changed in the last 12 months
Activities	☐ *If you participate in activities that could damage the LASIK flap, including contact sports (e.g., football) ☐ *If you participate in activities that require good vision in poor lighting conditions to avoid (e.g., driving at night)
Repeated attached of sharp eye pain due to epithelial basement membrane dystrophy	☐ ⚠ If you have a condition in which the outer layer of corneal cells does not stick well to other layers (epithelial basement membrane dystrophy)
Decreased vision in one eye (amblyopia, "lazy eye")	☐ ⚠ If you have decreased vision in one eye
Severe redness, burning or itching of the eyelid (blepharitis)	☐ ⚠ If you have severe redness, burning or itching of the eyelid
Age < 18 years	☐ *If you are less than 18 years of age
History of Keloids	☐ *If you have history of Keloid
Problems with the cornea, lens, vitreous or iris	☐ *If you have a history of problems with the front of your eye, the lens of your eye, the jelly-like substance in your eye or the colored part of your eye

If you are considering LASIK, make sure you have been checked by your doctor for the characteristics and conditions above and let your doctor know if you have any of these characteristics or have ever experienced any of these conditions.

WHAT ARE THE RISKS OF LASIK SURGERY?

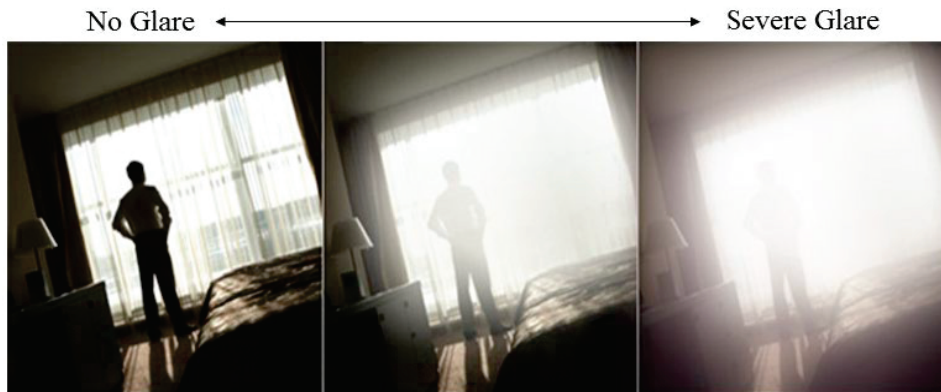
Some problems that patients experience after LASIK commonly occur right after surgery and are usually greatly reduced within 3 to 6 months. However, in some patients these problems can be permanent and, in rare cases, may impact their ability to perform daily tasks.

The risks of LASIK include, but are not limited to, the following:

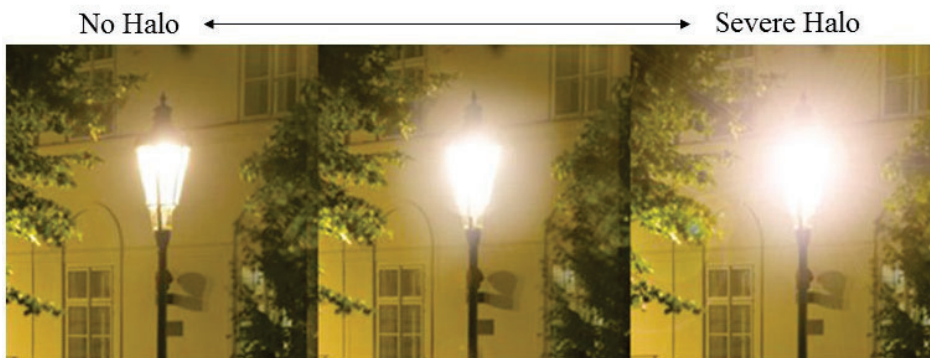
- **Loss of vision.** This means that vision may become unclear (blurry or hazy) even with glasses and contact lenses. In rare cases, your vision might be worse after LASIK even with glasses or contact lenses. Some of the potential causes of vision loss following LASIK are described below.
 - **Corneal Complications.** The following corneal complications may lead to permanent vision loss, for example, due to loss of corneal clarity from scarring or swelling, and in certain instances may require corneal transplant surgery for treatment.
 - **Corneal flap complications.** LASIK requires the cutting of the flap on the front-most part of the cornea. The flap is moved out of the way so the laser can treat underlying tissue and is returned to its original position after treatment. Flap complications include irregular cutting of the flap, the flap not properly returning to its original position, or the flap coming off and even getting lost, and irregular healing. If a flap complication occurs during surgery, the surgery may need to be interrupted and rescheduled. This can result in the need for additional surgery or, rarely, permanent loss of vision. The corneal flap can come loose or can be torn or cut off the eye completely and be lost, making your vision much worse.
 - **Infection.** The cornea may get infected right after surgery. This can be treated with topical (local) medication, which may or may not successfully control the infection. In rare cases, an infection may cause a hole in the cornea (clear covering of the eye).
 - **Inflammation.** Inflammation after LASIK is the body's reaction to tissue disruption during surgery or infection. Excessive inflammation of the cornea can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal clarity).
 - **Irregular corneal shape.** The LASIK surgical procedure or the healing process after surgery may result in an irregular shape to the cornea. This can cause blurry vision or other visual symptoms.
 - **Bulging of the cornea (corneal ectasia)** is the most extreme irregularity. This complication is uncommon, but can cause permanent and significantly blurry vision, sometimes requiring a corneal transplant.
- **Dry eyes.** LASIK may cause or increase eye dryness, which may also cause discomfort and visual problems. The doctor may see dry spots on the normally moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go away.

Your doctor should test you for dry eyes before you have LASIK. LASIK can make dry eyes worse, and it can give you dry eyes even if you did not have them before. Symptoms may include burning, feeling as though something is in the eye, excessive tearing, pain, redness, and blurred vision. In some cases, the symptoms interfere with the ability to do daily tasks.

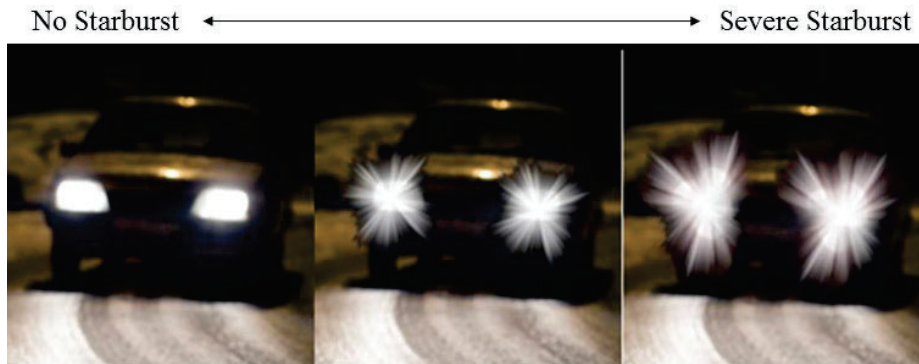
- **Discomfort or pain.** It is not unusual for patients to have some mild discomfort right after LASIK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities. A small number of patients may develop severe chronic pain that is resistant to therapy, caused by damages to the corneal nerves. This is known as “neuropathic corneal pain” and may be debilitating.
- **Visual Symptoms.** LASIK may cause or worsen visual symptoms, such as glare, halos, starbursts, and ghost images/double images, commonly experienced in dim lighting conditions as well as blurred and fluctuating vision. These problems usually improve within 3 to 6 months after surgery, but in some rare cases never go away, even when glasses are worn. Specific visual symptoms are described below with images to help explain the visual symptoms. The images shown may not represent exactly what you might see, and your symptoms may be more or less severe than what is shown below.
 - **Glare.** Glare is difficulty seeing well when there are bright lights like car headlights or sunlight, as shown in the images below.



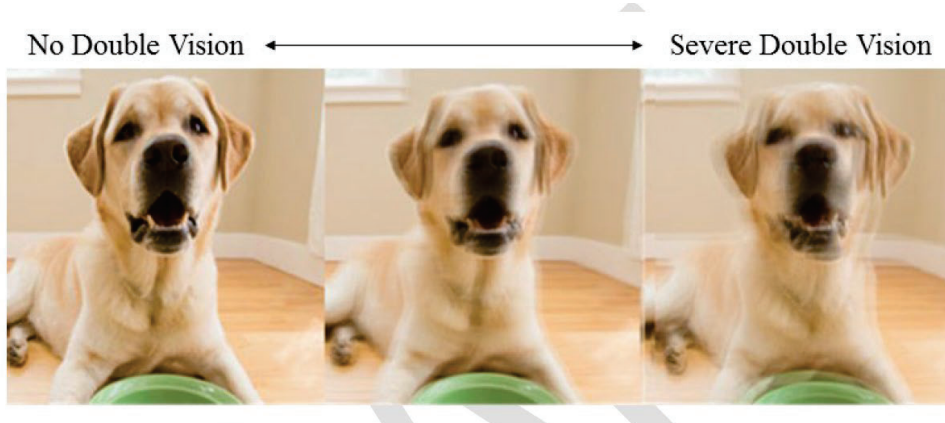
- **Halos.** You may see halos, a fuzzy cloud of light around lighted objects, such as the ones shown in the images below.



- **Starbursts.** You may see rays of light coming from lighted objects, such as in the car headlights in the images below.



- **Ghost images/Double vision.** You may experience distorted or blurry images in one or both eyes. If you think you are seeing two of the same image or double images: close one eye, and then the other eye to determine whether you only have this symptom. Let your doctor know at your next visit when you still see double images with one eye so the cause of this visual symptom can be determined.



- **Decreased ability to see in low light conditions.** After LASIK, you may have some difficulty seeing under low lighting conditions. You might notice some difficulty reading a restaurant menu in a dimly lit environment or moving around in a low light place such as a movie theater. Also, after LASIK surgery it might be difficult to drive under low light conditions, such as dusk, dawn or at night.

- **Desired correction not achieved.** LASIK may not result in the desired amount of visual correction, or the visual correction can gradually decrease over time due to natural processes, such as aging. When additional correction is needed, additional surgery may not be an option. You may have to rely on glasses or contact lenses to improve your vision.
- **Unintentional imbalance between two eyes.** Some imbalance between the two eyes may occur following LASIK. If both eyes are not able to focus at the same time and distance you may experience headaches, eyestrain, double vision, and reduced depth perception.
- **Need for glasses for close work.** Almost all people in their 40s or older lose their ability to focus from far to near (accommodation). LASIK does not treat this condition (called “presbyopia”). After surgery, patients who are already over 40 years old (or once they reach their 40’s) usually need to wear glasses for close work, such as reading, even if they did not need to wear them before surgery.
- **Drooping eyelid.** The lid of the eye(s) may droop after LASIK surgery. This can be a complication from an instrument used to hold the lid open during surgery. Besides uneven eyelids, this may result in a feeling of the eyes getting tired during the day or difficulty seeing. In some cases, eyelid surgery is needed to correct the drooping eyelid.

WHAT TO EXPECT BEFORE, DURING AND AFTER SURGERY?

Unrealistic Expectations about Surgery

Before LASIK, talk to your doctor about your expectations for LASIK surgery. Unrealistic expectations may lead you to be disappointed with the results of LASIK or cause you to make the wrong decision about whether to have surgery. You should discuss with your doctor whether your expectations are realistic, particularly about how LASIK will change your quality of life.

If you expect “perfect vision” and believe that you will never need to wear glasses again, then this is an unrealistic expectation. For most patients, it is realistic to expect to be able to perform most distance tasks without glasses. However, a significant number of people will not achieve 20/20 vision (normal eyesight) without glasses. Patients should consider whether they will be happy with less than “perfect vision” or will be able to do their work. Patients should consider whether they would be willing to wear glasses for certain activities such as driving at night, or for reading.

As people age, they lose the ability to focus their eyes from far to near. This usually occurs after forty years of age. If patients have their eyes fully corrected for distance vision, they will need reading glasses in middle age. In some cases, patients with LASIK surgery may need reading glasses sooner than if they had not had the surgery.

Before the Surgery

If you are considering LASIK, you will need an exam first to assess your eyes. This is to make sure your eyes are healthy and suitable for LASIK. This would include a medical exam and eye history. Both eyes will be checked.

CAUTION: If you wear contact lenses, the doctor will ask you to stop wearing them before your examination. For accurate eye measurements, you must stop wearing hard contact lenses for at least two weeks or soft contact lenses for at least one week before examination of your eyes. Failure to do this may lead to poor LASIK results.

Before LASIK, tell your doctor if you take any medications or if you have any allergies because they may cause healing problems. Also discuss whether you can eat or drink just before surgery. You should arrange to have someone drive you home after surgery and to your next doctor's visit. You should not drive after surgery until your doctor gives his permission.

The Day of LASIK Surgery

Before the day of surgery, you will be given a chance to hear the sounds the laser makes so you will be prepared for the noise. On the actual day of surgery, you will be given some numbing drops in the eye that will be treated. If necessary, the surgeon may also place a reference mark on your cornea to aid in alignment prior to the surgical procedure. This is a temporary dot made on your cornea with an instrument similar to a felt tipped marker. You will not feel any pain during this additional procedure. You will enter the surgery room where you will see one or more large machines with computer screens, a surgeon's chair, and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes 10 to 20 minutes in total, but the excimer laser is used for only about 30 to 60 seconds. The doctor will place a small spring-like device between your eyelids to hold them open. The surgery will be done in two steps. First a flap of your cornea will be created and then your vision will be treated.

When the flap creation surgery begins, the doctor will put a suction ring onto your eye. This will serve as a track for a small device called a microkeratome or the femtosecond laser. This device will create a thin flap of the corneal tissue. While this is done, your vision will become blurry. This is due to the suction ring, which can cause extreme, temporary increase in eye pressure. After the flap is made, the suction will be switched off. Then the doctor will lift the flap away from the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the blinking light. Try to keep both eyes open without squinting. A patch may cover the eye not having LASIK. This makes it easier to keep looking at the blinking light. Then you will hear the noise of the working laser. After correction of your vision with the laser, the flap of the corneal tissue will be placed back on the cornea.

CAUTION: It is important to keep looking right at the blinking light, even if the light fades or dims. Your results depend on how well you keep focus on this blinking light throughout the treatment.

Immediately After the Surgery

After LASIK surgery, your doctor will put medicine drops or ointment on your eye. Your doctor may apply a patch or shield to protect your operated eye(s) for better comfort.

Numbing drops make the surgery painless. When the numbing effect of these drops decreases, your eye will probably be painful for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so.

CAUTION: You should never rub or touch your treated eye after surgery! This can cause a shift of the flap, which leads to poor outcomes including blurred vision, risk of infection, inflammation, edema or epithelial in-growth (a condition where epithelial cells grow in between the undersurface of the flap and the front surface of the cornea, which can decrease the quality of vision).

First Days After Surgery

The patch or shield is usually removed by your doctor the next day after LASIK. Your eyes may be sensitive to light and glare. You can wear sunglasses to decrease your discomfort. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea is healing.

Your vision should stabilize within the next few weeks after LASIK. Some patients report small changes of their vision. These may be better or worse and can occur up to six months or more after LASIK.

You may see haze or cloudiness in the cornea after LASIK which tends to decrease over time. Usually, it does not affect your vision. In most cases it disappears by 12 to 24 months after LASIK. However, some patients continue to see haze.

Use the drops and lubricants that your doctor prescribes. Your results depend on following your doctor's orders. If you use topical steroids for a long time, your doctor will watch you for side effects. One side effect may be increased eye pressure of more than 21 millimeter mercury (mm Hg) (ocular hypertension) with no other signs of glaucoma. Increased pressure in the eye may damage the eye nerve fiber layer and cause loss of vision. Another effect of high eye pressure could be cataract formation. It also can cause a loss of vision.

WARNING: You should contact your doctor if you have eye pain, notice visual changes or loss of vision in the operated eye. These may be signs of a serious medical condition.

During the First Week Following Surgery

You may have pain and discomfort for up to 7 days after surgery.

You may have blurred vision and tearing as the cornea heals.

You may be sensitive to bright lights, or you may have a feeling of a foreign body on the surface of your eye.

You may have short-term swelling of the front surface of your eye or eyelids.

The pressure in your eye may increase. This is often due to the use of eye drops to control inflammation. To control this, your doctor may prescribe another eye drop, or stop giving you such drops. Increase of eye pressure does not usually cause any symptoms. But to be sure, your doctor will check your eyes for increased eye pressure. Severe increase in eye pressure could also cause eye pain or nausea. You should contact your doctor if you have any of these symptoms.

You must never rub your eyes. This can cause a shift of the flap, which leads to bad effects. These can include blurred vision, risk of infection, inflammation, edema, loss of cornea cells or cells to start growing under the LASIK flap, which can cause bumps in the flap.

During the First Week to One Month Following Surgery

The pressure in your eye may increase. This is often due to eye drops to control inflammation. The pressure goes back to normal when you stop the drug therapy.

Your cornea may become so hazy or cloudy that it affects your vision. This haze disappears over time and may be related to the cells being introduced between the corneal flap and underlying tissue. Some patients see haze up to 6 months after LASIK.

Three Months or Longer After Surgery

You may have a wrinkle in the inner layer of the cornea. This layer is made up of strong collagen fibers and helps the cornea maintain its shape. A wrinkle in the flap may be caused by rubbing the eye, eye squeezing or due to lack of the corneal tissue that was removed during the LASIK procedure. The wrinkles can be removed during re-lifting of the LASIK flap. Re-lifting of the flap may cause a decrease in best corrected visual acuity, which should return as the eye heals.

Some patients may have vision complaints and might experience a loss of best corrected vision (with glasses).

CLINICAL STUDY INFORMATION

A clinical study was conducted to evaluate the safety and effectiveness of the MEL 90 LASIK procedure for the correction of nearsightedness or farsightedness with or without astigmatism and for eyes with mixed astigmatism. The study included 714 treated eyes of 358 patients from 9 U.S. medical centers and was started in October 2019. Out of the 714 eyes receiving treatment, 358 eyes underwent treatment for myopia (nearsightedness) with or without astigmatism, 221 eyes underwent treatment for hyperopia (farsightedness) with or without astigmatism and 135 eyes underwent mixed astigmatism treatment.

Patient Characteristics

- Patients' ages ranged from 18 to 63 years, with an average of 36 years of age.
- 181 patients were females and 177 were males.
- 329 of the patients were white, 11 were black, 8 were Asian and 10 were of any other racial/ethnic group.
- Treatment ranges differed depending on the refractive error, measured in diopters (D), as follows:
 - For eyes with myopia with or without astigmatism, the amount of myopia treated ranged from 0.00 D to -10.00 D and the amount of astigmatism treated ranged from 0.00 D to -4.00 D.
 - For eyes with hyperopia with or without astigmatism, the amount of hyperopia treated ranged from 0.00 D to +5.00 D and the amount of astigmatism treated ranged from 0.00 D to +4.00 D.
 - For eyes with mixed astigmatism, the amount of hyperopia treated ranged from +0.25 D to +3.50 D and the amount of astigmatism treated ranged from -0.75 D to -4.00 D.

RESULTS TO EVALUATE RISKS

Distance Vision with Glasses (Best Vision) after Treatment

In the clinical study, distance vision corrected with glasses (distance vision with glasses, or best vision) was measured using a standard letter chart before the LASIK procedure and then at each of the follow up visits (1 day, 1 week, 3, 6, 9 and 12 month) after treatment. Table 2 shows the change in best vision with glasses. Most of the study patients experienced no change, meaning they did not lose any vision due to the surgery. Others experienced an improvement of at least one line on the vision chart. However, 35 patients at Month 6 showed a one-line decrease in best distance vision and only one patient had more than a two-line decrease in best vision. This patient's vision improved after the Month 6 visit to 20/25, a one-line decrease in best vision.

TABLE 2
CHANGE IN DISTANCE VISION WITH GLASSES (BEST VISION) AFTER SURGERY

Change in Best Vision	Week 1	Month 1	Month 3	Month 6	Month 9	Month 12
	Number of eyes out of 700	Number of eyes out of 686	Number of eyes out of 684	Number of eyes out of 685	Number of eyes out of 667	Number of eyes out of 675
More than 2 Lines Better	0	2	2	7	7	4
2 Lines Better	2	9	13	5	12	10
1 Line Better	102	117	118	129	125	152
No Change	518	519	526	508	504	488
1 Line Worse	74	36	24	35	19	21
2 Lines Worse	1	1	0	0	0	0
More than 2 Lines Worse	3	2	1	1	0	0

Table 3 presents the change in best distance vision at 6 months after the surgery in all three treatment groups. In the nearsighted (myopia) group, 246 out of 342 eyes could see as well with glasses after the LASIK procedure as they had seen before the procedure, and 76 eyes could see 1 line or better with glasses than before the procedure. Eleven myopic eyes could see 1 line less when compared with their vision with glasses before the procedure and one eye could see more than 2 lines less compared to the best vision before the procedure. In the mixed astigmatism group, 128 out of 132 eyes could see as well or better with glasses after the LASIK procedure as they had seen before the procedure and only 5 eyes could see one line less when compared to their best vision before the procedure. The majority of farsighted (hyperopia) eyes (162 out of 210 eyes) had no change in best vision with glasses after the procedure, whereas 27 eyes improved 1 line and 19 eyes lost one line of (best) visual acuity.

TABLE 3
CHANGE IN DISTANCE VISION AT MONTH 6 AFTER
SURGERY COMPARED TO BEST VISION WITH GLASSES BEFORE SURGERY FOR EACH TREATMENT GROUP

Change in Best Vision	Myopia Number of eyes out of 342	Hyperopia Number of eyes out of 210	Mixed Astigmatism Number of eyes out of 133	Total Number of eyes out of 685
More than 2 Lines Better	5	1	1	7
2 Lines Better	3	1	1	5
1 Line Better	76	27	26	129
No Change	246	162	100	508
1 Line Worse	11	19	5	35
2 Lines Worse	0	0	0	0
More than 2 Lines Worse	1	0	0	1

Adverse Events

An adverse event is any untoward medical occurrence in a patient or study participant. Adverse events can occur during the surgery or afterwards.

Table 4 contains a short description of adverse events that occurred during LASIK surgery as well as numbers of eyes in the study that experienced adverse events. Most of the events were related to particles being found underneath the corneal flap. Other events reported were defects in the flap or alignment and completion issues with the flap. The most significant event was treatment of astigmatism in the wrong direction due to a mistake while entering the treatment parameters into the laser. This can be easily prevented by careful checks of treatment information before treatment. The affected eye was later successfully treated with the laser, a process known as “secondary surgical intervention.” For more details see the next section below. One patient experienced a seizure during the procedure and the treatment could not be completed.

TABLE 4
ADVERSE EVENTS DURING SURGERY

Adverse Events During Surgery	Number of eyes out of 714
Particles present underneath the flap	14
Flap is not of the size and shape as initially intended	1
Flap not properly aligned when it was closed	1
Tear in the edge of the flap	1
Flap no longer connected at one edge	1
A portion of the edge of the flap, where it is connected, received laser pulses	1
Treatment was on wrong orientation (wrong cylinder angle direction)	1
¹ Interruption of LASIK procedure due to a seizure	2

¹ The seizure was unlikely related to the treatment by the research doctor; however, due to medical seriousness of the event, it was considered a serious adverse event.

A listing of adverse events reported after LASIK surgery and the numbers of affected eyes are presented in Table 5. The most commonly reported adverse events were dry eye and corneal epithelial cells present under the flap that were not removed during LASIK surgery. Corneal cells under the flap were associated with a decrease in best vision with glasses in one case only. There were two adverse events called “retinal detachment” and “melting of the flap” that might cause loss of vision. The “retinal detachment” was not related to the LASIK procedure. Both the “melting of the flap” and the “retinal detachment” were treated successfully without loss of best vision with glasses.

TABLE 5
ADVERSE EVENTS AFTER SURGERY

Adverse Events After Surgery	Number of eyes out of 714
Symptoms:	
Dry eye - patient indicated dryness and signs were seen clinically	20
Transient light sensitivity syndrome (TLSS) – the patient’s eye is sensitive to light after surgery, but the condition goes away	2
Corneal dryness - signs of dry eye were seen clinically	1
Foreign body sensation – the patient reported feeling that something was in the eye	1
Conditions related to the LASIK flap:	
Corneal cells (epithelium) present underneath the flap	8
Inflammation present underneath the flap	6
Corneal cells (epithelium) present underneath the flap with loss of 10 letters or more of best vision with glasses	1
Irregular flap margin	1
Melting of the flap	1
Conditions related to the Cornea:	
Corneal swelling between 1 week and 1 month after the procedure	4
Corneal swelling at 1 month or later	1
Corneal cut or scrape	3
Corneal epithelial defect – small area where there is a break in the surface of the cornea	1
Small folds in the cornea	4
Chemical splash in eye	1
Metallic foreign body	1
Foreign body	1
Conditions affecting the front of the eye:	
Conjunctivitis (eye redness) due to allergy	3
Conjunctivitis (eye redness) due to virus	2
Cut on the conjunctiva (white part of the eye around the cornea)	1
MGD (Meibomian Gland Dysfunction) – a decrease in the oils produced by the eyelids that help keep the tears on the surface of the eye	2
Conditions within the eye:	
Posterior Vitreous Detachment (PVD) – the natural gel within the eye has pulled away from its attachment around the optic nerve within the back of the eye	2
Vitreous syneresis – small pools of fluid are formed within the natural gel within the eye	2
Retinal detachment ¹ - a condition in which the retina of the eye is no longer attached within the eye as it should be	1
Eye infection or inflammation within the front portion of the eye	1
Increase in pressure within the eye 10 mmHg above the preoperative measurement on 2 consecutive visits or an eye pressure reading greater than 30 mmHg on 2 consecutive visits	1
Visual acuity:	
A decrease of 10 or more letters (2 lines on the eye chart) in best vision that is not due to astigmatism at 3 or more months after surgery	1
Loss of best vision with glasses	1
An additional surgical procedure to correct an outcome (secondary surgical intervention):	
A second laser procedure was completed to fix the initial treatment that was done at the wrong axis	1
Corneal cells (epithelium) present underneath the flap were removed	1
A procedure (Scleral buckle) to treat a retinal detachment	1

¹ The retinal detachment was not related to the treatment; however, because a retinal detachment can be sight-threatening, it was considered a serious adverse event.

Patient Symptoms Before and After the LASIK Procedure with MEL 90

At the visit before surgery (baseline) and Months 3, 6, 9, and 12 after surgery, the patients were asked to complete a questionnaire on visual symptoms that they experienced before LASIK surgery and after the surgery. The specific symptoms included in the questionnaire were double vision, glare, halos and starbursts.

Table 6 shows the number of patients who reported having any type of symptom, including patients reporting one or more symptoms. As shown in Section 1 of Table 6 (Number of patients reporting having symptoms), Baseline (before surgery) 252 patients out of 358 reported having symptoms. After LASIK surgery, the number of patients reporting symptoms decreased, especially those reporting double images and glare. Section 2 of Table 6, (Number of patients reporting development of symptoms) shows that some patients who did not have symptoms prior to LASIK surgery developed them, mostly halos and starbursts, after LASIK. Section 3 of Table 6 (Number of patients reporting the resolution of symptoms) shows that most patients with symptoms prior to LASIK surgery reported that symptoms disappeared after surgery. The rate of symptom resolution was similar for all four types of symptoms. Symptom occurrence and their resolution was nearly constant throughout the study through Month 12.

TABLE 6
VISUAL SYMPTOMS BEFORE AND AFTER SURGERY

Symptom Information	Baseline Number of patients out of 358	Month 3 Number of patients out of 341	Month 6 Number of patients out of 341	Month 9 Number of patients out of 331	Month 12 Number of patients out of 338
Section 1: Number of patients reporting having symptoms¹					
Any type of symptom	252	164	140	120	130
Double images	117	17	28	17	18
Glare	140	56	47	38	46
Halos	156	101	84	74	79
Starbursts	200	134	114	101	107
Section 2: Number of patients reporting the development of symptoms^{1,2}					
Any type of symptom	-	74	65	52	56
Double images	-	6	10	6	3
Glare	-	20	17	14	16
Halos	-	42	36	26	29
Starbursts	-	43	29	31	32
Section 3: Number of patients reporting the resolution of symptoms					
Any type of symptom	-	201	196	195	199
Double images	-	101	92	92	93
Glare	-	97	101	104	102
Halos	-	89	98	96	99
Starbursts	-	99	107	114	115

¹ The symptom was considered present if it was experienced either with or without glasses

² Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

In Table 7, a list of visual symptoms reported at the Month 6 visit for each treatment group is shown. Section 1 of Table 7 (Number of patients reporting having symptoms) shows that halos and starbursts were the most reported symptoms in all three groups. Symptom development and resolution was also similar across the three groups. Table 7 also shows whether patients felt symptoms caused them difficulties performing activities due to symptoms (Section 4 and Section 5 of Table 7) or whether they were bothered by the symptoms (Section 6 and Section 7 of Table 7). Importantly, some patients reported having some difficulties due to symptoms but only 4 patients in the hyperopia group and 2 patients in the mixed astigmatism group reported that they had “very” or “extreme” difficulty due to symptoms. Only 1 myopia patient, 7 hyperopia patients and 3 mixed astigmatism patients reported that they were “very” or “extremely” bothered by the symptoms.

TABLE 7
VISUAL SYMPTOMS AFTER SURGERY AT MONTH 6 FOR EACH TREATMENT GROUP

Symptom Information	Myopia Group Number of patients out of 174	Hyperopia Group Number of patients out of 110	Mixed Astigmatism Group Number of patients out of 76	Total Number of patients out of 341
Section 1: Number of patients reporting having symptoms¹				
Any type of symptom	54	57	36	140
Double images	6	17	6	28
Glare	24	15	9	47
Halos	33	32	23	84
Starbursts	45	45	28	114
Section 2: Number of patients reporting the development of symptoms^{1,2}				
Any type of symptom	24	30	14	65
Double images	4	5	2	10
Glare	7	7	4	17
Halos	14	16	8	36
Starbursts	11	13	5	29
Section 3: Number of patients reporting the resolution of symptoms				
Any type of symptom	93	68	49	196
Double images	38	38	21	92
Glare	49	38	23	101
Halos	52	29	21	98
Starbursts	58	31	25	107
Section 4: Number of patients that reported difficulty performing activities due to symptoms				
Any type of symptom	35	36	18	85
Double images	5	8	4	16
Glare	11	11	6	27
Halos	16	17	9	40
Starbursts	27	27	12	64
Section 5: Number of patients with “very” or “extreme difficulty” performing activities due to symptoms				
Any type of symptom	1	4	2	7
Double images	1	1	1	3
Glare	0	0	0	0
Halos	0	2	0	2
Starbursts	0	2	1	3
Section 6: Number of patients that reported bothersome symptoms				
Any type of symptom	44	49	24	112
Double images	6	14	5	24
Glare	19	14	8	40
Halos	27	25	14	63
Starbursts	36	35	17	86
Section 7: Number of patients with “very” or “extremely” bothersome symptoms				
Any type of symptom	1	7	3	10
Double images	1	2	1	4
Glare	0	1	0	1
Halos	0	3	0	3
Starbursts	0	5	2	6

¹ The symptom was considered present if it was experienced either with or without optical correction.

² Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

The study patients were asked to assess the symptoms of dry eye using the Ocular Surface Disease Index (OSDI) survey. They were asked their experience during the week prior to the study visit about five (5) dry eye symptoms, including light sensitivity, grittiness, ocular pain or soreness, blurred vision and poor vision and the impact of three (3) environmental triggers for dry eye, including windy conditions, low humidity, and air-conditioned environments. The results of the eight questions were recorded as their “combined dry eye score”.

Patients who had a “combined dry eye score” between 0 and 12 were classified as “normal” meaning that they had none or minimal dry eye symptoms. Alternatively, patients were classified as having “mild” (scores between 13 to 22), “moderate” (scores between 23 and 32), or “severe” (scores between 33 to 100) dry eye disease symptoms. Based on this rule of classification, Table 8 shows that after surgery, the number of patients who had “normal” dry eye symptoms increased slightly, and fewer patients had “mild”, “moderate”, or “severe” dry eye symptoms.

One thing to note is that these “normal”, “mild”, “moderate”, and “severe” labels are from a published study that used more questions in calculating the “combined dry eye score”. Since this study used fewer questions (8 versus 12 in the published study), the results in this study may not reflect dry eye symptoms as well as the full questionnaire. The results in Table 8 may over- or underestimate the true number of participants in each category.

TABLE 8
COMBINED DRY EYE SCORE BEFORE AND AFTER SURGERY

	Baseline Number of patients out of 358	Month 3 Number of patients out of 341	Month 6 Number of patients out of 341	Month 9 Number of patients out of 331	Month 12 Number of patients out of 338
Normal	217	232	250	255	269
Mild	80	76	62	54	48
Moderate	33	16	15	12	5
Severe	28	17	14	10	16

Categories for score: normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100)

RESULTS TO EVALUATE BENEFITS

The effectiveness, or benefit, of the procedure was determined by the improvement in vision without glasses and the accuracy of the procedure to reduce the need for glasses. Seven-hundred and fourteen (714) eyes were treated in the study; however, some patients either missed a visit or did not return to the doctor during the study. As a result, the number of eyes changes across all the visits through Month 12.

Visual Acuity without Glasses Before and After LASIK

In the clinical study, vision without glasses was measured using a standard letter chart before the LASIK procedure, and then at each of the follow up visits after LASIK. Just like the acuity for best vision with glasses, acuity without glasses is presented using Snellen acuity values, such as “20/20 vision” which represents “normal vision” or “20/40 vision” which would indicate “vision worse than average” or “20/15” which would mean “vision better than average”. At the Month 6 follow-up after treatment, 676 out of 684 eyes were seeing 20/40 or better, 488 eyes were 20/20 or better (“normal vision”), and 243 eyes were 20/16 or better (“better than normal vision”).

TABLE 9
VISION WITHOUT GLASSES AFTER TREATMENT

Vision without glasses	Month 6 Number of eyes out of 684	Month 12 Number of eyes out of 674
20/16 or better	243	259
20/20 or better	488	511
20/25 or better	616	616
20/32 or better	663	662
20/40 or better	676	668

Table 10 shows the vision without glasses at Month 6 for eyes in each of the treatment groups. Most eyes in all three groups had 20/40 or better vision without glasses at this visit. In terms of achieving 20/20 or better vision without glasses, 295 of 342 nearsighted (myopia) eyes, 102 of 210 farsighted (hyperopia) eyes and 91 of 132 mixed astigmatism eyes achieved this level.

TABLE 10
VISION WITHOUT GLASSES AT MONTH 6 AFTER TREATMENT
FOR EACH TREATMENT GROUP

Vision without glasses	Myopia Number of eyes out of 342	Hyperopia Number of eyes out of 210	Mixed Astigmatism Number of eyes out of 132	Total Number of eyes out of 684
20/16 or better	168	31	44	243
20/20 or better	295	102	91	488
20/25 or better	324	175	117	616
20/32 or better	334	200	129	663
20/40 or better	338	206	132	676

Vision without Glasses after LASIK Compared to Vision with Glasses before Treatment

Table 11 shows a comparison of vision with glasses before LASIK to vision without glasses after the procedure, in terms of lines on an eye chart. At 6 months following surgery, more than half of the treated eyes (362 of 712) saw as well or better *without* glasses than they did before *with* glasses. The myopia (nearsighted) group had almost two-thirds of eyes achieving this level at Month 6 (230 of 342 eyes); while the hyperopia (farsighted) and mixed astigmatism eyes achieved a lower proportion at Month 6 and slight improvements at Months 12.

TABLE 11
NUMBER OF EYES AFTER LASIK ACHIEVING THE SAME OR SUPERIOR VISION WITHOUT GLASSES
COMPARED TO VISION WITH GLASSES BEFORE LASIK

	Month 6	Month 12
Total Eyes		
Number of eyes out of 684	362	399
Myopia Group		
Number of eyes out of 342	230	237
Hyperopia Group		
Number of eyes out of 210	68	84
Mixed Astigmatism Group		
Number of eyes out of 132	64	78

Accuracy of Correction

To determine how accurate the LASIK procedure was, the amount of vision correction measured for the eyes after LASIK procedure (achieved correction) was compared to the amount of planned vision correction (attempted correction). Table 12 shows the accuracy for all treated eyes and for each treatment cohort 6 months after surgery, the time point at which the correction was determined to be stable. Of all treated eyes, the accuracy was within ± 0.50 diopter of attempted correction in 614 out of 684 eyes and within ± 1.00 diopter in 670 out of 684 eyes. The accuracy was very similar across all the three treatment groups.

TABLE 12
ACCURACY OF CORRECTION AT MONTH 6 AFTER TREATMENT
FOR EACH TREATMENT GROUP

	Myopia Number of eyes out of 342	Hyperopia Number of eyes out of 210	Mixed Astigmatism Number of eyes out of 132	Total Number of eyes out of 684
results within ± 0.50 D of attempted correction	318	174	122	614
results within ± 1.00 D of attempted correction	338	203	129	670

The accuracy of the astigmatic correction with the LASIK procedure was determined in a similar way. The amount of astigmatic correction (also called cylinder) that was measured for eyes after treatment (achieved correction) was compared to the amount of correction they were supposed to receive (intended correction). Table 13 shows the accuracy of the astigmatic correction for all treated eyes and for each treatment cohort 6 months after surgery. Of all eyes that received an astigmatic correction, the accuracy was within ± 1.00 diopter of attempted correction in 526 out of 538 eyes and within ± 0.50 diopter in 477 out of 538 eyes. The accuracy of the astigmatic correction was very similar across all the three treatment groups, as shown in Table 13.

TABLE 13
ACCURACY OF ASTIGMATISM CORRECTION AT MONTH 6 AFTER TREATMENT
FOR EACH TREATMENT GROUP

	Myopia Number of eyes out of 252	Hyperopia Number of eyes out of 154	Mixed Astigmatism Number of eyes out of 132	Total Number of eyes out of 538
results within ± 0.50 D of attempted correction	234	130	113	477
results within ± 1.00 D of attempted correction	249	149	128	526

ARE YOU A GOOD CANDIDATE FOR LASIK WITH THE MEL 90?

To have LASIK, you must:

- Be 18 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have nearsightedness with or without astigmatism, farsightedness with or without astigmatism, or mixed astigmatism within the range of treatment.
- Have proof that your vision has not changed more than one half diopter (0.50 D) for at least one year before your pre-surgery exam.
- Be fully informed about the risks and benefits of LASIK procedure as compared to other treatments for nearsightedness, farsightedness with or without astigmatism, or mixed astigmatism.
- Be able to lie flat on your back without difficulty.
- Be able to keep your eye on the blinking fixation light during the whole LASIK process.
- Be able to tolerate eye drops to numb your eye.

QUESTIONS TO ASK YOUR DOCTOR

You may want to ask the questions below to help you decide if LASIK procedure with the MEL 90 is right for you.

- What are the other options to correct nearsightedness, farsightedness with or without astigmatism or mixed astigmatism?
- Will I have to limit what I do after the LASIK procedure? If yes, what kind of restrictions and for how long?
- What are the benefits of LASIK for my level of nearsightedness, farsightedness with or without astigmatism or mixed astigmatism?
- What quality of vision can I expect in the first few months after LASIK?
- If LASIK does not correct my vision, could my vision become worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after LASIK?
- How is LASIK likely to affect my need to use glasses or contact lenses when I get older?
- Will my cornea heal differently if I injure it after LASIK?
- Should I have LASIK surgery on one eye only or should I have LASIK on both eyes on the same day?
- If LASIK will be done on one eye, how long will I have to wait before I can have LASIK surgery on my other eye?
- What vision problems will I have if I have LASIK surgery on only one eye?

Discuss the cost of LASIK procedure, medications after LASIK and any necessary follow-up care with your doctor. Most health insurance does not cover LASIK for vision correction in the USA.

SELF-TEST

Are you an informed and educated patient?

Take the self-test below to see if you can correctly answer these questions after reading the patient booklet.

Number	Question	TRUE	FALSE
1.	LASIK surgery is risk-free		
2.	It does not matter if I wear my contact lenses when my doctor told me not to.		
3.	The laser does all the work; I just have to lie on the chair.		
4.	After the surgery, there is a good chance that I will be less dependent on eyeglasses.		
5.	I may need reading glasses after laser surgery.		
6.	There is a risk that I may lose some vision after the LASIK procedure.		
7.	It does not matter if I am pregnant.		
8.	Even if I have an autoimmune disease, I am still a good candidate for laser vision correction.		

ANSWERS TO SELF-TEST QUESTIONS

1. FALSE
2. FALSE
3. FALSE
4. TRUE
5. TRUE
6. TRUE
7. FALSE
8. FALSE

SUMMARY OF KEY RISKS

1. LASIK Surgery Information

LASIK may not result in the desired amount of vision correction. Even if your vision results are generally good, you may still need glasses or contact lenses to perform certain tasks, and the results achieved may decline over time.

During LASIK surgery, a flap is cut in the cornea and corneal tissue is vaporized:

- Corneal tissues and nerves cut during this process must heal following surgery. Corneal nerves may not fully recover resulting in dry eyes and/or chronic pain.
- Even after the corneal flap has fully healed, the cornea will not be as strong as it was before surgery.

2. Considerations for a good candidate for LASIK surgery

You are not a good candidate for LASIK if:

- You have severe dry eyes.
- Your cornea is not thick enough.
- Your doctor has told you, you have a condition that causes corneal bulging, such as keratoconus or pellucid marginal degeneration.
- You have problems resulting from a past herpes infection.
- You have an autoimmune disease or connective tissue disease.
- You are pregnant or nursing.

3. What to expect in the first 6 months?

Dry eye following surgery is common and the symptoms of dry eye, including blurred vision, can vary from mild to severe. You may need to regularly use lubricating eye drops to manage dry eye symptoms.

You may experience visual symptoms such as glare, halos, starbursts, and double images. Severity of visual symptoms varies in patients who experience them. Though rare, some patients may have "very" or "extremely bothersome" symptoms.

Some patients may have "a lot of difficulty" or "so much difficulty that I can no longer do some of my usual activities" when not wearing glasses or contact lenses.

4. Long-Term Risks

Although rare, there have been reports that some patients, who have had LASIK, have experienced severe depression or suicidality that they believe to be a result of complications following the procedure. A definitive causal link between LASIK and these reported psychological harms has not been established.

Dry eye may persist beyond six months.

Some patients may also experience persistence of certain symptoms:

- Continued eye drops daily for dry eye

- Visual disturbances, such as glare, halos, starbursts, and double vision
- Decreased ability to see under low light conditions, with moderate difficulty or a lot of difficulty driving at night
- Very rare reports of severe, constant pain that may prevent normal activities.

PATIENT ASSISTANCE INFORMATION

PRIMARY DOCTOR

Name:

Address:

Telephone Number:

LASIK DOCTOR

Name:

Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:

Address:

Telephone Number:

LASER MANUFACTURER

Carl Zeiss Meditec AG
Carl Zeiss Promenade 10
Jena, Germany 07740

SALES AND SERVICE

Carl Zeiss Meditec USA, Inc.
5300 Central Parkway
Dublin, California 94568 USA
(925) 557-4100

PATIENT DECISION CHECKLIST

To the Patient considering LASIK surgery:

Your review and understanding of this document is a critical step in making the decision about whether you should choose to have LASIK. You should carefully consider the benefits and risks associated with the surgery before you make any decisions. This checklist outlines the important discussion items you should talk about with your doctor.

Vision Correction Options

I understand that eyeglasses or contact lenses are proven methods for vision correction, and alternative surgical methods for vision correction. I was also informed of the associated benefits and risks of other alternatives. I understand that LASIK may not result in the desired amount of vision correction. Even if my vision results are generally good, I may still need glasses or contact lenses to perform certain tasks, and the results achieved may decline over time.

I understand that during LASIK, a flap is cut in the cornea and tiny amount of corneal tissue is then permanently removed by the laser beam

- Corneal tissues and nerves cut during this process must heal following surgery. Corneal nerves may not fully recover and result in dry eyes and/or chronic pain.
- Even after the corneal flap healed, the cornea will not be as strong as it was before surgery.

Patient Initials _____

Considerations for a good candidate for LASIK

I understand that I should not have LASIK while I have an active eye inflammation or infection.

I understand that I am not a good candidate for LASIK if:

- I have severe dry eyes.
- My cornea(s) is not thick enough.
- My eye doctor told me that I have a condition that causes thinning or bulging of the cornea, such as keratoconus or pellucid marginal degeneration.
- I have problems after herpes infection in the eye.
- I have an autoimmune disease or connective tissue disease (like lupus or rheumatoid arthritis) or diabetes.

Patient Initials _____

What to Expect in the First Six Months

- On the day of LASIK procedure, I understand that I will need to be able to lie flat on my back for at least 20 minutes, that instruments will be gently placed in my eye to keep it opened for the duration of the procedure, and that I will be asked to look directly at a blinking light, while the LASIK procedure is being performed by the eye surgeon.

Patient Initials _____

- I understand that I may experience some symptoms like light sensitivity, glare, or see cloudiness during the healing phase after LASIK, and my vision begins to stabilize during the first few weeks after LASIK procedure. Sunglasses and lubricating drops can reduce these symptoms during the healing process.

Patient Initials _____

- I understand that it may take several months before my vision gets stable (e.g., up to 6 months) and I may experience my vision going from better to worse, and vice versa as the healing process continues during this time.

Patient Initials _____

- I have reasonable expectations for vision quality after LASIK and that I may probably wear contact lenses or glasses). I understand that LASIK treatment is permanent, and I may have to take certain protective precautions with my eyes after surgery if I participate in certain activities (e.g., sports).

Patient Initials _____

- I understand that I may have some long-term vision impairment after LASIK. This may be blurriness or haziness, while driving at night, or functioning in low light environments (for example, movie, theatre, reading a restaurant menu, etc).

Patient Initials _____

- I acknowledge that in some rare cases some patients who experienced severe depression and suicidality after LASIK procedure believed that their symptoms might be associated with complications following LASIK procedure.

Patient Initials _____

Confirmation of Discussion about LASIK Surgery using the MEL 90 Excimer Laser

Patient: I acknowledge that I have received and read the MEL 90 Patient Brochure. I had the opportunity to discuss the items above along with any other additional questions I had about my surgery with my eye doctor. I have been informed of and understand both, the benefits and risks, of LASIK procedure as they apply to me, and my specific visual health. Additionally, I had enough time to learn about the alternatives to LASIK, such as contact lenses, eyeglasses, and other surgical treatments along with their risks and benefits.

Patient Signature

Date

Physician/Optomtrist: I acknowledge that I have discussed the content of the MEL 90 Patient Brochure with this patient and shared with them the benefits and risks of LASIK surgery using the MEL 90. This discussion with my patient included the items above in the Patient Decision Checklist, and any questions he/she had about their upcoming surgery. I have also explained the benefits and risks for the alternative treatments available to treat their eye condition. I have encouraged the patient to freely ask questions, and I have addressed all questions and concerns.

Physician/ Optometrist Signature

Date

Manufacturer

Carl Zeiss Meditec AG

Goeschwitzer Str. 51-52
07745 Jena
Germany

Phone: +49 3641 220 444

Fax: +49 3641 220 442

Email: support.refractivelaser@zeiss.comInternet: www.zeiss.com/med

Distributor

Carl Zeiss Meditec USA, Inc.

5300 Central Parkway
Dublin, CA 94568
USA

Toll Free: +1 877 486 7473

Phone: +1 925 557 4100

Fax: +1 925 557 4101

Email: support.refractivelaser@zeiss.comInternet: www.zeiss.com/med/us

000000-2179-684-PatInf-MEL 90 mod.

51 Con-en-US-18112024

MEL 90