

**Facts You Need to Know About
IDESIGN System Driven Laser Assisted
In-Situ Keratomileusis (LASIK)
Procedure for Monovision**

Patient Information Booklet

For Monovision Treatment of Presbyopic Patients with Low to Moderate Nearsightedness (Myopia) with and without Astigmatism

Please read this entire booklet. Discuss its contents with your doctor. Make sure your doctor answers all your questions to your satisfaction. Ask all questions you may have before you agree to the surgery.

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GLOSSARY

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

Antibiotic Medication: a drug used to treat or prevent infection.

Anti-inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. They may be a corticosteroid, or a non-steroidal anti-inflammatory drug.

Astigmatism: The cornea and lens focus light rays from horizontal and vertical lines at different distances from the retina. The multiple focal distances result in blurred vision. Astigmatism may occur alone or along with nearsightedness and other refractive errors.

Automated Lamellar Keratectomy (ALK): a type of surgery used to correct vision by removing a small piece of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

Cataract: opacity or clouding of the lens inside the eye that can cause a loss of vision.

Collagen Vascular Disease: a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

Coma: a complex focusing error that makes off center images appear distorted, like the tail of a comet.

Contraindications: any special condition that results in the treatment being inadvisable.

Cornea: the clear front surface of the eye.

Corneal Haze: a cloudiness of the cornea that occurs rarely after LASIK.

Corneal Ulcer: an infection of the cornea that may result in a loss of vision.

Diopter (D): a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object.

Herpes Simplex: a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or blisters to appear on the face or other parts of the body.

Herpes Zoster: a type of infection caused by a virus that can recur. Blisters typically appear on only one side of the body.

Immunodeficiency Disease: a condition that alters the body's ability to fight infection. An example is AIDS.

Intraocular Pressure (IOP): fluid pressure inside the eye.

iDESIGN[®] Refractive Studio: the **iDESIGN[®] Refractive Studio** is a diagnostic instrument to objectively measure the refractive errors of the eye. The **iDESIGN[®] Refractive Studio** also measures the surface of your eye (topography) as well as other eye data.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

Keratometry: is a measurement of the corneal curvature determines the power of the cornea.

LASIK: a type of surgery used to correct vision by creating a flap in the cornea using a femtosecond laser or a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

Lens: a structure inside the eye that helps to focus light onto the back of the eye. Also an optical instrument for forming an image by focusing rays of light.

Microkeratome: an automated surgical tool that cuts a flap of tissue from the front surface of the cornea with a blade or laser.

Monovision: a clinical technique for visually correcting presbyopia by treating one eye for viewing close up and the other eye for viewing far away.

Myopia: a refractive error in which the eye focus light rays from distant objects in front of the retina. This causes images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: another term for myopia.

Ocular Hypertension: an increase in the pressure inside the eye.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the top surface of the cornea using an excimer laser.

Presbyopia: is the normal age-related loss of ability to focus on near objects.

Pupil: the opening in the iris that controls the amount of light entering the eye.

Pupillometry: the measurement of the diameter or width of the pupil of the eye

Radial Keratotomy (RK): a type of surgery used to correct vision by flattening the cornea with a scalpel.

Refract: to bend or focus rays of light.

Refraction: the focusing power of a lens or eye.

Refractive Error: a focusing error of the eye. The eye does not bring light rays to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

Regression: a decrease in the amount of vision correction after LASIK surgery.

Retina: the back surface of the eye. The retina senses focused light. It transfers signals to the brain.

Spherical aberration: a complex focusing error that makes images appear distorted, like they have a halo around them.

Wavefront: a surface representing the cross-section of the paths that light rays follow as they travel through the eye.

Wavefront error: simple and complex focusing errors in the eye that reveal differences in the paths of light rays as the eye bends them.

Wavefront Error Maps: a color map that displays wavefront errors measured by the *iDESIGN*[®] *Refractive* Studio.

INTRODUCTION

iDESIGN[®] System driven LASIK (laser assisted *in situ* keratomileusis) Treatments may help nearsighted patients with *presbyopia* see well close-up and far away. Presbyopia is the gradual loss of the eye's ability to focus close-up, such as for reading. Presbyopia gets worse with age. *Monovision* is a method used to visually correct presbyopia. The goal of monovision is for you to use one eye (your dominant eye) for seeing far away and one eye (your non-dominant eye) for seeing close up. Most people are able to ignore the image from the eye that is not in clear focus when both eyes are working together.

Having nearsightedness in one eye may enable you to see up close. You may already have an ideal amount of nearsightedness to see close up. You may only need treatment in your other eye for seeing far away. If you have one or both eyes treated, the result is monovision if the dominant eye sees at distance and the non- dominant eye sees close up.

Your doctor and **AMO**, provide the information in this booklet to help you decide if you should have an **iDESIGN**[®] System driven LASIK Treatments to reduce your need for glasses or contact lenses. There are other ways to correct both your distance and near vision. You can wear bifocal glasses or multi-focal contact lenses. You can wear contact lenses of different strengths in each eye to have monovision. There are other surgical options. Traditional **iDESIGN**[®] System driven LASIK Treatments can correct both eyes for seeing far away and you can wear reading glasses when needed. RK (radial keratotomy) and ALK (automated lamellar keratectomy) are also available.

Since monovision corrects one eye for seeing far and the other eye for seeing close up, the two eyes may not work together as well as they did before. This might be noticed more in dim light or when performing tasks requiring very sharp vision. You may still need to wear glasses or contact lenses to correct both eyes for distance when driving at night or operating dangerous equipment. You may still need to wear glasses or contact lenses to correct both eyes for near when reading small print.

Some patients cannot get used to having one eye blurred at all times. **If you are considering an iDESIGN[®] System driven LASIK Treatments, find out if you can tolerate monovision by wearing monovision contact lenses before having the surgery performed on your eyes.** Find out if you can pass your state's driver's license requirements with monovision.

Consider how much your doctor expects your presbyopia to increase in the future. Ask your doctor when glasses may be required to see close up objects clearly.

Please read this booklet completely. Ask your doctor any questions before you decide if ***IDESIGN***[®] System driven LASIK Treatments is right for you. Only an eye care professional trained in laser vision correction can decide if you are a good candidate. Some people, such as pilots, have job-related vision requirements and cannot have Monovision LASIK.

If after Monovision LASIK you have problems getting used to your vision, you may wish to have your eyes treated again to remove the unequal vision. Discuss the risks of a second treatment with your doctor.

How Refractive (Wavefront) Errors Affect Your Vision

The eye works like a camera that focuses images onto film. The *cornea* and *lens* of the eye bend light rays to focus on the *retina* at the back of the eye.

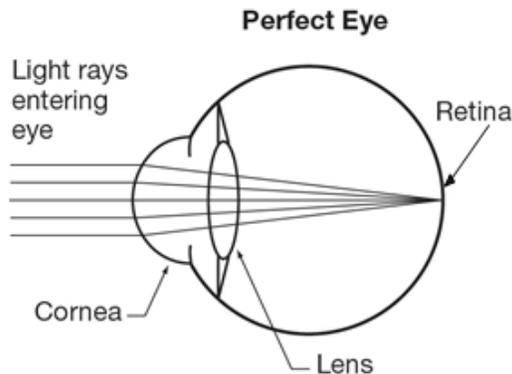


Figure 1: A diagram of an eye with good vision without glasses, showing how light rays entering the eye are focused (by the cornea and lens) to a sharp point on the retina.

Actually, all eyes have some focusing imperfections. One way to measure them is to measure the wavefront of the eye. The wavefront of a perfect eye is uniform because all of the light rays travel evenly through the eye. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others.

Wavefront errors include both simple and complex errors. Glasses can correct the simple wavefront errors, which are called *refractive errors*. Refractive errors include *myopia and astigmatism*.

Myopia (nearsightedness) usually starts in childhood and can get worse through your teens. It usually stops changing by your late teens. Sometimes it continues to get worse into your mid-twenties.

As shown in **Figure 2**, nearsighted eyes bend light too much, so that light rays focus in front of the retina. Things that are far away look blurry because the rays spread apart instead of focus sharply when they strike the retina.

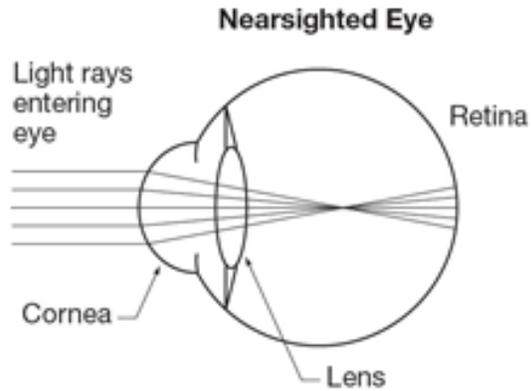


Figure 2: A diagram of a nearsighted eye showing the light rays focusing in front of the retina.

As shown in **Figure 3**, astigmatism causes the rays of light entering through different parts of the eye to focus unequally on the retina. Some rays may focus on the retina but other rays focus in front of it. Things look blurry because images never focus clearly on the retina.

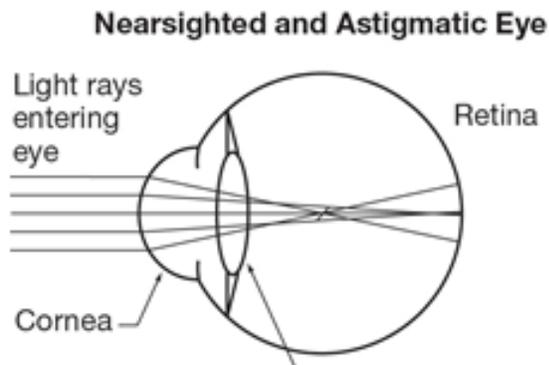


Figure 3: A diagram of an eye with astigmatism showing light rays that do not ever come to a focus at one point.

The **iDESIGN**[®] Refractive Studio is a tool to measure the wavefront of an eye. The **iDESIGN**[®] Refractive Studio measures the wavefront errors using a camera sensor.

The **iDESIGN**[®] Refractive Studio can measure the simple and complex focusing errors. Examples of complex errors include *spherical aberration* and *coma*. Spherical aberration is when light rays going through the pupil's edge focus differently than those going through the center. It can cause blurry images that have a halo around them. Coma is caused when light rays going through part of the eye focus differently than light rays going through the opposite part. It can cause blurry images that look like they have a tail like a comet.

The combination of simple and complex wavefront errors in any eye is unique. The **iDESIGN**[®] System driven LASIK Treatments is "custom" because it includes information from the **iDESIGN**[®] Refractive Studio that is more individualized than what a doctor uses to program a non-custom treatment. The doctor uses information from the **iDESIGN**[®] Refractive Studio, as well as other measurements of how you see, to design your **iDESIGN**[®] System driven LASIK Treatments.

How Presbyopia Affects Your Vision

Presbyopia is a part of the normal aging process. It causes you to have trouble focusing while reading up close. Presbyopia begins around age 40 and gets worse as you get older. This normal aging change happens to all people in different amounts. The **iDESIGN**[®] System driven LASIK Treatments does not cure presbyopia. It adjusts one eye to see well close up and the other eye to see well far away.

The **iDESIGN**[®] Refractive Studio

Before the doctor can program the laser for your **iDESIGN**[®] System driven LASIK Treatments, the **iDESIGN**[®] Refractive Studio must measure your eyes. The **iDESIGN**[®] Refractive Studio is a tabletop system that measures your eyes with special cameras. You will sit in front of the **iDESIGN**[®] Refractive Studio and look into it at a light through an opening in the system while it scans your eye. Your doctor may take more than one measurement and then choose the most appropriate measurement to use as the basis for the **iDESIGN**[®] System driven LASIK Treatments. Your doctor will also take other routine measurements of your vision to help design your treatment.

The **AMO STAR S4 IR**[®] Excimer Laser

The excimer laser system produces a beam of cool ultraviolet light. The doctor transfers the information from the **iDESIGN**[®] Refractive Studio into a computer that controls the laser. The laser produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) untouched.

The laser system also contains an auto-centering eye tracking system which will align the treatment and automatically compensate for many of your eye movements during the **iDESIGN**[®] System driven LASIK Treatments. And the Iris Registration feature of the **STAR S4 IR**[®] Excimer Laser System adjusts for rotation (twisting) of your eye between time of wavefront measurement and start of the treatment.

How the **iDESIGN**[®] System driven LASIK Treatments Works

LASIK is a type of laser surgery that corrects refractive errors of the eye. They include nearsightedness and astigmatism. Before starting the laser, the doctor creates a flap on your cornea using either a different type of laser or an automatic cutting device that uses a blade (microkeratome). A suction ring is placed on the eye, as shown in **Figure 4** below, and then a circular flap of tissue is created from the surface of the cornea. After the flap is cut, the doctor lifts the flap and folds it out of the way of the laser. After the laser finishes, the doctor repositions the flap.

As shown in **Figure 5**, the laser changes your vision by changing the shape of the cornea. To correct nearsightedness the laser removes more from the center of the cornea. When there is astigmatism, the laser sculpts the eye vertically or horizontally. The doctor creates a unique treatment plan from the **iDESIGN**[®] Refractive Studio to guide the laser. The laser removes tissue from the eye according to the treatment plan.

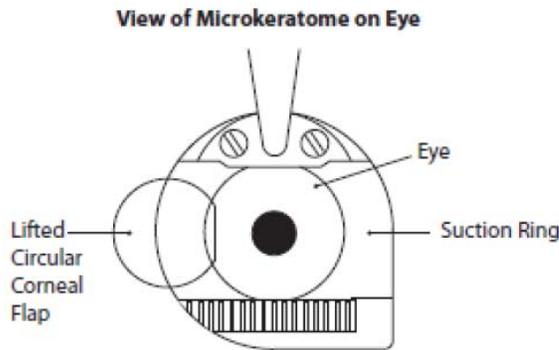


Figure 4: View (from above) of microkeratome on the eye.

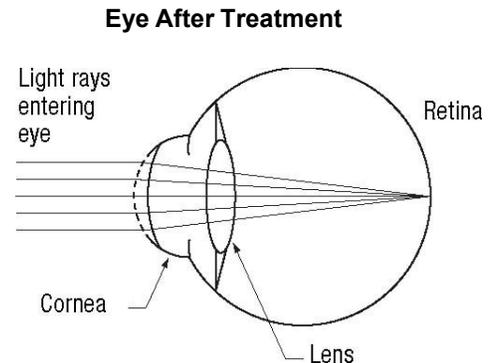


Figure 5: A diagram of an eye after treatment showing where tissue is removed

Important Things to Consider Regarding Monovision

- Monovision may not be good for you if you have unrealistic expectations. **iDESIGN**[®] LASIK Treatments do not guarantee perfect results. If you expect perfect vision under all light conditions, or you expect your vision to improve right away, you are probably a poor candidate for an **iDESIGN**[®] LASIK Treatment. Your vision may not be perfect and you may need to wear glasses or contact lenses after the procedure.
- You should be aware that there are advantages and disadvantages to monovision. To get the benefit of improved near vision without glasses, you may have to put up with worse visual acuity and depth perception for distance and near tasks than you could have with glasses. You may have symptoms such as blurred vision, dizziness, headaches and a feeling of imbalance.
- You will need to wear glasses or contact lenses that give you monovision for a one-week contact lens trial with your individualized monovision prescription and evaluate your vision over a range of tasks during this trial period. It is important for you to follow your doctor's suggestions for getting used to monovision during this trial period. You should discuss any concerns that you may have during the adaptation period. It is important for you to be sure that you are comfortable with monovision before you go ahead with an **iDESIGN**[®] LASIK Treatment.

- The goal of the ***IDESIGN***[®] LASIK Treatment is to let you see objects up close without glasses or contacts. Because you will have improved near vision in one eye and distance vision in the other, it is important to avoid differences between your eyes, that are so large that you get symptoms such as reduced depth perception, blurred distance vision, and problems with night vision. Your doctor will try to keep the amount of difference between your eyes small enough for you to avoid these visual symptoms, but this may also limit the amount of improvement in your near vision.
- After monovision treatment, you may still need glasses to provide clear vision for important tasks and activities:
 - Your vision may not be good enough under dim lighting conditions for you to be comfortable driving at night. You may want to discuss whether your doctor should prescribe glasses that correct both eyes for distance for situations when you need sharp distance vision using both eyes.
 - If you spend a lot of time doing close work, you may want to have additional glasses prescribed that give you sharp near vision in both eyes.
- If either your job or your recreational activities require very sharp near vision, depth perception, or vision with both eyes, you should check to be sure that you can do these activities satisfactorily during the one-week monovision contact lens trial before you agree to an ***IDESIGN***[®] LASIK Treatment.

Monovision may not be optimal for activities such as:

- Operating heavy machinery or performing other potentially dangerous activities that require excellent vision.
 - Driving automobiles (e.g. driving at night). If you cannot pass your state driver's license requirements with monovision correction, you may require that additional over-correction (glasses) be prescribed.
- Your vision may continue to change over time. Your ability to read is a combination of your eye's current focusing ability and the power (add) used in your reading glasses. As you get older, your focusing abilities diminish, requiring stronger reading glasses to compensate. Therefore after the ***IDESIGN***[®] System driven LASIK Treatment, as you continue to age and your focusing abilities diminish, your near vision may change over time with eventual need for glasses or contact lens correction.
 - Your presbyopia will increase over time.

- If your results with the **iDESIGN**[®] LASIK Treatment are not satisfactory and you want a second procedure, retreatment procedures with **iDESIGN**[®] LASIK Treatments may not be successful.
- Your vision may not be perfect and you may need to wear glasses or contact lenses for some activities even after having the **iDESIGN**[®] System LASIK Treatments.
- You may not be able to do some tasks as well with this correction as before with bifocal reading glasses.
- The **iDESIGN**[®] LASIK Treatment is likely to result in a significant reduction in distance vision in the eye treated for near.
- After considering you vision needs, the information in this booklet, any your doctor's recommendations, remember that the decision whether to undergo an **iDESIGN**[®] LASIK Treatment is yours alone.

BENEFITS

iDESIGN[®] System driven LASIK Treatments for Monovision of presbyopic patients with low to moderate nearsightedness can correct up to -6 diopters(D) of nearsightedness. It can also correct up to -3 diopters of astigmatism. *iDESIGN*[®] System driven LASIK Treatments may help you to see clearly both far away and close up without glasses or contact lenses.

RISKS

As with any surgery, *iDESIGN*[®] System driven LASIK Treatments has risks. It is important to discuss the risks with your doctor before you decide to have surgery. If the results of the surgery are not satisfactory, you may need to have another laser treatment. Usually, your doctor will perform *iDESIGN*[®] System driven LASIK Treatments on both eyes. Sometimes it is better to have this treatment on one eye. Ask your doctor if it would be better to treat one or both of your eyes.

Some risks are related to the creation of the corneal flap. Corneal flap complications include but are not limited to:

- Cutting an incomplete, irregular flap or free flap.
- Misalignment of the flap.
- Perforation of the cornea.
- Inflammation of the cornea under the flap.
- Corneal surface cell growth under the flap.

Corneal flap complications range in severity. Some require the treatment to be postponed for several months. Others can create corneal irregularities causing permanently blurred vision.

Other risks of LASIK include:

- Eye movement during treatment. Even though the **STAR S4 IR**[®] System has an eye tracker, you will be asked to look at a blinking light while the laser is running. It is important to stare at the light for the entire laser procedure. The treatment may not be positioned correctly on your eye if your eye moved too much during treatment. This may result in blurry vision after LASIK.
- Inaccurate **iDESIGN**[®] Refractive Studio measurement. If your contact lenses were worn too close to the exam time for the doctor to obtain a stable measurement, your **iDESIGN**[®] Refractive Studio measurement may be inaccurate. This may result in poor vision after LASIK.
- Some patients had the following adverse events and complications during clinical studies:
 - Dry eyes.
 - Blurry vision.
 - Fluctuation of vision.
 - Increase of pressure in the eye.
 - Ghost or double images.
 - Night vision difficulties.
 - Halos around lights.

WARNING:

Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities, such as driving at night or reading small type, after monovision laser vision correction.

CONTRAINDICATIONS — When Can't You Have LASIK?

If you have any of the following situations or conditions you should not have LASIK because the risk is greater than the benefit:

- You are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea. LASIK treatment may improperly change the shape of your cornea.
- You have collagen vascular disease (e.g., rheumatoid arthritis). You have autoimmune disease (e.g., lupus). You have immunodeficiency diseases (e.g., AIDS). These conditions affect the body's ability to heal.
- You show signs of keratoconus (cone-shaped cornea) or another condition that causes a thinning of your cornea. These conditions can lead to serious corneal problems during and after LASIK surgery. They may result in need for additional surgery. They may result in poor vision after LASIK.
- You are taking medications with ocular side effects. Examples are Isotretinoin (Accutane^{®1}) for acne treatment or Amiodarone hydrochloride (Cordarone^{®2}) for normalizing heart rhythm. They may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- Diabetes. If you have diabetes, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.

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² Cordarone[®] is a registered trademark of Sanofi-Synthelabo, Inc.

- Documented evidence of a change in manifest refraction of more than +0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination. This suggests that your nearsightedness or astigmatism is getting worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK.
- Corneal disease or abnormality. This includes scars and infections of the eye. If you have an abnormal cornea it may affect the accuracy of the LASIK treatment. It may affect the way your cornea heals after LASIK. This may result in poor vision after LASIK. If your eyes have an active disease, it is not known if LASIK is safe and effective for your condition.
- History of injury or surgery to the center of the cornea (for example, surgery to correct vision such as RK, PRK, LASIK). Other surgery on your eye. If your eyes are injured or you have had surgery, it is not known if LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- Corneas are thin. Your corneas may be too thin to allow your doctor to cut a proper flap in the LASIK procedure. You cannot have LASIK because it is necessary to have a flap.
- History of glaucoma or have had eye pressure greater than 21 mmHg. It is not known if LASIK is safe and effective for you.

WARNINGS

If you have any of the following conditions, discuss the seriousness of your condition with your doctor.

- History of *Herpes simplex* or *Herpes zoster* infection that has affected your eyes. If you have ever had *Herpes simplex* or a *Herpes zoster* in your eyes, LASIK may be more risky for you because you may have problems healing.
- Symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase the dryness. This may or may not go away. This dryness may delay healing of the flap. Dryness may interfere with the surface of the eye after surgery.
- Severe allergies. If you have severe allergies and take medicines for them, LASIK may be more risky for you. You may have problems healing.

Additional warnings you need to consider:

- Eye movement during treatment. Even though the **STAR S4 IR**[®] System has an eye tracker, you will be asked to look at a blinking light while the laser is running. It is important to stare at the light for the entire laser procedure. The treatment may not be positioned correctly on your eye if your eye moved too much during treatment. This may result in blurry vision after LASIK.
- If your contact lenses were worn too close to the exam time for the doctor to obtain a stable measurement, your **iDESIGN**[®] Refractive Studio measurements, as well as other measurements may be inaccurate. This may result in poor vision after LASIK.

PRECAUTIONS

It is not known if LASIK is safe and effective for the following conditions. You should discuss these conditions with your doctor:

- No prior experience of monovision. You should first try out monovision with contact lenses to see if you like having unequal vision. In the clinical trial for **CustomVue™** Monovision LASIK, about 20% of patients who tried monovision using contact lenses decided not to have monovision LASIK treatment.
- Take medicines that might make it harder for wounds to heal, such as Sumatriptan (Imitrex^{®3}) used for migraine headaches. It is not known if LASIK is safe and effective for this condition.
- Younger than 40 years of age or over 65 years of age. It is not known if Monovision LASIK is safe and effective for you.
- Nearsightedness is worse than 6 diopters or astigmatism is worse than 3 diopters. It is not known if LASIK is safe and effective for you.
- For retreatment with this laser for LASIK. It is not known if LASIK is safe and effective for repeating the LASIK procedure on the same eye.
- Undiagnosed dry eyes. Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery. Dry eyes may cause some fluctuation in your vision.
- Large pupils. Before surgery, your doctor should measure your pupil size under dim lighting conditions. Your doctor can check if you are over-focusing in your **iDESIGN®** Refractive Studio measurements by comparing pupil size.
- You might have difficulty seeing in dim lighting, rain, snow, fog, or bright glare. It is hard to predict if you will have poor vision under these conditions because it has been studied so little.
- Any other medications you are taking. Tell your doctor if you are taking any medicines including ones you bought without a prescription. Your doctor will know if the medicine may interfere with healing or may contribute to poor vision after surgery.
- It is not known if LASIK is safe and effective for periods longer than 1 year.

³ Imitrex[®] is a registered trademark of GlaxoSmithKline.

Are You A Good Candidate For *iDESIGN*[®] System Driven LASIK Treatments?

If you are considering *iDESIGN*[®] System driven LASIK Treatments, you must:

- Be at least 40 years of age (with presbyopia) and have nearsightedness with or without astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality such as scars and infections.
- Have documented evidence of a change in manifest refraction of no more than +0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.
- Be informed of LASIK risks and benefits as compared to other available treatments for nearsightedness with or without astigmatism.
- Be able to tolerate monovision. AMO recommends that you undergo a monovision trial period of wearing contact lenses to see if you can tolerate Monovision LASIK.
- Be willing to undergo a one-week contact lens trial with your individualized monovision prescription and evaluate your vision over a range of tasks during this trial period.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign the informed consent form provided by your doctor.
- Be able to fix your gaze on the blinking light for the entire laser procedure.

If you are considering *iDESIGN*[®] System driven LASIK Treatments, you must NOT:

- Have advanced glaucoma, uncontrolled diabetes, collagen vascular, autoimmune or immunodeficiency diseases as the surgery may lead to poor outcomes and possible vision loss.
- Be pregnant or nursing as your refraction is unstable and could result in a poor outcome.

WHAT TO EXPECT

Before Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical exam to determine if your eye is healthy and suitable for surgery. This will include a complete medical and eye history, and thorough examination of both eyes, including wavefront-based refractive errors and computerized mapping of your cornea.

Ask your doctor about undergoing a trial period wearing monovision contact lenses. You should be willing to undergo a one-week contact lens trial with your individualized monovision prescription and evaluate your vision over a range of tasks during this trial period. You will find out if you can tolerate Monovision LASIK. Some patients cannot get used to having one eye blurred at all times.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2 to 4 weeks before your pre-surgical exam and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, ask your doctor about eating or drinking immediately before surgery. You should also plan a ride home from your doctor's office. You must not drive immediately after the surgery. You may start driving again when you receive permission from your doctor.

The Day of Surgery

Before the surgery, the doctor places local anesthetic (numbing) drops into the eye to be treated and escorts you into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will hold your eyelids open during the surgery.

There will also be a temporary shield covering the eye not having surgery. Listen to the sounds that the laser makes to prepare you for the surgery.

The surgery begins with the placement of a suction ring that elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The microkeratome (a surgical tool) creates a thin flap of tissue. The doctor will lift this flap of tissue after the suction releases. Vision will return to the eye after the suction releases, but it may be blurry.

The doctor will then reposition your head in the chair and refocus the microscope. You will need to look directly at a blinking light while the laser is running. It is important to fix your gaze on the light for the entire laser procedure. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the light. The **STAR S4 IR®** Excimer Laser system then quickly removes small amounts of your cornea.

PRECAUTION:

It is very important that you keep looking at the flashing fixation light during the procedure, even if the light fades, blurs or becomes dim. You need to concentrate on looking at this light throughout the treatment to ensure the best results possible.

Typically, the laser beam will be applied to your eye less than 3 minutes and, overall, the surgery may last about 10 minutes. The doctor may place some eye drops on your eye when the laser pulses are finished. The surgery is painless because of the numbing drop. When the numbness wears off (about 30 to 60 minutes), your eye may hurt moderately for 1 to 2 days. The discomfort is typically described as “a sandy sensation.”

Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and lessen the risk of infection, do **NOT** rub your eye after surgery until your doctor tells you it is safe.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for 1 to 2 days. Sunglasses may make you more comfortable during this time. You will need to instill lubricating drops and wear an eye shield to bed for at least a week.

The First Week Following Surgery

- Mild to moderate pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing may occur as the cornea heals.
- You may be sensitive to bright lights.

During the early stages, especially during the first week, your eyesight may not have fully adjusted to new changes, and may not be able to demonstrate the full effectiveness of monovision. It may take several weeks for your eyes to adjust.

You may want to avoid or decrease your participation in visually demanding situations such as driving, until you have adjusted to your monovision and the potential change in your depth perception.

The First Two to Six Months Following Surgery

- Your vision may change during this period. You may also have some eye dryness. Your doctor may prescribe eye drops to help resolve your dry eyes. Use the drops as prescribed.

IMPORTANT:

Use lubricants and eye medications as directed by your doctor.

Your results depend upon you following your doctor's instructions.

WARNING:

Your doctor will monitor you for any side effects if you need to use a topical steroid medication. Possible side effects of prolonged topical steroid use are:

- **Glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision).**
- **cataract formation (an opacity or clouding of the lens inside the eye that can cause a loss of vision).**

Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if **iDESIGN**[®] System driven LASIK Treatment is right for you:

- What other options are available for correcting my vision?
- Will I have to limit my activities after surgery? If so, for how long?
- What are the benefits of **iDESIGN**[®] System driven LASIK Treatments for my amount of refractive error?
- What vision can I expect in the first few months after surgery?
- If **iDESIGN**[®] System driven LASIK Treatments does not correct my vision, what is the possibility that my glasses will need to be stronger than before?
- Could my need for glasses increase over time?
- Will I be able to wear contact lenses after laser surgery if I need them?
- How will **iDESIGN**[®] System driven LASIK Treatments affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having laser surgery?
- What if I can't get used to monovision?
- When can I have surgery on my other eye?

Discuss the cost of surgery and follow-up care requirements with your doctor. Most health insurance policies do not cover **iDESIGN**[®] System driven LASIK Treatments.

SELF-TEST

Are you an Informed and Educated Patient? Take the test below and see if you can correctly answer these questions after reading this booklet.

Find answers to SELF-TEST on page 27.

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

SUMMARY OF IMPORTANT INFORMATION

- **iDESIGN®** System driven LASIK Treatments is a permanent operation to the cornea and is irreversible.
- **iDESIGN®** System driven LASIK Treatments may not eliminate the need for reading glasses.
- Your vision must be stable for at least one year before **iDESIGN®** System driven LASIK Treatments. You will need written evidence of a change in manifest refraction of no more than +0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- **iDESIGN®** System driven LASIK Treatments may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- Alternatives to **iDESIGN®** System driven LASIK Treatments, but are not limited to, glasses, contact lenses, RK, and ALK.
- **iDESIGN®** System driven LASIK Treatments cannot meet the job-related vision requirements for some people such as pilots.
- You should be willing to undergo a one-week contact lens trial with your individualized monovision prescription and evaluate your vision over a range of tasks during this trial period, this will help you find out if you can tolerate Monovision LASIK.
- It may take several weeks for your eyes to adjust to monovision. You may want to avoid or decrease your participation in visually demanding situations such as driving until you have adjusted to your monovision.
- It is very important to stop wearing contact lenses before the pre-surgical eye exam.
- Before considering laser vision correction you should:
 - a. Have a complete eye exam.
 - b. Talk with one or more eye care professionals about the potential benefits of laser refractive surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions

1. False (see Risks on page 13)
2. False (see What to Expect - Before Surgery on page 20)
3. False (see What to Expect - The Day of Surgery on page 21)
4. True (see Benefits on page 13)
5. True (see Risks on page 13)
6. True (see Risks on page 13)
7. False (see Contraindications on page 15)
8. False (see Contraindications on page 15)

CLINICAL STUDY TO EVALUATE RISKS

A clinical performance study of *iDESIGN* driven Monovision LASIK Treatment was not conducted. However, results of prior clinical study of monovision LASIK using the *WaveScan WaveFront* System aberrometer, supports the safety and effectiveness of *iDESIGN* driven Monovision LASIK Treatment, in that it used a prior version of the *iDESIGN* aberrometer device to drive the monovision treatment in myopic presbyopes.

The study with the *WaveScan WaveFront* System using the *CustomVue* Monovision LASIK treatment, involved 320 eyes of 160 patients treated at seven U.S. centers. This study started in September 2004. The last patient in this study was treated in September 2005. The study results shown in this booklet (**Tables 1- 21**) include all the available reported outcomes on these patients through November 2006. Each table lists the numbers of eyes (N) for which data were available at the reported time point.

Vision with Glasses After Treatment

Table 1 shows that after treatment 87% of eyes in the study saw as well or better with glasses close up. Ninety percent (90%) saw as well or better with glasses far away.

Table 1 — Change in Vision with Glasses Before and After Treatment

6 Months After Treatment (n = 292)	Change in Near Vision	Change in Far Vision
Decrease >2 lines	0%	0%
Decrease >1 to 2 lines	0%	1%
Decrease > 0 to 1 line	13%	9%
No change	43%	41%
Increase >0 to 1 line	38%	46%
Increase >1 to 2 lines	5%	3%
Increase >2 lines	0%	0%

Contrast Sensitivity

Normal vision tests measure your ability to see a black and white eye chart. Contrast sensitivity tests measure how well you see in low contrast conditions such as in rain or fog. Contrast sensitivity was measured with glasses before and after surgery. More patients improved than got worse in three different tests. In one test (far vision in dim light), more patients (10%) got worse than improved better (9%).

Table 2— Change in Contrast Sensitivity with Glasses 6 Months After Treatment

Condition	6 Months (n=158)		
	% of Eyes with Loss	% of Eyes That Stay the Same	% of Eyes with Gain
Far vision in bright light	1%	94%	5%
Far vision in dim light	10%	81%	9%
Far vision in dim light with glare	10%	75%	15%
Near vision in bright light	5%	88%	7%

Table 3— Change in Contrast Sensitivity without Glasses 24 Months After Treatment

Thirty (30) patients had their contrast sensitivity without glasses measured two years after surgery. Compared to their contrast sensitivity with glasses before surgery, more people decreased their contrast sensitivity than increased.

Condition	24 Months (n=30)		
	% of Eyes with Decrease	% of Eyes That Stay the Same	% of Eyes with Increase
Far vision in bright light	3%	93%	3%
Far vision in dim light	27%	57%	17%
Far vision in dim light with glare	30%	57%	13%
Near vision in bright light	13%	87%	0%

Depth Perception

A special vision test (viewed close up) measured depth perception (the ability to see 3-D) in the study. A decrease in depth perception can make some tasks more difficult such as walking down stairs or pouring a cup of coffee. On average, the test showed that depth perception for near tasks decreased moderately after treatment. Adverse Events and Complications

Table 4 shows the overall percentages of eyes in the clinical study that had adverse events and complications after **CustomVue** Monovision LASIK treatment.

Table 4— Adverse Events and Complications

Greater than or equal to 1% of eyes (n=296) had:	
Inflammation of the cornea under the flap	4.1%
Corneal surface cells under the flap	1.0%
Ghost or double images*	17.5%
Less than 1% of eyes (n=296) had:	
Inflammation of the iris	0.3%
Infection of the cornea	0.3%
Increase of pressure in the eye	0.7%
Misaligned flap	0.3%
Peripheral defect of the cornea	0.3%
Feeling of something in the eye	0.7%

* The percentage of ghost or double images is reported as the percentage of patients (n=160) rather than eyes.

At 6 months or later, 10.6% of patients experienced ghost or double images. One year after the surgery, ghost images were reported as occurring “often” by one 4 patients, and “always” by one patient. No patients reported double images occurring “often” or “always”.

Patient Symptoms

The questionnaire asked patients to rank the frequency of their symptoms both before and after treatment. **Table 5** lists the patient symptoms reported as “often” or “always” before treatment on 155 patients and at 6 months after treatment on 157 patients.

Table 5 — Comparison of Symptoms Before and After Treatment

Often or Always		
Symptoms	Before Treatment	6 Months After Treatment
Dryness	6%	11%
Blurry vision	3%	3%
Fluctuation of vision	3%	2%
Glare	3%	4%
Halos around lights	8%	10%
Difficulty at night	13%	10%
Ghosting or shadowing of images	2%	4%
Double images	1%	1%
Things appear distorted	1%	0%
My vision makes me dizzy	0%	0%
My vision gives me headaches	1%	0%

The study compared vision without glasses after treatment to vision with glasses before treatment for 152 patients. The questionnaire asked patients to rate their symptoms after treatment. They used a 5-level scale. An improvement or worsening reflects a change of 2 or more levels. **Table 6** presents the results of this comparison.

Table 6 — Change in Patient Symptoms for Vision *Without* Glasses After Treatment Compared to Vision *With* Glasses Before Treatment

Symptoms	Improve	No Change	Worsen
Dryness	9%	77%	14%
Blurry vision	6%	90%	5%
Fluctuation of vision	12%	84%	5%
Glare	9%	83%	8%
Halos around lights	12%	77%	11%
Difficulty at night	14%	76%	11%
Ghosting or shadowing of images	6%	88%	6%
Double images	1%	97%	2%
Things appear distorted	3%	94%	3%
My vision makes me dizzy	3%	97%	0%
My vision gives me headaches	5%	95%	1%

CLINICAL STUDY TO EVALUATE BENEFITS

Study Patient Demographics

The age of study patients ranged from 40 to 65 years. **Table 7** lists the age, gender, race, eye dominance, and contact lens history of study patients.

Table 7 – Demographics of 160 Study Patients

Gender	Male	35%
	Female	65%
Race	Caucasian	82%
	African American	5%
	Native American/ Alaskan Native	1%
	Asian	4%
	Other (Hispanic)	8%
Eye Dominance	Right	71%
	Left	29%
Age	Average	50 years
	Range	40 – 65 years
Contact Lens Wear	None	22%
	Soft	72%
	Hard	6%

Vision Without Glasses After Treatment

A letter chart tested the sharpness of vision at three different distances. The exam tested vision with both eyes open (binocular) and with each eye separately (monocular). The exam tested “near” vision 16 inches away. This is a typical distance for reading. The exam tested “intermediate” vision at a distance of two feet. This is a typical distance for viewing a computer screen. The exam tested “far” vision about 13 feet away. This is a common distance for viewing television in your home.

Binocular Far and Near Vision

Binocular vision (both eyes open) was tested without glasses for either distance or near. Before treatment 3% of patients were able to see 20/40 or better for objects both close up and far away. **Table 8** shows that 100% of patients were able to see 20/40 or better for both far and near. Eighty percent (80%) were able to see 20/20 or better at both distances six months after treatment.

Table 8 – Binocular Far and Near Vision Without Glasses after Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/20 or better	76%	80%	80%	86%	86%
20/25 or better	96%	94%	92%	95%	97%
20/32 or better	99%	98%	99%	99%	99%
20/40 or better	100%	99%	100%	99%	99%

Binocular Far Vision

Table 9 shows that 100% of patients were able to see 20/40 or better far away. Approximately 87% were able to see 20/20 or better six months after treatment.

Table 9 — Binocular Far Vision Without Glasses After Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	12%	18%	18%	24%	20%
20/16 or better	64%	67%	71%	69%	69%
20/20 or better	86%	88%	87%	93%	93%
20/25 or better	98%	98%	96%	96%	97%
20/32 or better	100%	99%	99%	99%	99%
20/40 or better	100%	99%	100%	100%	99%

Binocular Intermediate Vision

An eye exam tested binocular intermediate vision without any glasses after **CustomVue** Monovision LASIK treatment. **Table 10** shows that 99% of patients were able to see 20/40 or better at intermediate distances. Eighty-five percent (85%) were able to see 20/20 or better six months after treatment.

Table 10 — Binocular Intermediate Vision Without Glasses After Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	11%	13%	8%	9%	12%
20/16 or better	41%	48%	50%	55%	52%
20/20 or better	77%	78%	85%	89%	89%
20/25 or better	93%	93%	96%	97%	97%
20/32 or better	98%	98%	99%	100%	100%
20/40 or better	98%	99%	99%	100%	100%
20/80 or better	100%	100%	100%	100%	100%
20/100 or better	100%	100%	100%	100%	100%
Worse than 20/100	0%	0%	0%	0%	0%

Binocular Near Vision

The study tested binocular near vision without any glasses after **CustomVue** Monovision LASIK treatment. **Table 11** shows that 100% of patients were able to see 20/40 or better close up. Eighty-eight percent (88%) were able to see 20/20 or better six months after treatment.

Table 11 — Binocular Near Vision Without Glasses After Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	6%	8%	8%	11%	9%
20/16 or better	43%	50%	45%	49%	44%
20/20 or better	87%	89%	88%	90%	92%
20/25 or better	98%	96%	97%	97%	99%
20/32 or better	99%	99%	100%	99%	99%
20/40 or better	100%	100%	100%	100%	100%
20/80 or better	100%	100%	100%	100%	100%
20/100 or better	100%	100%	100%	100%	100%
Worse than 20/100	0%	0%	0%	0%	0%

Far Vision in the Dominant Eye Without Glasses

The Monovision LASIK treatment targeted the dominant eye of patients to see well at far distances. Table 6 shows that 88% of dominant eyes could see 20/20 or better in the eye treated for seeing far away six months after treatment.

Table 12 — Far Vision in the Dominant Eye Without Glasses After Treatment

Time After Treatment	1 Month n=158	3 Months n=156	6 Months n=157	9 Months n=151	12 Months n=148
20/12.5 or better	12%	16%	15%	19%	20%
20/16 or better	55%	64%	66%	64%	66%
20/20 or better	85%	86%	88%	90%	89%
20/25 or better	98%	97%	96%	96%	97%
20/32 or better	99%	99%	98%	99%	99%
20/40 or better	100%	100%	99%	100%	100%
20/80 or better	100%	100%	100%	100%	100%

Near Vision in the Non-Dominant Eye

The Monovision LASIK treatment targeted the non-dominant eye of patients to see well close up. **Table 13** shows that 81% of non-dominant eyes could see 20/20 or better six months after treatment.

Table 13 — Near Vision in the Non-Dominant Eye Without Glasses After Treatment

Time After Treatment	1 Month n=136	3 Months n=134	6 Months n=135	9 Months n=133	12 Months n=133
20/12.5 or better	5%	5%	7%	7%	6%
20/16 or better	34%	46%	43%	44%	37%
20/20 or better	75%	84%	81%	87%	86%
20/25 or better	94%	95%	96%	97%	98%
20/32 or better	98%	97%	100%	100%	98%
20/40 or better	100%	99%	100%	100%	99%

Vision Without Glasses After Treatment Compared to With Glasses Before Treatment

The study compared eye chart scores before treatment with glasses or contact lenses to the eye chart scores after treatment with no glasses or contact lenses. On average, the study patients scored within one line of their vision with glasses before treatment. The average score after treatment was 20/16 far away and 20/20 close up. **Table 14** shows that six months after treatment, 51% of patients were able to see as well or better at near with no glasses as they could see using glasses or contact lenses before treatment.

Table 14 — Near Vision Without Glasses After Treatment Compared to With Glasses Before Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
More than 2 lines better	0%	0%	0%	0%	0%
2 lines better	1%	1%	2%	2%	2%
1 line better	8%	11%	11%	13%	11%
Less than 1-line change	38%	42%	38%	40%	40%
1 line worse	39%	29%	31%	29%	31%
2 lines worse	10%	14%	16%	13%	15%
More than 2 lines worse	4%	3%	3%	3%	1%

Table 15 shows that six months after treatment, 64% of patients were able to see as well or better far away with no glasses as they could see using glasses or contact lenses before treatment.

Table 15— Distance Vision Without Glasses After Treatment Compared to With Glasses Before Treatment

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
More than 2 lines better	0%	0%	0%	0%	0%
2 lines better	0%	1%	1%	0%	1%
1 line better	12%	15%	17%	22%	18%
Less than 1 line change	45%	44%	47%	44%	43%
1 line worse	30%	29%	22%	24%	29%
2 lines worse	10%	8%	10%	5%	5%
More than 2 lines worse	3%	4%	4%	5%	3%

Quality of Vision

Patients rated their quality of vision before treatment with glasses or contact lenses. They rated their quality of vision after CustomVue™ Monovision LASIK without glasses or contact lenses. **Table 16** compares the patient satisfaction with quality of vision without glasses at 6 months after treatment for 157 patients with that of 155 patients with glasses before treatment.

Table 16 — Overall Quality of Vision Before and After Treatment

Satisfaction with Quality of Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Overall satisfaction	66%	94%	5%	3%	29%	4%
Intermediate vision	81%	94%	0%	1%	19%	5%
Depth perception	90%	98%	1%	0%	9%	2%
Peripheral vision	85%	97%	3%	1%	12%	3%

Table 17 compares the patient satisfaction with quality of near vision without glasses at 6 months after treatment for 157 patients with that of 155 patients with glasses before treatment.

Table 17 — Quality of Near Vision Before and After Treatment

Satisfaction with Quality of Near Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Sustained near vision	76%	93%	1%	2%	23%	5%
Brief near vision	76%	96%	2%	1%	23%	3%
Reading small print	53%	85%	8%	5%	39%	10%

Table 18 compares the patient responses for satisfaction with quality of far vision without glasses at 6 months after treatment for 157 patients with those of 155 patients with glasses before treatment.

Table 18 — Quality of Far Vision Before and After Treatment

Satisfaction with Quality of Far Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Far vision at night	72%	84%	6%	6%	23%	10%
Far vision at night with glare	63%	82%	10%	6%	27%	13%
Far vision at dusk	78%	89%	9%	3%	13%	8%
Far vision under active conditions	74%	94%	3%	1%	23%	5%

Table 19 shows the overall satisfaction with the *CustomVue* Monovision LASIK treatment of 157 patients 6 months after treatment.

Table 19 — Overall Satisfaction with *CustomVue* Monovision LASIK Treatment

Would you choose to have CustomVue™ Monovision LASIK Treatment again?	6 Months (n=157)			12 Months (n=149)		
	Yes	No	Not Sure	Yes	No	Not Sure
	97%	0%	3%	98%	1%	1%

Table 20 shows the change in satisfaction with quality of vision without glasses at 6 months after treatment for 152 patients compared to the quality of vision with glasses before treatment.

Table 20 — Change in Satisfaction with Quality of Vision Before and After Treatment

6 Months (n = 152)	Improve	No Change	Worse
Intermediate vision	17%	78%	5%
Depth perception	9%	89%	2%
Peripheral vision	14%	85%	1%
Near vision (sustained)	22%	76%	3%
Near vision (brief)	23%	76%	1%
Near vision (small print)	39%	57%	4%
Far vision at night	17%	77%	6%
Far vision at night with glare	22%	70%	7%
Far vision at dusk	14%	80%	7%
Far vision under active conditions	25%	72%	3%
Overall satisfaction	30%	67%	3%

Glasses or Contact Lens Use

The questionnaire asked patients how often they used glasses or contact lenses after treatment. Patients used a five-level scale (never, rarely, sometimes, often, or always). **Table 21** shows the change (at least two levels) in use of lenses from before treatment to after treatment.

Table 21 — Change in Use of Glasses or Contact Lenses

6 Months (n=152)			12 Months (n=145)		
Decrease in Use	No Change	Increase in Use	Decrease in Use	No Change	Increase in Use
96%	4%	0%	91%	8%	1%

PATIENT ASSISTANCE INFORMATION

Primary Eye Care Professional

Name:

Address:

Phone:

Laser Vision Correction Doctor

Name:

Address:

Phone:

Treatment Location

Name:

Address:

Phone:

Laser Manufacturer:

AMO Manufacturing USA, LLC
510 Cottonwood Drive
Milpitas, CA USA 95035
1-877-266-4543
www.amo-inc.com
Product of USA