



EYE CONSULTANTS
OF TEXAS

DAY OF SURGERY: WHAT TO EXPECT
Laser Vision Correction (LASIK/PRK)

1. Patient is greeted by one of our Refractive Specialists.
2. If not completed prior to the day of surgery, financial arrangements are made with the patient and consents are reviewed and signed.
3. Patient is brought to an exam room where surgical attire (hat and booties) are placed on the patient.
4. Dr. Labor and his associates verify the treatment plan and any additional testing that was performed the day of surgery. They also visit with the patient to answer any additional questions the patient may have before their surgery.
5. Post-operative instructions are reviewed with the patient and their companion/escort. Verbal confirmation is obtained that both understand and agree to comply with instructions.
6. Eye(s) are prepped with lid scrubs and Betadine.
7. Patient is escorted to the Laser Suite and made comfortable. Anesthetic drops are instilled.
8. Treatment is initiated.
9. Once the laser treatment is complete, the patient is escorted to the exam room where the surgeon examines the eye(s) before the patient is released.
10. Patient is discharged with instructions to take their Xanax prescription (0.5mg) and to take a 3-4 hour nap as soon as they return home.



EYE CONSULTANTS
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Pre-Operative Medication & Lid Scrubs Instructions LASIK

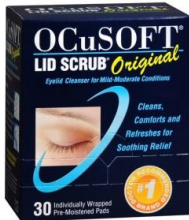


1. Oasis Preservative Free Artificial Tears

Clear individual use droppers

Use in both eyes **4 times a day**: Breakfast, Lunch, Dinner, and Bedtime (may use more often, if needed).

Start **2 weeks** prior to your surgery.



2. OCuSOFT Lid Scrubs

Use on both eyes to gently clean the upper and lower lids and lashes **1 time the night before surgery**.

Patient Name (Print) _____

Patient Signature _____

Date _____

Staff Initials _____



EYE CONSULTANTS
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Pre-Operative Medication & Lid Scrubs Instructions PRK



1. Oasis Preservative Free Artificial Tears

Clear individual use droppers

Use in both eyes **4 times a day**: Breakfast, Lunch, Dinner, and Bedtime (may use more often, if needed).

Start **2 weeks** prior to your surgery.



2. OCuSOFT Lid Scrubs

Use on both eyes by gently cleaning the upper and lower lids and lashes **1 time the night before surgery**.



3. Vitamin C 1000mg

Begin taking **1000mg** by mouth **once per day**.

Patient Name (Print) _____

Patient Signature _____

Date _____

Staff Initials _____



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Post-Operative Instructions **LASIK & PRK**

Prescriptions:

- **0.5mg Xanax:** As soon as you arrive home, take 1-2 tablets and take a nap for 3-4 hours with protective glasses/goggles on.
- **10/325mg Norco:** Take 1-2 tablets every 4-6 hours as needed for pain (PRK patients only).
- **Take all eye drops and medications as prescribed on your Post-Operative Medications handout.**

Instructions/Restrictions:

- Wear protective glasses/goggles for **1 week** while you sleep (including naps).
- Do not drive for the first **24 hours** after your procedure.
- Do not rub or touch your eyes.
- Wear dark sunglasses (polarized lenses are best) at all times when outdoors.
- You may shower and/or bathe but do not get water directly into the eye.
- Exercising may resume **after 3 days**. No contact sports that might involve blows to the face (e.g. boxing, kickboxing, martial arts, etc.) for **1 month**.
- No swimming, water sports, or hot tubs for **2 weeks**.
- No eye make-up for **1 week**.
- PRK patients only: a bandage contact lens has been placed in your eye. If it falls out or becomes dislodged, call our office immediately for further instructions. Do not attempt to put the contact lens back in your eye, as this can lead to infection.

Normal Symptoms to Expect After Your Procedure:

- A scratchy, gritty, or slight burning sensation for a couple of hours
- More tearing than usual for 1-2 days
- Fluctuation in your vision for the first month
- Mild sensitivity to light

Abnormal Symptoms:

- Worsening or loss of vision
- Increasing pain that is not relieved by pain medication
- An increase in swelling or eye discharge

If you experience any symptoms that are causing you concern, please call our office at (817) 410-2030 or contact your co-managing optometrist.

Follow-Up Appointment:

Your appointment is scheduled with Dr. _____ at _____ AM/PM on _____.

By signing this form, I understand and agree to follow the above instructions.

Signature: _____

Date: _____



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Post-Operative Medication Instructions: LASIK

Begin all drops immediately after waking up from nap on the day of surgery.
Wait **2-3 minutes** between instilling each drop.



1. Preservative-Free Artificial Tears: Oasis

Clear individual use vials

Use in both eyes **4 times a day**: Breakfast, Lunch, Dinner, and Bedtime
(may use more often, if needed). Continue for **4 weeks** after surgery.



2. Restasis

Use in the operative eye(s): **2 times a day** for at least 3 months.



3. Antibiotic Drop: Vigamox (moxifloxacin)

Tan Top

Use in the operative eye(s): **4 times a day** for **5 days**: Breakfast, Lunch, Dinner, and Bedtime.



4. Steroid Drop: Fluorometholone (FML) 0.1%

White Top in White Bottle: SHAKE WELL

Use in the operative eye(s): **1 drop every hour while awake** for the **first 48 hours** after surgery. Then decrease to **4 times a day** for **2 weeks**:
Breakfast, Lunch, Dinner, and Bedtime.



5. Xanax 0.5mg

Take **1-2 tablets** by mouth as soon as you arrive home **after surgery**.

Patient Name (Print) _____

Patient Signature _____

Date _____

Staff Initials _____



EYE CONSULTANTS
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Post-Operative Medication Instructions: PRK

Begin all drops immediately after waking up from nap on day of surgery.
Wait **2-3 minutes** between instilling each drop.



1. Preservative Free Artificial Tears: Oasis

Clear individual use droppers

Use in the operative eye(s): **1 time per hour while awake for the first 72 hours.** Then use **4 times a day** for **4 weeks** after surgery.



2. Antibiotic Drop: Vigamox (moxifloxacin)

Tan Top

Use in the operative eye(s): **4 times a day for 5 days:** Breakfast, Lunch, Dinner, and Bedtime.



3. Non-Steroidal Anti-inflammatory: Acular LS 0.4%

Grey Top

Use in the operative eye(s): **4 times a day as needed for discomfort.**



4. Steroid Drop: Fluorometholone 0.1% (FML)

White Top in White Bottle: SHAKE WELL

Use in the operative eye(s):

- **4 times a day for 1 month:** Breakfast, Lunch, Dinner, and Bedtime
- **3 times a day for 2 weeks:** Breakfast, Lunch, and Bedtime
- **2 times a day for 2 weeks:** Breakfast and Bedtime
- **1 time a day for 2 weeks:** Breakfast
- Then discontinue.



5. Comfort Drops

Use in the operative eye(s): **every 1 to 2 hours if needed for pain.**

IMPORTANT: DO NOT USE THESE DROPS FOR MORE THAN 24 HOURS. They slow the healing process, so it is best to use as little as possible.



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R_x

6. Xanax 0.5mg

Take **1-2 tablets** by mouth as soon as you arrive home **after surgery**.

R_x

7. Norco 10mg/325mg

Take **1-2 tablets** by mouth every **4-6 hours as needed** for pain.



8. Vitamin C 1000mg

Continue taking **1000mg** by mouth **once per day** for **3 months**.

Patient Name (Print) _____

Patient Signature _____

Date _____

Staff Initials _____

INFORMED CONSENT FOR LASER IN SITU KERATOMILEUSIS (LASIK) WITH INTRALASE

INTRODUCTION

It is our intention to fully inform you concerning side effects, limitations, and potential complications of LASIK surgery. It is important to understand that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent is designed to enhance your understanding of the LASIK procedure and its associated risks, benefits, and alternatives.

BACKGROUND SUMMARY

LASIK, a form of laser vision correction, reshapes the part of the eye known as the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of nearsightedness, farsightedness, and astigmatism. There are two primary techniques for reshaping the cornea with the excimer laser, PRK and LASIK. In both procedures, the clear covering (cornea) over the colored part of your eye (iris) is reshaped with your prescription. PRK reshapes the surface layers of the cornea while LASIK reshapes the inner corneal layers with the excimer laser. The excimer produces a cool beam of ultraviolet light energy capable of removing precise amounts of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision.

Both PRK and LASIK are performed on an outpatient basis and only take about 10-15 minutes to complete. Actual laser time ranges from several seconds to several minutes. Although patients often feel some pressure sensation, both procedures have little or no discomfort. No needles or injections are required. The eyes are made numb with topical anesthetic drops. An eyelid holder is used to prevent blinking during the procedure. Patients focus on a red blinking light during both procedures. A LASIK suction ring holds the eye in position while the flap is created. During this process vision is dim or dark and the patient cannot see the flap being created and the fixation target will be blurred or not visible. Whereas with Traditional LASIK, a microkeratome blade is used to create a flap on the cornea to expose the underlying tissue, the Intralase ISF laser creates a flap with laser energy. The Intralase ISF is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created, it is then lifted and the excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. During this process while the flap is lifted, vision becomes somewhat blurry as if looking through ground glass. Patients are asked to stare at the fixation target and the laser treatment begins. Once the treatment is completed, the flap is laid back in place and the natural suction within the cornea seals the flap within 1-5 minutes and no sutures are needed. Vision will be blurry immediately after the procedure. Patients are able to blink normally and there is rapid overnight visual improvement.

INDICATIONS AND CONTRAINDICATIONS

LASIK is indicated for the treatment of nearsightedness, farsightedness and astigmatism. Candidates must be at least 18 years of age, have a stable refractive error or prescription as the procedure will not change the natural growth or aging of the eye. Candidates must be aware that this is an elective procedure. There is no medical reason why patients should have LASIK and alternative treatments are available such as contact lenses, glasses, intracorneal rings, PRK (photorefractive keratotomy) and implantable contact lenses, etc.

Candidates must be free of certain eye diseases including clinical keratoconus, vision threatening cataracts, and certain retinal and optic nerve diseases.

There are some relative contradictions such as diabetes, glaucoma, strabismus (turned eye), amblyopia (lazy eye), monocular patients, severe dry eyes, keloid scarring, ocular herpes, autoimmune diseases, collagen vascular diseases, medications or conditions which render patients immunocompromised. Ocular muscle imbalance, implants such as a pacemaker, insulin or other electronic implanted device or other disorders that can impact the procedure or the recovery. Patients must make their eye care professional and surgeon aware of any of the above conditions prior to surgery.



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Patients should make their surgeon aware of any medication allergies and any medications they are taking to avoid any potential drug interactions and allergic reactions.

The FDA considers pregnancy and nursing contraindications, although their effects on LASIK have not been studied. Female patients agree to disclose to their surgeon if they are pregnant or could potentially be pregnant.

ALTERNATIVES

Intralase ISF is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have adequate visual acuity. There are also other types of refractive surgery, including LASIK with a microkeratome.

PRE AND POST-OPERATIVE CARE

Refractive surgery will not treat ocular disease. Patients should have a complete eye examination with retinal evaluation prior to refractive surgery and annually thereafter to identify and treat ocular disease. In general, patients with higher degrees of myopia have a higher risk of retinal problems and reducing the degree of myopia with laser vision correction does not lower that risk. Patients who wear contact lenses must discontinue their use prior to LASIK to allow the cornea to return to its natural contour. Soft contact lenses must be removed at least 2 weeks prior to the procedure date. Patients who wear rigid gas permeable contact lenses must discontinue their use a minimum of one month prior to LASIK. Post-operative care is recommended for a full year following LASIK in order to monitor healing, and annually thereafter. If an enhancement procedure is needed or a complication occurs, a patient may be required to return to Eye Consultants of Texas or lengthen their stay at their expense. The final clinical results are dependent upon properly following your post-operative care instructions.

PREBYOPIA AND MONOVISION OPTIONS

Presbyopia, or the inability to see close-up objects, usually becomes apparent to most individuals in their early forties. LASIK will not prevent this natural aging of the eyes or the need for reading glasses as you age, even if you don't need them now. Some patients, usually over forty, may elect to correct their distance vision in one eye while treating the other eye to be slightly nearsighted. This technique is called monovision and may allow improved distance vision with one eye and may allow the other eye to be effective for reading your watch, reading price tags, etc. **However, most people still need reading glasses for fine print.** It has been our experience that patients with very active lifestyles such as golf or tennis players are happier if both eyes are corrected for distance and reading glasses are used for close work. The disadvantage of monovision is that your distance vision will not be as good, and many people experience more difficulties driving at night and glasses may be needed to reduce night glare.

Please initial the appropriate statement below:

I would like to have the best distance vision in both eyes _____

I would like monovision _____

CONFIDENTIALITY

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted by Eye Consultants of Texas and its affiliates, the excimer and femtosecond laser manufacturers, and the governmental regulatory authorities. The data will be used for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Patient Initials: _____

GOVERNING LAW/JURISDICTION

By initialing below, you agree that the relationship and resolution of any and all disputes between yourself and the surgeon shall be governed by and construed in accordance with the laws of Texas in which the LASIK procedure is performed. You also

I have read and understand this page: Patient Initials: _____

ECT Staff Initials: _____

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acknowledge with your initials that courts of Texas shall have jurisdiction to entertain any complaints, demands, claims or cause of action, whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in Texas and you irrevocably submit to the exclusive jurisdiction of the courts of Texas.

Patient Initials: _____

RISKS AND POTENTIAL COMPLICATIONS

As discussed earlier, all forms of surgery carry a certain degree of risk for adverse effects and complications. Problems can be related to the surgical component of LASIK or the healing component. Most surgical complications are related to the surgical component of LASIK or the healing component. Most surgical complications are related to the creation of the corneal flap with a microkeratome or Femto LDV and most healing problems develop within the first month following the procedure. Most complications improve or resolve within the first 6-12 months or with re-treatment, but some surgical or healing complications may result in permanent visual blurring, glare, discomfort, or need for corrective contact lenses. The risk of a severe complication is not only dependent upon the functioning of the microkeratome, blade, and surgical technique, but upon a number of other factors including the prescription, orbital structure, and corneal curvature of the eye. In general, there is a small risk in the range of 1-5% of experiencing a complication and very small risks, less than 1%, of severe sight-threatening complications. You should also understand that there may be other risks not known to your doctor, which may become known later.

The risks of LASIK revolve around 5 primary areas:

- Post-operative side effects
- Refractive complications
- Corneal flap complications
- Corneal healing complications
- Other miscellaneous complications

1. Post-Operative Side Effects: There are several adverse effects which may be encountered early in the post-operative period, which include foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dryness of the eyes, tearing, and fluctuation in vision. A pink or red appearance of the eyes for several weeks after surgery is more common with Intralase ISF in comparison to Traditional LASIK. Persistent pain is uncommon following LASIK and may indicate a disturbance of the epithelial protective layer, displacement of the flap, or possible infection and should be evaluated promptly by your doctor.

Corneal infection following LASIK is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases infections can even result in blindness. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Corneal inflammation can also be produced from medication or healing reactions, which may be allergic, toxic or immune in nature. Although uncommon, diffuse interface keratitis (also known as Sands of Sahara) is an inflammatory reaction that can produce corneal hazing and blurred vision. Treatment would involve topical steroids or further surgery which may or may not restore vision fully. The most common long-term side effect is dryness of the eyes and it is very common for all patients to experience some dryness after the procedure. As a general rule, the dryness lasts from 1-3 months after the procedure but may last longer in some individuals. The most important long-term side effect is night glare, star-bursting, haloes or simply reduced visual quality under low light conditions. It is very common to have night glare early on in the recovery process and night glare is more common only when one eye is treated or when the monovision option is chosen. It is more common in nearsighted patients with severe prescriptions and large pupils. Some patients benefit from night driving glasses and most, but not all patients, improve substantially over 6-12 months. In a small percentage of patients, night glare may be permanent and affect your night driving abilities.

2. Refractive Complications: Refractive problems that may be encountered include too much correction, too little correction, prescription imbalance between the eyes, aggravation of muscle imbalance problems, or a loss of effect from regression.

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LASIK may result in over corrections and under-corrections due to the variability in patient healing patterns and other surgical variables, leaving patients nearsighted, farsighted, with astigmatism, or with a combination of these things. This may or may not require patients to wear spectacles, contact lenses, or undergo further surgery. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is typically achieved. Patients may also heal differently between eyes, based on differences between the eyes in post-operative prescriptions, corneal curvature, and variation in healing or other surgical variables. Differences in prescriptions between the eyes is termed anisometropia; this is most severe only when one eye is treated, and may result in a loss of depth perception, eyestrain, headache, double vision, and the need for contact lenses. Both farsightedness and anisometropia may result in worsening of the pre-existing muscle balance problems, causing an eye to wander more or produce eye fatigue. Lastly, depending upon the severity of the original prescription, the individual healing pattern of the patient and other surgical variables, regression may occur causing the eyes to return toward their original prescription partially or, very rarely, completely. Further enhancement surgery may be performed when the eye(s) is stable and if adequate corneal tissue is available and no other medical complications are present.

3. Corneal Flap Complications: The primary benefits of LASIK are related to the creation of the protective corneal flap. The corneal flap must be of clinically adequate quality, thickness and size to proceed with laser treatment. Corneal flap complications range in severity from those that simply require the procedure to be postponed by 3 to 6 months, to those that create permanent corneal irregularities results in blurred vision. The most severe LASIK complication is that of corneal perforation which has been reported several dozen times worldwide. Corneal flap complications that occur after the LASIK procedure during the recovery period include displacement of the flap, wrinkling of the flap and epithelial in-growth.

Corneal flap problems include but are not limited to:

Corneal flaps of inadequate size preventing laser treatment and requiring the LASIK procedures to be repeated in 3-6 months. Typically, no serious visual disturbance although glare and shadowing may occasionally be produced.

Corneal flaps of inadequate quality or smoothness include a variety of corneal flap problems which may produce serious permanent corneal irregularities and significant visual blurring. Corneal flap irregularities may be produced because of inadequate suction pressure, inadequate patient cooperation, malfunction or problems with the microkeratome or femtosecond laser, Blade or suction apparatus. Corneal flaps are routinely hinged either nasally or superiorly beneath the upper eyelid. A corneal hinge is not required for a good visual result, but a hinged corneal flap is more secure and typically heals faster and more smoothly. It is possible depending upon the corneal shape, the suction ring alignment and the microkeratome or femtosecond laser that a free corneal cap may be produced which is not hinged to the cornea. Although the laser treatment can still be performed, if any irregularities in flap quality or thickness are noted, the corneal disc is immediately replaced and allowed to heal. If the free corneal cap is of excellent quality then the procedure is completed, but special care must be taken during the first 24-48 hours not to displace or lose the corneal cap. Loss of the corneal cap may result in scarring, and permanent corneal irregularity and the need for more invasive surgery. Corneal perforation is the most serious LASIK complication. Corneal perforation is prevented by the microkeratome depth plate, which is checked before each and every procedure. Eye Consultants of Texas only utilizes microkeratomes with fixed corneal depth plates. Perforation of the cornea requires corneal suturing and the need for an intraocular lens implant as the natural lens is usually lost or damaged. It should be appreciated that corneal perforation may also potentially result in infection, the need for a corneal transplant, or rarely, even blindness.

Corneal flap displacement, partial or complete, occurs during the early post-operative period, typically during the first 12-24 hours, but may occur days to weeks later with trauma. Care should be taken to protect the eyes from trauma, as well as avoiding rubbing the eyes or forcefully closing the eyes because such actions may result in corneal striae or wrinkles, which blurs vision both qualitatively and quantitatively. Most corneal striae are treatable but some may be resistant to treatment especially in highly nearsighted patients. Complete displacement of the cornea is often painful and requires urgent replacement. There is a higher risk of epithelial in-growth and infection with corneal flap displacement.

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Epithelial in-growth occurs during the first month following LASIK and is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a factor. Epithelial in-growth is produced when epithelial surface cells grow underneath the corneal flap during the healing of the corneal incision. Epithelial in-growth is more common with any trauma or breakdown of the epithelium, which is more common in LASIK enhancement procedures and long-term contact lens wearers. Treatment of this condition involved lifting the flap and clearing the cells away. Although most small areas of epithelial in-growth only need to be monitored, untreated large areas of epithelial in-growth may distort vision and may actually damage the flap integrity if severe and progressive.

Corneal abrasions occasionally occur during the flap making process and are generally of little consequence; however, if the corneal abrasion is central (in front of pupil) it will delay visual recovery and could lead to corneal irregularities which may permanently affect the quality, crispness, and sharpness of vision. Most irregularities secondary to corneal abrasions improve over a 3 to 6-month period and require no further treatment. Some irregularities may be improved with further treatment; however, some may be permanent. The final decision on instrumentation to be used to create the flap (microkeratome or Femto LDV) is at the discretion of the surgeon.

4. Corneal Healing Complications: The protective corneal flap of LASIK reduces the healing component of LASIK refractive surgery compared to PRK, but significant healing is still required which can affect the quality and vision of the final result. Corneal healing problems with LASIK are more likely to be experienced by patients corrected for higher degrees of nearsightedness, farsightedness, and astigmatism, which may potentially slow visual recovery and increase the need for enhancement procedures for over and under-corrections. Corneal healing may not only affect the speed of visual recovery but the smoothness of the cornea, and may produce visual blurring. Rarely, corneal scarring may be produced with LASIK. The most important aspect of corneal healing following LASIK or any other form of refractive surgery is the development of corneal irregularities which may permanently affect the quality, crispness, and sharpness of the final visual result. Corneal irregularities or irregular astigmatism is produced when the cornea heals in an irregular pattern, which may or may not follow a surgical flap complication. Corneal irregularity may also be produced from abnormalities and complications of the laser treatment, including central islands and decentrations which may produce blurring, shadowing, glare, and double vision. Some corneal irregularity is commonly expected for the first several weeks following an uncomplicated LASIK, however if it persists beyond 6 months it is considered abnormal and may be permanent. Most corneal irregularity improves over 6 to 12-months and some causes of corneal irregularities may be surgically managed but other causes are permanent. The greatest limitation of the healing process is that further surgical intervention does not guarantee better healing and may, in fact, result in a further reduction of visual quality. Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that a patient may be unable to read the bottom few lines of the eye chart even with spectacle or contact lens correction. If the distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

Specifically, the best vision a patient measures after surgery even with lens correction may not be as good as the patient enjoyed before refractive surgery. In some cases, patients will actually lose best corrected vision.

Keratoconus, a degenerative corneal disease that occurs in approximately 1/2000 in the general population, may develop. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

In certain cases, the vision may be severely impaired and affect the ability of a patient to drive legally, this is most important to patients who already have reduced visual acuity from other causes. LASIK is not intended to increase the visual potential of a patient and many candidates with high prescriptions often are unable to read 20/20 before surgery and should not be expected to read 20/20 after surgery. Furthermore, a patient who is best corrected before surgery to 20/40 is already



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borderline for legal driving and any loss of best corrected vision from healing or surgical complications may prevent legal driving.

- 5. Other Miscellaneous Complications: Other potential complications include a malfunction of the excimer laser, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss. It is important to note that it is impossible to list every conceivable complication that is not listed above. Risks and complications that are considered unforeseeable, remote or not commonly known are not discussed. In addition, there may be long term effects not yet known or anticipated at the present time. The most severe possible complications would necessitate more invasive or repeated corneal surgery, including corneal transplantation and could potentially produce partial or complete loss of vision.

PATIENT UNDERSTANDING AND ACCEPTANCE OF RISKS

- 1. I understand that my vision after surgery using the Intralase ISF technology may not be clear immediately and that I might not notice improvement for several days to several weeks
- 2. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
- 3. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
- 4. I understand that an overcorrection or under-correction could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. If permanent, I may need to use glasses or contact lenses. I understand an overcorrection or under-correction is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
- 5. After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.
- 6. I understand that I may not get a full correction from my LASIK procedure and this may require future re-treatment procedures, such as more laser treatment or the use of glasses or contact lenses.
- 7. I understand that there may be a “balance” problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult.
- 8. I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
- 9. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

I have read and understand this page: Patient Initials: _____

ECT Staff Initials: _____



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- 10. I understand that there may be pain, irritation, or a foreign body sensation, particularly during the first 48 hours after surgery. I also understand that pain may be associated with complications such as infection.
- 11. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
- 12. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
- 13. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I, therefore, understand that I must not drive the day of surgery and should not drive until I am certain that my vision is adequate for driving.
- 14. I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

EXPECTATIONS/ENHANCEMENTS

The goal of LASIK is to achieve the best visual result the safest way. **The goal is not to eliminate glasses and contacts completely but to dramatically reduce your dependence on them in an attempt to help improve your quality of life.** Patients over 40 years of age who have both eyes corrected for clear distance vision will still need reading glasses for many close tasks. The strength of readers needed to see up close may vary throughout the duration of the healing process. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age for patients who undergo this procedure. Night driving glasses and reading glasses may always be needed even when an excellent visual result is achieved. It is also important to recognize that even 90% clarity of vision is still 10% blurry and glasses may be needed for certain activities that require fine or detailed vision.

Enhancement procedures can be performed when stable, unless medically unwise or unsafe. Re-treatment can be performed no sooner than three months after surgery, and for up to one year after surgery. Adequate corneal tissue must be available to proceed with an enhancement procedure and a repeat measurement of the residual corneal thickness will be taken. Typically, patients considered for an enhancement procedure should have at least 1.00 diopter of residual hyperopic, myopia, astigmatism, or unaided vision of 20/40 or worse. Enhancement procedures are typically performed by lifting the original flap during the first few months before full healing occurs, or by performing photorefractive keratectomy (PRK). **Rarely, a new flap may need to be created.** There are always risks which must be balanced against the benefits of performing further surgery. Complications are an inherent part of surgery and despite our best efforts, training and skill; we recognize that some patients will experience problems. It is simply our hope to educate you so that you can make an informed decision whether or not to proceed. **No one ever believes that they will be in the small percentage of people that develops a significant complication, so it is important for all candidates to appreciate that there are truly no guarantees.**

TREATMENT OF ONE OR BOTH EYES

There are both advantages and disadvantages of having LASIK on both eyes on the same day. The benefits of surgery on both eyes during the same session begin with the simple fact that patients often prefer this option as it is more convenient, with respect to either work or home life. Patients may also feel that their vision feels more balanced, with improved depth perception and night glare may dissipate more rapidly. Some patients find that they have less anxiety, while others prefer the safety of treating only one eye at a time to allow visual recovery of the first eye prior to proceeding with the second eye.

The primary risk of treating both eyes on the same day are related to unrecognized surgical complications or more commonly, unexpected healing complications, which can produce either temporary or permanent visual blurring. Adequate visual recovery from laser vision correction for activities such as driving, as well as returning to work, may take 1 day to 1 month, or even longer in patients who respond abnormally, whether one or both eyes are treated. If both eyes are treated, then visual recovery may be prolonged and there is no way to predict who will take longer to heal. There is also no opportunity to learn from the healing pattern

I have read and understand this page: Patient Initials: _____

ECT Staff Initials: _____



**INFORMED CONSENT FOR LASER IN SITU
KERATOMILEUSIS (LASIK) WITH INTRALASE**

of the first eye. If there is an under-correction or over-correction in one eye, this is likely to occur in both eyes and both eyes will require re-treatment. Other healing complications may also affect both eyes; most importantly the risk of infection may result in severe scarring, corneal transplantation, and even loss of vision in both eyes.

PATIENT CONSENT

The basic procedures of LASIK, as well as its associated advantages and disadvantages, risks, possible complications, and alternative treatments have been explained to me by my surgeon. I understand that LASIK is an elective procedure and the results cannot be guaranteed. LASIK may not eliminate all of my myopia, hyperopia, or astigmatism, and it is possible that I may need additional correction with glasses, contact lenses, or further surgery. **Although it is impossible for my surgeon to inform me of every possible complication that may occur, my surgeon has answered all my questions to my satisfaction.**

In signing this informed consent for LASIK, I am stating that I have been offered a copy of this consent, that I fully understand the risks, benefits, and potential complications of LASIK, and **I wish to proceed with LASIK surgery on my:**

Right Eye Left Eye Both Eyes

Please write in your own handwriting the following three statements:

I understand that **“there are risks and no guarantees.”**

I understand that **“I may still need to wear glasses for near, intermediate and distance vision.”**

I understand from the Eye Consultants team that: **“I have been given the opportunity to ask questions and all my questions have been answered to my satisfaction.”**

By signing this document, I acknowledge that I have read and understood this consent.

Patient Name (Print) _____ **Patient Signature** _____ **Date** _____

Phillips Kirk Labor, M.D.
Surgeon Name (Print) _____ **Surgeon Signature** _____ **Date** _____

Witness _____ **Witness Signature** _____ **Date** _____

INTRODUCTION

This information must be reviewed so you can make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce your nearsightedness, farsightedness, or astigmatism. Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to your doctor.

ALTERNATIVES TO PRK SURGERY

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

COMPLICATIONS AND SIDE EFFECTS

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

1. **Possible short-term effects of PRK surgery:** The following have been reported in the short-term post treatment period and are associated with the normal post treatment healing process: mild discomfort or pain (first 72-96 hours), corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity and tearing.

Possible long-term complications of PRK surgery:

2. Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
3. Starbursting: After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.
4. Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
5. IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.
6. Mild or severe infection: Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery, or if very severe, corneal transplantation.
7. Keratoconus: Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
8. **Infrequent complications**: The following complications have been reported infrequently by those who have had PRK surgery: itching, dryness of the eye, or foreign body feeling in the eye; double or ghost images; patient discomfort; inflammation of the cornea or iris; persistent corneal surface defect; persistent corneal scarring severe enough to affect vision; ulceration/infection/irregular astigmatism (warped corneal surface which causes distorted images); cataract; dropping of the eyelid; loss of bandage contact lens with increased pain (usually corrected by replacing with another contact lens); and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

IN GIVING MY PERMISSION FOR PRK SURGERY, I DECLARE THAT I UNDERSTAND THE FOLLOWING:

The long-term risks and effects of PRK surgery are unknown. The goal of PRK with the excimer laser is to reduce dependence upon or need for contact lenses and/or eyeglasses; however, I understand that as with all forms of treatment, the results in my case cannot be guaranteed.

1. I understand that an overcorrection or under-correction could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or under-correction is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
2. If I currently need reading glasses, I will likely still need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have PRK surgery.
3. Further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK or other refractive surgery.
4. My best vision, even with glasses or contacts, may become worse.
5. There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.
6. I understand there is a remote chance of partial or complete loss of vision in the eye that has had PRK surgery.
7. I understand that it is not possible to state every complication that may occur as a result of PRK surgery.
8. I also understand that complications or a poor outcome may manifest weeks, months, or even years after PRK surgery.
9. I understand this is an elective procedure and that PRK surgery is not reversible.
10. My ophthalmologist has informed me that Mitomycin-C will be used “off-label” as part of my PRK surgery.
11. My ophthalmologist has informed me and I understand that custom PRK is an “off-label” use of the Excimer Laser.

ADDENDUM: INFORMED CONSENT FOR MITOMYCIN-C (MMC) WITH REFRACTIVE SURGERY INDICATIONS AND ALTERNATIVES OF MITOMYCIN

The correction of high degrees of nearsightedness (or myopia), farsightedness (hyperopia), astigmatism, treatment after previous radial keratometry (RK), LASIK or PRK, using the excimer laser is associated with a higher chance of developing corneal scarring or “haze.” This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), and Advanced Surface Ablation (ASA) have been associated with corneal haze in some individuals.

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

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

COMPLICATIONS RELATED TO MITOMYCIN

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain. Although the complications listed above have been seen in various types of eye surgeries, **no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery.** This technique uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for up to two minutes. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

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

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING REGARDING MITOMYCIN

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

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

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

I give my informed consent to my surgeon (indicated below) and/or his or her assistants to use MMC on my:

Right Eye Left Eye Both Eyes

WRITTEN CONFIRMATION

Please write in your own handwriting the following three statements to confirm that you understand and accept that PRK is an elective surgical procedure and as with all surgical procedures, the result cannot be guaranteed. You acknowledge that although vision-threatening complications are quite rare, it is possible that partial or complete loss of vision may be produced as a result of a surgical or healing complication. The procedure may not eliminate all of your myopia, hyperopia, or astigmatism and that additional correction with glasses, contact lenses, or further surgery may be required.

I therefore consent to having PRK surgery on my:

Right Eye Left Eye Both Eyes

Please write the following statements in your own handwriting:

I understand that: "I may still need to wear glasses for distance, intermediate, and near vision."

INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

I understand from the Eye Consultants team that: **“I have been given the opportunity to ask questions and all my questions have been answered to my satisfaction.”**

I understand that: **“There are risks and no guarantees.”**

By signing this document, I acknowledge that I have read and understood this consent.

Patient Name (Print)

Patient Signature

Date

Phillips Kirk Labor, M.D.

Surgeon Name (Print)

Surgeon Signature

Date

Witness

Witness Signature

Date



EYE CONSULTANTS
OF TEXAS

Laser Vision Correction Frequently Asked Questions

1. What are the long-term effects of laser vision correction?

Laser vision correction has been performed since 1987. The FDA has approved the use of the excimer laser and recognized laser vision correction as being safe and effective for the treatment of nearsightedness, farsightedness, and astigmatism in eligible patients. In the United States alone, well over 6 million procedures have been performed.

Most experts worldwide are confident that they will discover no long-term problems with the laser vision correction and the procedure has become the most commonly performed refractive surgery in the world.

2. What if I currently wear contact lenses?

Prior to laser vision correction, it is important that the curvature of the corneas return to the natural shape. The only way to ensure this is for the contact lens use to be discontinued. For most patients who wear soft contact lenses the cornea will return to its natural shape within 1-2 weeks. 30 days without contact lenses is generally required to reach corneal stability for patients who wear rigid or gas permeable lenses. *Your surgeon will determine exactly how long you will need to be out of your lenses.*

3. Can laser vision correction eliminate the need for reading glasses?

Yes and no. The need for reading glasses usually begins at age 40-45 and is caused by a loss of elasticity of the natural lens inside the eye. This loss of elasticity results in an inability to focus on small print or objects at near. This condition is called presbyopia. Laser vision correction cannot restore the elasticity to the natural lens inside the eye, however, there is a technique that is commonly used with contact lenses called monovision in which one eye is fit with a contact lens to see at a distance and the other eye is fit with a contact lens to see at near. This technique can also be used with laser vision correction. One eye would be treated to see at a distance and the other eye would be treated to see at near.

It has been our experience that monovision is helpful for near tasks as reading a watch, restaurant menu, or price tags, but not for reading fine print or prolonged close work. It is important to understand that even with monovision, almost everyone will still need reading glasses at some point.

It is very important for people who are nearsighted and who are over the age of 40 to understand that prior to laser vision correction, it is possible to remove their glasses and see objects at near without corrective eyewear. However, after laser vision correction, if both eyes are treated for distance vision, more than likely reading glasses will become necessary in order to focus on near objects.

4. What can I expect on the day of my procedure?

It is recommended that you wear comfortable clothing on the day of your procedure. The laser is kept in a controlled environment. Please refrain from wearing any cologne or



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perfume. Also, it is important that you do not wear any eye make up on that day. Please leave your cell phone at home or with someone in the lobby.

5. How long does it take to perform the procedure?

The actual laser time is typically less than 2 minutes per eye. A person will be in the laser suite only 15-20 minutes for the actual procedure. Most people are on their way 20-30 minutes following the procedure. Expect to spend approximately 1-2 hours at the facility on the day of your procedure.

6. Will the procedure hurt?

The feeling of anxiety and the fear of the unknown is worse than the actual procedure. Anesthetic drops are used to numb the front surface of the eye just before the procedure. You may also be given a mild sedative. After your procedure, your eye may feel a foreign body sensation (scratchy feeling) for a few hours. It is recommended that you take a short nap after the procedure. You will be given a steroid, antibiotic, and lubricating drops to be used for the first few days after your procedure.

7. Are both eyes treated on the same day?

Most patients who undergo laser vision correction have the procedure on both eyes on the same day, however, the procedure can be performed one at a time as well.

8. Can I drive home from surgery?

You may not drive after the surgery. A family member or friend must accompany you to and from the surgery facility.

9. How much time will I need to recover?

Most patients notice a dramatic improvement within the first few days following the procedure and are able to drive a car and return to work within 1-3 days. However, the speed of visual recovery ultimately depends on personal healing patterns. You will be given a post-operative instruction sheet and will be required to use all your eye drops as directed post-operatively. You will be seen by either the surgeon or your optometrist at 1 day, 1 week, 1 month, 3 months, and 1 year after your procedure, but this may vary according to your referring optometrist's protocol.

10. What can I expect my vision to be after laser vision correction?

As with any surgical procedure, results cannot be guaranteed. The results of laser vision correction have been overwhelmingly successful in eliminating or reducing the dependence on glasses or contact lenses. In a recent study, 98% of patients treated for nearsightedness and/or astigmatism achieved 20/40 vision after one or more treatments. This means they can drive legally, play sports, and join the police or fire department without depending on corrective eyewear.

Ultimately, how well a person sees and how quickly their vision improves depends on the degree of their prescription and their particular healing pattern. During your complimentary consultation we will discuss the range of probable outcomes based on your prescription.

11. What are the risks of laser vision correction?

No surgical procedure is without risks. Long term sight-threatening complications from PRK and LASIK are very uncommon. The chance of having a serious vision threatening complication is much less than 1%. Some potential complications include conditions such as dryness, complications in creating the surgical flap, night glare, under or over-correction, and loss of best corrected vision. Proper pre-operative screening ensures that we proceed with the procedure only when it is medically advisable. As well, diligent post-operative care helps to identify and address any potential healing complications.

Understanding potential risks allows you to make an informed decision before undergoing laser vision correction. Your surgeon will discuss potential risks in greater detail and answer any questions you may have during your consultation.

12. How do I determine if I am a candidate for laser vision correction?

Schedule a complimentary laser vision correction screening with our office. During the consultation we will determine candidacy and which procedure would offer the greatest benefit for your particular needs.

13. What is custom LASIK?

Custom LASIK is a procedure that involves the use of a wavefront analyzer and enables your surgeon to customize the Conventional LASIK procedure to your individual eyes. In essence, we determine the unique fingerprint or “waveprint” of your visual system for each eye. This can result in you seeing clearer and sharper than ever.

14. Does insurance cover laser vision correction?

Generally, laser vision correction is considered elective and is not covered by many health insurance plans. However, some companies have started covering the procedure. Our staff will be happy to call your insurance carrier to determine if laser vision correction is an included benefit.

15. Is there financing available?

Yes, our office provides monthly payment plans, zero percent financing for those who qualify, and offers competitive pricing that makes laser vision correction easily affordable.

Please call our Refractive Coordinator with any questions at **(817) 410-2030 ext. 208**