



1-800-246-1000

Informed Consent for Refractive Surgery
7/2006

**Please read the entire packet and bring it with you on the day of your consultation/surgery with Dr. Zimmer.
Please leave page six blank. We will go over this with you at the time of your appointment.**

General Information

The following information is intended to help you make an informed decision about having refractive surgery. We continually strive to balance the benefits of this surgery with the known and unknown risks. *Refractive surgery, procedures designed to help you decrease or eliminate your dependence on corrective lenses, is a relatively innovative concept and there may be long-term effects that are not yet known or anticipated.* Therefore, it is impossible to list all risks and complications associated with this surgery or any other treatment. It is important to understand that it is impossible to perform surgery without the patient accepting a certain degree of risk and responsibility. The only way a patient can avoid all surgical risks is by not proceeding with surgery.

****One of the following procedures has been chosen by you and your physicians to be the most beneficial to correct your vision. It is important to read and understand all of the following information related to your surgery.**

LASIK

*Laser Assisted In-Situ Keratomileusis
Conventional and Custom*

You have been diagnosed with myopia (nearsightedness), hyperopia (farsightedness), with or without astigmatism. LASIK is a form of refractive surgery to help correct these conditions. Before the surgery is performed, an anesthetic eye drop is placed in the eye to numb it. Then, a suction ring is placed on the cornea. When suction is applied to your eye your vision will gradually become completely gray. An instrument called a microkeratome is then used to create a thin flap from the surface of the cornea. After the flap is made, your vision will brighten. The corneal flap made by the microkeratome is approximately three hairs thick, while the entire cornea is typically eleven hairs thick. The flap is folded back and the surgeon uses the excimer laser to remove a thin layer of corneal tissue to reshape the eye. The removal of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea. The surgeon then carefully puts the flap back into place where it usually bonds without the need for stitches.

Post Treatment Precautions

Your eye shield should be worn for the first four hours after surgery and for the first four nights while sleeping. As with any corneal scar, the cornea will not be as strong at the point of incision after it heals as it was before surgery. Therefore, the eye is somewhat vulnerable to all varieties of injuries for at least the first year after LASIK. It is advisable to wear protective eyewear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist, etc. contacting the eye may be high. In addition, avoid rubbing your eye

PRK

Photorefractive Keratectomy

You have been diagnosed with myopia (nearsightedness), hyperopia (farsightedness), with or without astigmatism. PRK, also known as the "Touchless Technique," is a form of refractive surgery to help correct these conditions. Before the surgery is performed, an anesthetic eye drop is placed in the eye to numb it. The excimer laser is used

to remove the top layer of the cornea, the epithelium. Thin layers of tissue beneath the epithelium are removed by the excimer laser, thus reshaping the eye. The removal of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea. An extended wear bandage contact lens is inserted in the eye immediately following the procedure to protect it until the epithelium grows back, usually within two to five days after surgery. You will use steroidal drops to aid in the healing process for approximately one to three months.

Post Treatment Precautions

Following surgery, your cornea will be covered with a bandage contact lens. This should remain on your eye for the first two to five days. Avoid rubbing or squeezing your eye as this may cause the lens to fall out. If this happens, do not attempt to replace it. Contact your doctor's office immediately. Your doctor will remove the lens when it is determined that the cornea has healed.

RK

Radial Keratotomy

You have been diagnosed with myopia (nearsightedness). RK is an incision procedure used to correct this condition. Before the surgery is performed, an anesthetic eye drop is placed in the eye to numb it. The surgeon uses a diamond blade to make microscopic incisions, much like the spokes of a bicycle wheel, on the cornea. These incisions will flatten the cornea, thus reshaping the eye and changing its focusing power.

AK

Astigmatic Keratotomy

You have been diagnosed with astigmatism. AK is an incision procedure used to correct this condition. Before the surgery is performed, an anesthetic eye drop is placed in the eye to numb it. The surgeon uses a diamond blade to make microscopic arc-like incisions on the cornea. These incisions will create a more spherical cornea, thus reshaping the eye and changing its focusing power.

You may require one or both of these procedures. They are performed simultaneously if you have both nearsightedness and astigmatism.

LTK

Laser Thermal Keratoplasty

You have been diagnosed with hyperopia (farsightedness) or presbyopia (the inability to read at near). LTK is a refractive procedure performed with a holmium: YAG laser. Before the surgery is performed, an anesthetic eye drop is placed in the eye to numb it. You will be seated at the LTK laser and asked to focus on a blinking light to help steady your eye. As the procedure is performed, you will hear a series of clicks as the laser makes a pattern of tiny dots on your cornea. This pattern causes the cornea to slightly shrink, which in turn causes the cornea to become steeper, thus changing the focusing power of your eye. The actual treatment time is only a few seconds and it is important to remain still during this time. You may feel a slight sensation during the laser treatment. This is normal and indicates that the laser energy is interacting with the cornea.

After surgery you may be initially nearsighted which will allow you to see things well closely. Over time, your distance vision will improve while some of your near vision will decrease. This is a normal healing response.

You may still require reading glasses for close-up activities, unless monovision has been chosen to correct presbyopia.

Post Treatment Precautions

You may experience some discomfort or tearing after treatment. In addition, some risks include: anisometropia (a temporary inability for the eyes to focus together), no change in vision, vision becoming worse, change in vision followed by a return to pre-treatment vision, astigmatism, allergic reactions to the drops, light sensitivity, and transient corneal haze (the spots are visible for the first few days and gradually fade).

Due to the nature of hyperopia, there is a loss of effect with time.

CLEAR LENSECTOMY

You have been diagnosed with a degree of myopia (nearsightedness) or hyperopia (farsightedness) beyond what may be easily corrected with other forms of refractive surgery. Unlike other corrective surgeries that alter the shape of the cornea, clear lensectomy changes the focusing power of the lens within the eye. For this procedure the eye's natural lens is removed and replaced by a manufactured lens implant that has been selected to provide clear focusing ability. The lens implant remains within the eye, without needing further care after surgery. It provides a wide range of focusing freedom, but since it is fixed, you may still require corrective lenses for some tasks.

Clear lensectomy is an outpatient procedure and is performed in an ambulatory surgery center. You will not be put to sleep during the procedure, but may be sedated with oral or intravenous medications.

Similar to cataract surgery, the surgeon makes a small incision in either the white sclera or on the edge of the cornea. Using an ultrasonic probe, the surgeon gently breaks apart and suctions the gel from the lens capsule. The surgeon then inserts a high quality lens implant of appropriate power and positions it securely within the natural lens capsule. Because the incision is designed to be self-healing, the surgery can usually be completed without stitches. It takes approximately 15 minutes to complete the procedure. If needed, other refractive procedures can be performed after clear lensectomy to enhance the result. This procedure is usually not performed on those under 40 years of age unless the diagnosis and testing reveals it is the best option. People under 40 years of age will lose their ability to focus up-close and will need reading glasses.

Post Treatment Precautions

As with any surgery, there is always a risk of complications. Complications with clear lensectomy include the following: retinal detachment (less than 1%), infection (less than 1%), and corneal surface surgery complications such as induced astigmatism (less than 1%). In addition, you may need a lens exchange (10% chance). We may bill your insurance for these additional procedures.

LIMITS OF REFRACTIVE SURGERY

Although the goal of refractive surgery is to improve vision to the point that the need for corrective lenses is reduced or even eliminated, this result is not guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve adequate vision. Refractive surgery does not correct the condition known as presbyopia, a process of aging within the eye. It occurs in most people around age 38 and may cause the need for reading glasses for close-up work. If you presently need reading glasses, you will still need them after this treatment. If you do not need reading glasses, but are age 38 or older, you may need them after the procedure, or at a later age. If you currently remove your distance vision glasses to read better or see better close-up, you may require reading glasses after having the procedure. Refractive surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachments.

Monovision

Everyone between the ages of 38 and 52 will experience presbyopia which is a process of aging within the eye and may result in the need for reading glasses or bifocals. One option to reduce the chance of needing reading glasses or bifocals is monovision, in monovision; one eye is corrected for distance vision while the other eye is corrected for near vision. This option involves losing some distance sharpness. Night driving glasses are more common and reading glasses may still be required for fine print or prolonged reading. Monovision helps with the simple near tasks such as opening mail, reading price tag or looking at your wristwatch. Patients, who desire the best distance or night vision unaided, such as golfers, should avoid monovision.

_____ I desire monovision correction.

_____ I desire distance correction only.

Risks

Refractive surgery can include, but is not limited to the following risks. Refractive surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection and/or irregular scarring or other causes. If these are not successfully controlled by antibiotics, steroids or other necessary treatment, loss of the infected eye can occur. The cornea may heal irregularly which may add astigmatism and make wearing glasses or contact lenses necessary or may lead to the loss of useful vision. In addition, irregular corneal healing could result in a distorted corneal surface so that distorted vision or "ghosting" occurs. This may or may not be correctable by glasses or contact lenses.

Additional Risks

Other reported complications include: corneal ulcer formation, endothelial cell loss – loss of cell density in the inner layer of the cornea which can possibly result in corneal swelling, ptosis – droopy eyelid, corneal swelling, contact lens intolerance, retinal detachment, and hemorrhage. Complications could arise requiring further corrective procedures including either a partial (lamellar) or full thickness corneal transplant using a donor cornea. These complications include, but are not limited to: loss of corneal disc, damage to the corneal disc, disc decentration, and progressive corneal thinning (ectasia). Sutures may be required which could induce astigmatism. There are potential complications due to anesthesia and medications that may involve other parts of your body. It is possible that the microkeratome or excimer laser could malfunction and the procedure would be stopped. It is possible due to the microkeratome in LASIK; you could experience an incomplete flap creation, also requiring the procedure to be stopped. The procedure may be attempted again after three months. Epithelial ingrowths – epithelial cells growing underneath the corneal flap in LASIK – can also occur, possibly requiring treatment.

Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.

Visual Side Effects

Other complications that can occur with refractive surgery include: anisometropia – difference in power between the two eyes, aniseikonia – difference in imaging size between the two eyes, double vision, hazy vision, fluctuating vision during the day and from day to day, increases or decreases in sensitivity to light that may be incapacitating for some time and may not completely go away, glare and halos around lights which may not completely go away.

Over Response or Under Response

Refractive surgery may not give you the result you desired if your eye under responds. If this occurs, it may be necessary to have additional surgery to “fine tune” or enhance the initial result. It is also possible that your eye may over respond to the point of becoming farsighted (by over treating nearsightedness) or nearsighted (by over treating farsightedness). It is possible that your initial results could regress over time. In some, but not all cases, re-treatment, glasses, or contact lenses could be effective in correcting vision. The goal of refractive surgery is to achieve the best visual result the safest way. The goal is NOT to eliminate glasses and contacts completely, but to dramatically reduce the dependence upon them in an attempt to help improve your quality of life. Night driving glasses and reading glasses may always be needed even with a successful procedure. The surgery does not improve visual potential and it is quite possible that rigid gas permeable lenses may actually provide certain patients with better vision than glasses, soft contact lenses and refractive surgery.

Bilateral Surgery

There are advantages and disadvantages of having bilateral surgery – surgery on both eyes at the same time. The benefits include: convenience, more quickly restored balance, more quickly reduced night glare, and possibly a reduction in patient anxiety. The disadvantages of having both eyes corrected at the same time include: the risk of infection or other healing complications is applicable to both eyes simultaneously, if there is an over correction or under correction in one eye, chances are greater that it will occur in both eyes, and if a re-treatment is required in one eye it is possible that the other eye will also require re-treatment.

Cost of Procedure

All pre and post operative treatment for one year is covered in the cost of refractive surgery. This fee also includes any enhancements for one year after your procedure. This cost does NOT include eye care problems unrelated to the surgery (i.e.: injury, retinal detachment surgery, lens exchange or Yag laser in clear lensectomy, punctal plugs, etc.

Lasik, PRK, AK, RK	\$1750/eye
<i>Clearlensectomy with Standard Lens</i>	<i>\$3500/eye</i>
<i>Clearlensectomy with Premium IOL'S</i>	<i>\$4500/eye</i>
Lifetime Enhancement	\$1000 total

Contraindications

The procedure should not be performed if you: Have been diagnosed with keratoconus or told you have early signs of keratoconus, are taking one or both of the following medications – Accutane (Isotretinoin) or Cordarone (Amiodarone Hydrochloride), have any collagen vascular, autoimmune or immunodeficiency diseases (i.e. Lupus, AIDS, etc.), or are currently taking chemotherapy or radiation treatments. Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy. In addition, pregnancy may affect your healing process and some medications may pose a risk to an unborn or nursing child. If you are pregnant or expect to become pregnant you should not have refractive surgery until after the baby is born or until you have stopped nursing for three months. If you become pregnant in the six months following treatment, you should notify your eye doctor immediately.

You should discuss with your doctor if you: are currently taking fertility drugs or hormones of any kind, your eye prescription is still changing or unstable, are a diabetic, or if you have severe allergies, or have a history of herpes simplex or herpes zoster of the eye.

Alternatives to Refractive Surgery

LASIK, PRK, RK, AK, LTK and Clearlensectomy are purely elective procedures and you may decide not to have these procedures performed. Other alternatives include: eye glasses, contact lenses, orthokeratology, corneal rings, and corneal relaxing incisions. Please feel free to discuss these options with your doctor.

Medications and Allergies You should inform your doctor of any medications you are currently taking to reduce the risk of adverse drug interactions. In addition, your doctor should be made aware of any allergies you have to any medications to reduce the risk of any potential complications during the surgery and subsequent treatment.

Contact Lens Wearers

Timely removal of your contact lenses is vital to the accuracy of the measurements taken during your preoperative examinations and your surgery.

- **Soft Contact Lenses** - Must remain out of your eyes for a minimum of ONE to TWO WEEKS prior to your preoperative examination, consult, and surgery.
- **Hard or Gas Permeable Contact Lenses** – Must remain out of your eyes for a minimum of THREE to FOUR WEEKS prior to your preoperative examination, consultation and surgery.

You must not put your contact lenses in for even a few hours. We understand that special occasions arise when you would prefer to wear your contacts. In this case, we request that the examination and surgery be postponed until you can commit to this requirement.

Transportation

For the day of surgery we strongly recommend that you arrange transportation. The drive you choose should have a flexible schedule as delays may be possible and unavoidable. If you have chosen to have BILATERAL surgery, it is MANDATORY for you to have someone drive you to both the surgery and the first postoperative visit.

Pain and Discomfort

The amount of pain and discomfort that can be expected after the procedure varies depending on each individual. However, after surgery, you can expect to have some discomfort. Vision may be blurry and you may experience some redness and/or swelling. Some patients report the sensation of a foreign body in the eye. Patient comfort levels vary greatly and are impossible to predict.

PATIENT STATEMENT

I have read this informed consent form. Refractive Surgery has been explained to me in terms I understand. I understand there are NO guarantees.

_____ Patients Initials
_____ Witness Initials

I have been informed about the possible benefits and possible complications, risks, consequences and contraindications associated with refractive surgery. I understand that it is impossible for any doctor to inform me of every conceivable complication that may occur and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that I was given no guarantee of a particular outcome.

_____ Patient Initials
_____ Witness Initials

My decision to undergo refractive surgery was made without duress of any kind. I understand that it is an elective procedure and my myopia or hyperopia and/or astigmatism may be treated by alternative means such as glasses, contact lenses, orthokeratology, corneal rings, and corneal relaxing incisions. It is hoped that the outcome of refractive surgery will reduce or possibly eliminate my dependence on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that the additional correction may be needed.

_____ Patient Initials
_____ Patient Initials

I CONSENT TO HAVE;

LASIK PRK RK AK LTK
Clearlensectomy – Standard or Premium Lens

PERFORMED ON MY:

Right Eye Left Eye Both Eyes

Patient Signature _____ Date _____

Physician Signature _____ Date _____

Witness Signature _____ Date _____

Please take a moment to tell us, in your own words, what your expectations are and why you wish to have refractive surgery.

Thank you!
From Dr. Dan Zimmer
&
The Associates in Ophthalmology Staff