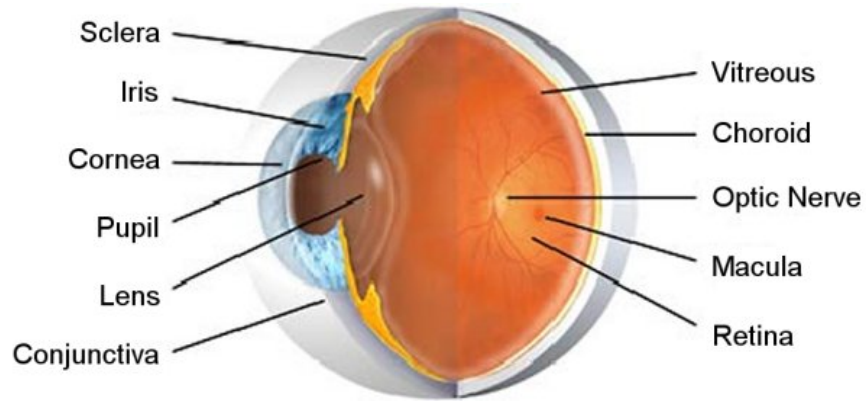




What is LASIK? The eye and vision errors



The cornea is a part of the eye that helps focus light to create an image on the retina. It works in much the same way that the lens of a camera focuses light to create an image on film.

The bending and focusing of light is also known as refraction. Usually the shape of the cornea and the eye are not perfect and the image on the retina is out-of-focus (blurred) or distorted. These imperfections in the focusing power of the eye are called refractive errors. There are three primary types of refractive errors: myopia, hyperopia and astigmatism.

- Persons with myopia, or nearsightedness, have more difficulty seeing distant objects as clearly as near objects.
- Persons with hyperopia, or farsightedness, have more difficulty seeing near objects as clearly as distant objects.
- Astigmatism is a distortion of the image on the retina caused by irregularities in the cornea or lens of the eye.

Combinations of myopia and astigmatism or hyperopia and astigmatism are common. Glasses or contact lenses are designed to compensate for the eye's imperfections.

Surgical procedures aimed at improving the focusing power of the eye are called refractive surgery. In LASIK surgery, precise and controlled removal of corneal tissue by a special laser reshapes the cornea changing its focusing power.

Other types of refractive surgery

Radial Keratotomy or RK and Photorefractive Keratectomy or PRK are other refractive surgeries used to reshape the cornea. In RK, a very sharp knife is used to cut slits in the cornea changing its shape. PRK was the first surgical procedure developed to reshape the cornea, by sculpting, using a laser. Later, LASIK was developed. The same type of laser is used for LASIK and PRK. Often the exact same laser is used for the two types of surgery. The major difference between the two surgeries is the way that the stroma, the middle layer of the cornea, is exposed before it is vaporized with the laser. In PRK, the top layer of the cornea, called the epithelium, is scraped away to expose the stromal layer underneath. In LASIK, a flap is cut in the stromal layer and the flap is folded back.



Another type of refractive surgery is thermokeratoplasty in which heat is used to reshape the cornea. The source of the heat can be a laser, but it is a different kind of laser than is used for LASIK and PRK. Other refractive devices include corneal ring segments that are inserted into the stroma and special contact lenses that temporarily reshape the cornea (orthokeratology).

What the FDA regulates

In the United States, the Food and Drug Administration (FDA) regulates the sale of medical devices such as the lasers used for LASIK. Before a medical device can be legally sold in the U.S., the person or company that wants to sell the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use, the "indication." Once the FDA has approved a medical device, a doctor may decide to use that device for other indications if the doctor feels it is in the best interest of a patient. The use of an approved device for other than its FDA-approved indication is called "off-label use." The FDA does not regulate the practice of medicine.

The FDA does not have the authority to:

- Regulate a doctor's practice. In other words, FDA does not tell doctors what to do when running their business or what they can or cannot tell their patients.
- Set the amount a doctor can charge for LASIK eye surgery.
- "Insist" the patient information booklet from the laser manufacturer be provided to the potential patient.
- Make recommendations for individual doctors, clinics, or eye centers. FDA does not maintain nor have access to any such list of doctors performing LASIK eye surgery.
- Conduct or provide a rating system on any medical device it regulates.

The first refractive laser systems approved by FDA were excimer lasers for use in PRK to treat myopia and later to treat astigmatism. However, doctors began using these lasers for LASIK (not just PRK), and to treat other refractive errors (not just myopia). Over the last several years, LASIK has become the main surgery doctors use to treat myopia in the United States. More recently, some laser manufacturers have gained FDA approval for laser systems for LASIK to treat myopia, hyperopia and astigmatism and for PRK to treat hyperopia and astigmatism.



What should I expect before, during, and after surgery?

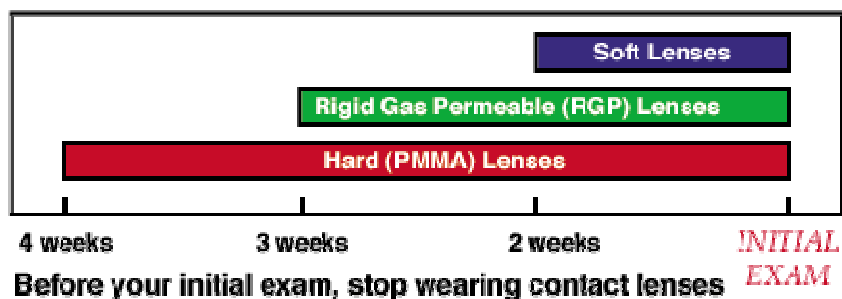
What to expect before, during, and after surgery will vary from doctor to doctor and patient to patient. This section is a compilation of patient information developed by manufacturers and healthcare professionals, but cannot replace the dialogue you should have with your doctor. Read this information carefully and with the [checklist](#), discuss your expectations with your doctor.

Before Surgery

If you decide to go ahead with LASIK surgery, you will need an initial or baseline evaluation by your eye doctor to determine if you are a good candidate. This is what you need to know to prepare for the exam and what you should expect:

If you wear contact lenses, it is a good idea to stop wearing them **before your baseline evaluation** and switch to wearing your glasses full-time. Contact lenses change the shape of your cornea for up to several weeks after you have stopped using them depending on the type of contact lenses you wear. Not leaving your contact lenses out long enough for your cornea to assume its natural shape before surgery can have negative consequences. These consequences include inaccurate measurements and a poor surgical plan, resulting in poor vision after surgery. These measurements, which determine how much corneal tissue to remove, may need to be repeated at least a week after your initial evaluation and before surgery to make sure they have not changed, especially if you wear RGP or hard lenses. If you wear:

- **soft contact lenses**, you should stop wearing them for 2 weeks before your initial evaluation.
- **toric soft lenses or rigid gas permeable (RGP) lenses**, you should stop wearing them for at least 3 weeks before your initial evaluation.
- **hard lenses**, you should stop wearing them for at least 4 weeks before your initial evaluation.
-



You should tell your doctor:

- about your past and present medical and eye conditions
- about all the medications you are taking, including over-the-counter medications and any medications you may be allergic to

Your doctor should perform a **thorough eye exam** and discuss:

- whether you are a **good candidate**
- what the risks, benefits, and alternatives of the surgery are
- what you should expect before, during, and after surgery
- what your responsibilities will be before, during, and after surgery



You should have the opportunity to ask your doctor questions during this discussion. Give yourself plenty of time to think about the risk/benefit discussion, to review any informational literature provided by your doctor, and to have any additional questions answered by your doctor before deciding to go through with surgery and **before signing the informed consent form**.

You should not feel pressured by your doctor, family, friends, or anyone else to make a decision about having surgery. Carefully consider the pros and cons.

The **day before surgery**, you should stop using:

- creams
- lotions
- makeup
- perfumes

These products as well as debris along the eyelashes may increase the risk of infection during and after surgery. Your doctor may ask you to scrub your eyelashes for a period of time before surgery to get rid of residues and debris along the lashes.

Also **before surgery**, arrange for transportation to and from your surgery and your first follow-up visit. On the day of surgery, your doctor may give you some medicine to make you relax. Because this medicine impairs your ability to drive and because your vision may be blurry, even if you don't drive make sure someone can bring you home after surgery.

During Surgery

The surgery should take less than 30 minutes. You will lie on your back in a reclining chair in an exam room containing the laser system. The laser system includes a large machine with a microscope attached to it and a computer screen.

A numbing drop will be placed in your eye, the area around your eye will be cleaned, and an instrument called a lid speculum will be used to hold your eyelids open. A ring will be placed on your eye and very high pressures will be applied to create suction to the cornea. Your vision will dim while the suction ring is on and you may feel the pressure and experience some discomfort during this part of the procedure. The microkeratome, a cutting instrument, is attached to the suction ring. Your doctor will use the blade of the microkeratome to cut a flap in your cornea.

The microkeratome and the suction ring are then removed. You will be able to see, but you will experience fluctuating degrees of blurred vision during the rest of the procedure. The doctor will then lift the flap and fold it back on its hinge, and dry the exposed tissue.

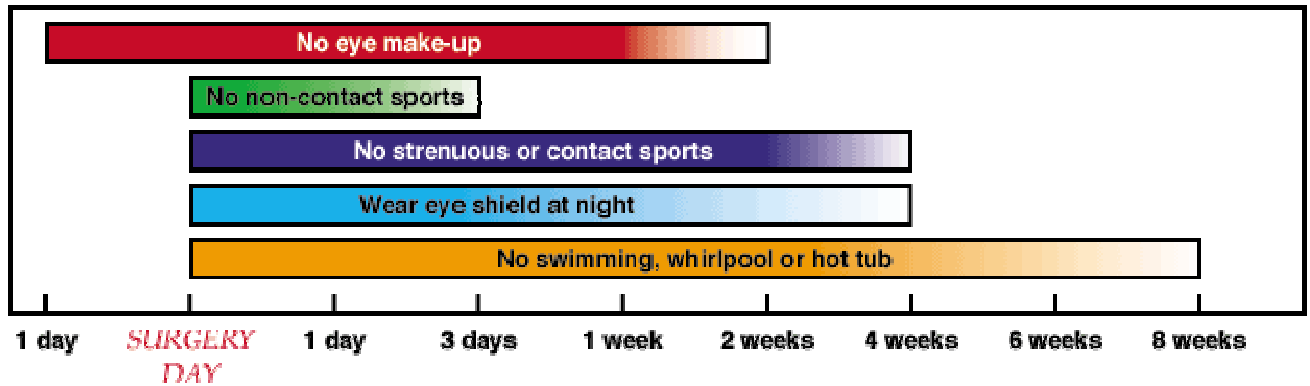
The laser will be positioned over your eye and you will be asked to stare at a light. This is **not** the laser used to remove tissue from the cornea. This light is to help you keep your eye fixed on one spot once the laser comes on. **NOTE: If you cannot stare at a fixed object for at least 60 seconds, you may not be a good candidate for this surgery.**

When your eye is in the correct position, your doctor will start the laser. At this point in the surgery, you may become aware of new sounds and smells. The pulse of the laser makes a ticking sound. As the laser removes corneal tissue, some people have reported a smell similar to burning hair. A computer controls the amount of laser delivered to your eye. Before the start of surgery, your doctor will have programmed the computer to vaporize a particular amount of tissue based on the measurements taken at your initial evaluation. After the pulses of laser energy vaporize the corneal tissue, the flap is put back into position.

A shield should be placed over your eye at the end of the procedure as protection, since no stitches are used to hold the flap in place. It is important for you to wear this shield to prevent you



from rubbing your eye and putting pressure on your eye while you sleep, and to protect your eye from accidentally being hit or poked until the flap has healed.

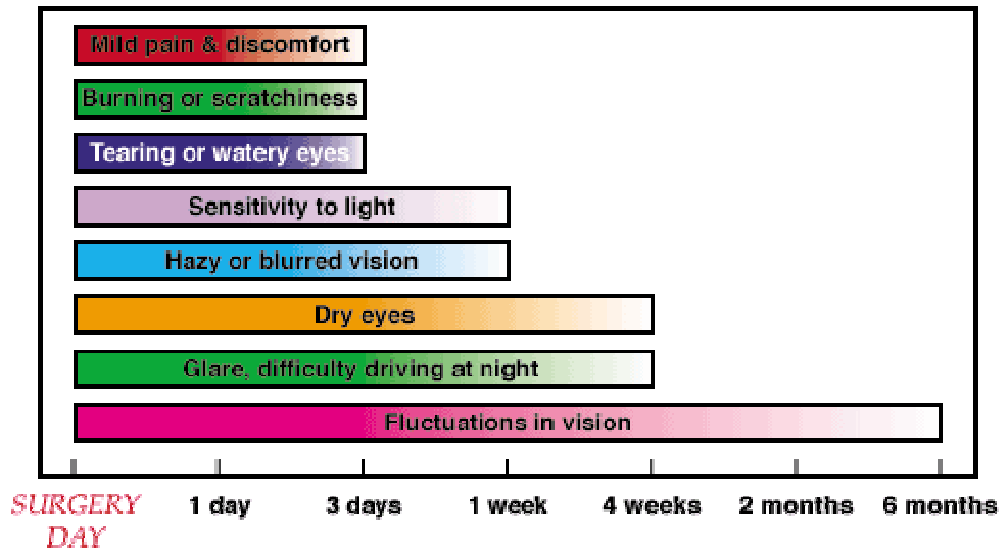


Good practices to follow before and after surgery

After Surgery

Immediately after the procedure, your eye may burn, itch, or feel like there is something in it. You may experience some discomfort, or in some cases, mild pain and your doctor may suggest you take a mild pain reliever. Both your eyes may tear or water. Your vision will probably be hazy or blurry. You will instinctively want to rub your eye, but don't! Rubbing your eye could dislodge the flap, requiring further treatment. In addition, you may experience sensitivity to light, glare, starbursts or haloes around lights, or the whites of your eye may look red or bloodshot. These symptoms should improve considerably within the first few days after surgery. You should plan on taking a few days off from work until these symptoms subside. **You should contact your doctor immediately** and not wait for your scheduled visit, if you experience severe pain, or if your vision or other symptoms get worse instead of better.

You should see your doctor within the **first 24 to 48 hours** after surgery and at regular intervals after that for at least the first six months. At the first postoperative visit, your doctor will remove the eye shield, test your vision, and examine your eye. Your doctor may give you one or more types of eye drops to take at home to help prevent infection and/or inflammation. You may also be advised to use artificial tears to help lubricate the eye. Do not resume wearing a contact lens in the operated eye, even if your vision is blurry.



What to expect after surgery

You should wait **one to three days** following surgery before beginning any non-contact sports, depending on the amount of activity required, how you feel, and your doctor's instructions. To help prevent infection, you may need to wait for up to **two weeks after surgery or until your doctor advises you otherwise** before using lotions, creams, or make-up around the eye. Your doctor may advise you to continue scrubbing your eyelashes for a period of time after surgery. You should also avoid swimming and using hot tubs or whirlpools for 1-2 months.

Strenuous contact sports such as boxing, football, karate, etc. should not be attempted for at least **four weeks** after surgery. It is important to protect your eyes from anything that might get in them and from being hit or bumped.

During the **first few months** after surgery, your vision may fluctuate.

- It may take up to three to six months for your vision to stabilize after surgery.
- Glare, haloes, difficulty driving at night, and other visual symptoms may also persist during this stabilization period. If further correction or enhancement is necessary, you should wait until your eye measurements are consistent for two consecutive visits at least 3 months apart before re-operation.
- It is important to realize that although distance vision may improve after re-operation, it is unlikely that other visual symptoms such as glare or haloes will improve.
- It is also important to note that no laser company has presented enough evidence for the FDA to make conclusions about the safety or effectiveness of enhancement surgery.

Contact your eye doctor immediately, if you develop any new, unusual or worsening symptoms at any point after surgery. Such symptoms could signal a problem that, if not treated early enough, may lead to a loss of vision.



LASIK Surgery Checklist

Know what makes you a poor candidate

- Career impact** - does your job prohibit refractive surgery?
- Cost** - can you really afford this procedure?
- Medical conditions** - e.g., do you have an autoimmune disease or other major illness? Do you have a chronic illness that might slow or alter healing?
- Eye conditions** - do you have or have you ever had any problems with your eyes other than needing glasses or contacts?
- Medications** - do you take steroids or other drugs that might prevent healing?
- Stable refraction** - has your prescription changed in the last year?
- High or Low refractive error** - do you use glasses/contacts only some of the time? Do you need an unusually strong prescription?
- Pupil size** - are your pupils extra large in dim conditions?
- Corneal thickness** - do you have thin corneas?

Know all the risks and procedure limitations

- Overtreatment or undertreatment** - are you willing and able to have more than one surgery to get the desired result?
- May still need reading glasses** - do you have presbyopia?
- Results may not be lasting** - do you think this is the last correction you will ever need? Do you realize that long-term results are not known?
- May permanently lose vision** - do you know some patients may lose some vision or experience blindness?
- Development of visual symptoms** - do you know about glare, halos, starbursts, etc. and that night driving might be difficult?
- Contrast sensitivity** - do you know your vision could be significantly reduced in dim light conditions?
- Bilateral treatment** - do you know the additional risks of having both eyes treated at the same time?
- Patient information** - have you read the patient information booklet about the laser being used for your procedure?

Know how to find the right doctor

- Experienced** - how many eyes has your doctor performed LASIK surgery on with the same laser?
- Equipment** - does your doctor use an FDA-approved laser for the procedure you need?
- Informative** - is your doctor willing to spend the time to answer all your questions?

- Long-term Care** - does your doctor encourage follow-up and management of you as a patient? Your preop and postop care could be provided by a doctor other than the surgeon at another practice.
- Be Comfortable** - do you feel you know your doctor and are comfortable with an equal exchange of information?

Know preoperative, operative, and postoperative expectations

- No contact lenses prior to evaluation and surgery** - can you go for an extended period of time without wearing contact lenses?
- Have a thorough exam** - have you arranged not to drive or work after the exam?
- Read and understand the informed consent** - has your doctor given you an informed consent form to take home and answered all your questions?
- No makeup before surgery** - can you go 24-36 hours without makeup prior to surgery?
- Arrange for transportation** - can someone drive you home after surgery?
- Plan to take a few days to recover** - can you take time off to take it easy for a couple of days if necessary?
- Expect not to see clearly for a few days** - do you know you will not see clearly immediately?
- Know sights, smells, sounds of surgery** - has your doctor made you feel comfortable with the actual steps of the procedure?
- Be prepared to take drops/medications**- are you willing and able to put drops in your eyes at regular intervals?
- Be prepared to wear an eye shield** - do you know you need to protect the eye for a period of time after surgery to avoid injury?
- Expect some pain/discomfort** - do you know how much pain to expect?
- Know when to seek help** - do you understand what problems could occur and when to seek medical intervention?
- Know when to expect your vision to stop changing** - are you aware that final results could take months?
- Make sure your refraction is stable before any further surgery** - if you don't get the desired result, do you know not to have an enhancement until the prescription stops changing?



Refractive Surgery Fee Schedule

	<u>Immediate Pymt. Rate</u>	<u>Financed Rate</u>
Phototherapeutic Keratectomy (PTK)	\$1,500.00 per eye	\$1,650.00 per eye
Excimer Laser (PRK)	\$1,500.00 per eye	\$1,650.00 per eye
Laser-Assisted in Situ Keratomileusis (LASIK)	\$1800.00 per eye	\$2,000.00 per eye
Custom Ablation Fees (In addition to procedure)	\$450.00 per eye	\$500.00 per eye

Immediate Payment Methods: Cash, Visa, Master Card, or Discover (Same price applies for all payment methods). **Payment in full must be made at least 24 hours prior to the procedure.** *Personal checks can be used but must be provided at least 5 business days in advance.*

Finance Payment Methods: Payment arrangements can be made with Vision Fee Plan. Please ask for information regarding vision fee plan or check their website at www.visionfeeplan.com. Applications for payment terms and financing limits can be made online. Financing payment in full will be recognized based on approval from Vision Fee Plan.

Patients can elect to have one eye done under the terms of the immediate payment method and finance the other eye. The surgical fee would be based on the payment terms for each eye.

The pre-surgical comprehensive eye exam fee of \$135.00 will be applied to the cost of the surgery.

This visit will be billed to a patient's medical insurance provider if there is a valid medical diagnosis. All normal eye exams will not be billed to insurance and payment is due at the time of service. If the refractive surgery candidate decides to have surgery, then the \$135.00 exam payment will be applied towards the total cost of the surgery.

You can call your insurance company to see if your policy covers refractive surgery. The following procedure codes will aid you in the process of pursuing coverage:

CPT Code for LASIK: 66999

Please note that if your insurance should cover the procedure in full, we will need written confirmation of this on your insurance company's letterhead stating the following:

- Coverage exists
- The patient is eligible for the coverage,
- Payment will be approved
- The approved amount of payment will be for the fee Simpson Eye Associates charges