

Is LASIK for me?

Part 1 of a 3-Part Series

MAKING THE
DECISIONS

Answers
to your
laser eye
surgery
FAQs

Refractive
**Myth
Busters**

Patient stories and photographs are based on real-life experiences, portrayed by models. Individual results may vary.

Is LASIK for me?

No doubt you've heard about laser eye surgery—especially LASIK. In fact, you probably haven't been able to turn on your radio, TV, computer, or opened a magazine without ads popping up, telling how fast, easy, and life changing laser eye surgery can be.

“But you have questions. Like, ‘How do I find out about what to expect during surgery?’”

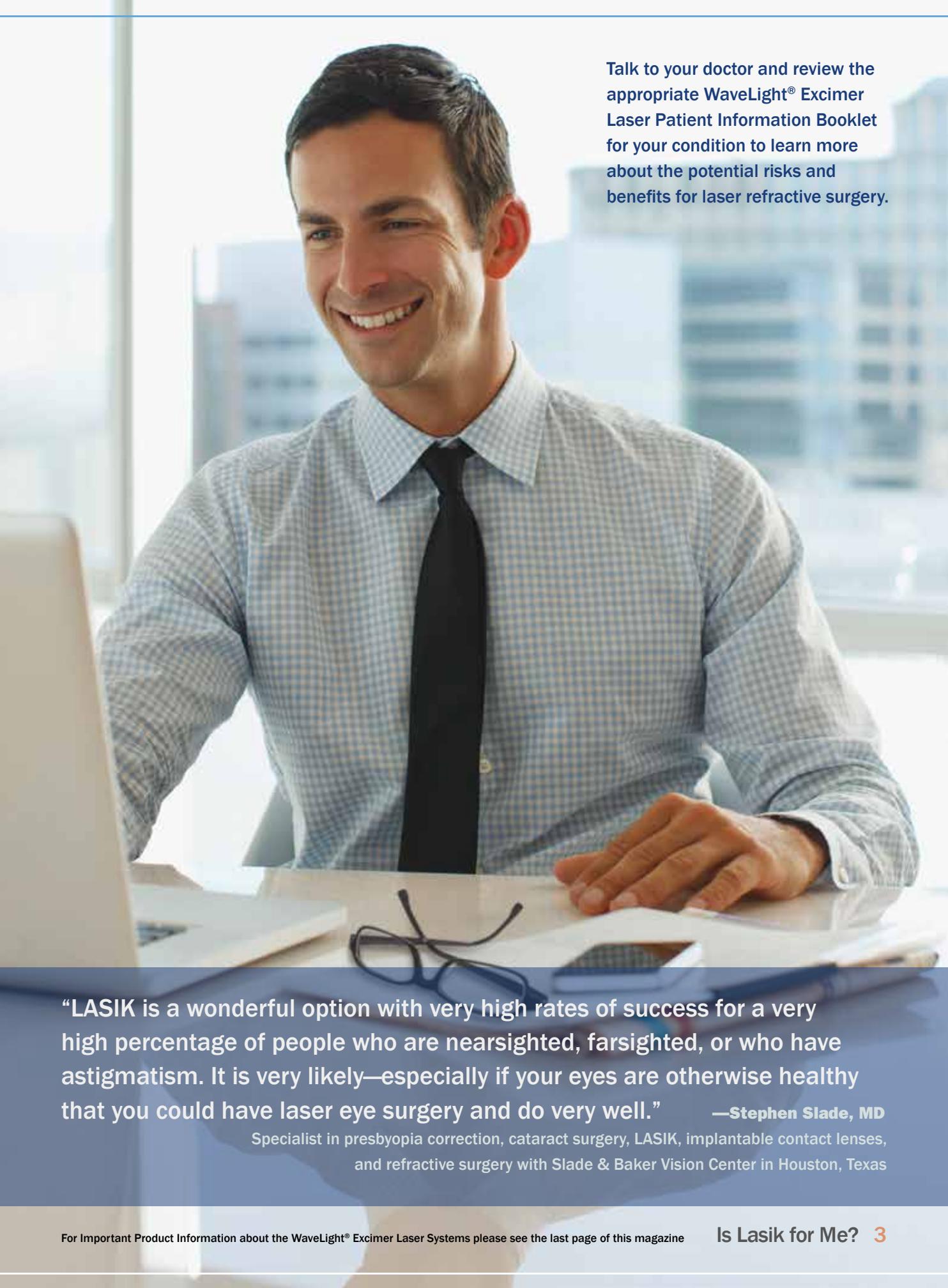
“To be free of those glasses or contacts and be able to function with good quality vision—that’s an enjoyable experience.

There’s a ‘wow effect’ that comes from that.”

— Ron Krueger, MD
Ophthalmologist, Refractive Surgeon with the Cole Eye Institute at the Cleveland Clinic in Cleveland, Ohio

We designed the publication you're holding now to answer the questions people ask most often about laser eye correction—and to answer them in a way that you don't need a medical degree to understand. Your eye surgeon will also give you patient information telling you what to expect.

Ron Krueger, MD, ophthalmologist, refractive surgeon with the Cole Eye Institute at the Cleveland Clinic in Cleveland, Ohio, says there is “low” risk of problems with the flap when the surgeon uses a femto-second laser to create the flap. He explains, “We used to use devices with a blade to cut a flap. We’ve moved away from that and now have a laser that does it. I usually tell people there’s very little that can go wrong making the flap because the laser is so precise. But, after surgery, we want to make sure that flap is in good position; when the patient comes back the next day following the procedure, we want to make sure that the flap has no wrinkles or creases.”



Talk to your doctor and review the appropriate WaveLight® Excimer Laser Patient Information Booklet for your condition to learn more about the potential risks and benefits for laser refractive surgery.

“LASIK is a wonderful option with very high rates of success for a very high percentage of people who are nearsighted, farsighted, or who have astigmatism. It is very likely—especially if your eyes are otherwise healthy that you could have laser eye surgery and do very well.”

—Stephen Slade, MD

Specialist in presbyopia correction, cataract surgery, LASIK, implantable contact lenses, and refractive surgery with Slade & Baker Vision Center in Houston, Texas

Am I a candidate?

The simple answer is: Maybe

You may be a candidate if your vision problem is due to how your cornea bends or refracts the light that enters your eye. If you are the right age, are nearsighted, farsighted, or have astigmatism, and your eyes are otherwise healthy, you are very likely a candidate for corrective surgery.

That being said, you—and your eyes—need to meet certain criteria to be a good candidate. First, you need to have a stable prescription—that is, you’ve experienced no significant change in your prescription over the last year. You should also be free of any eye or other health problems that would affect healing.

It’s important that you be an educated consumer, but the only way to know for sure if you’re a good candidate is to have an evaluation by an ophthalmologist who specializes in laser eye surgery. “We have people who will spend hours and hours and hours of time on the Internet learning about LASIK and then they come in and they’re not a good candidate for it,” says Stephen Slade, MD, Slade & Baker Vision Center, Houston, Texas.

Do I have to have a certain prescription or vision loss?

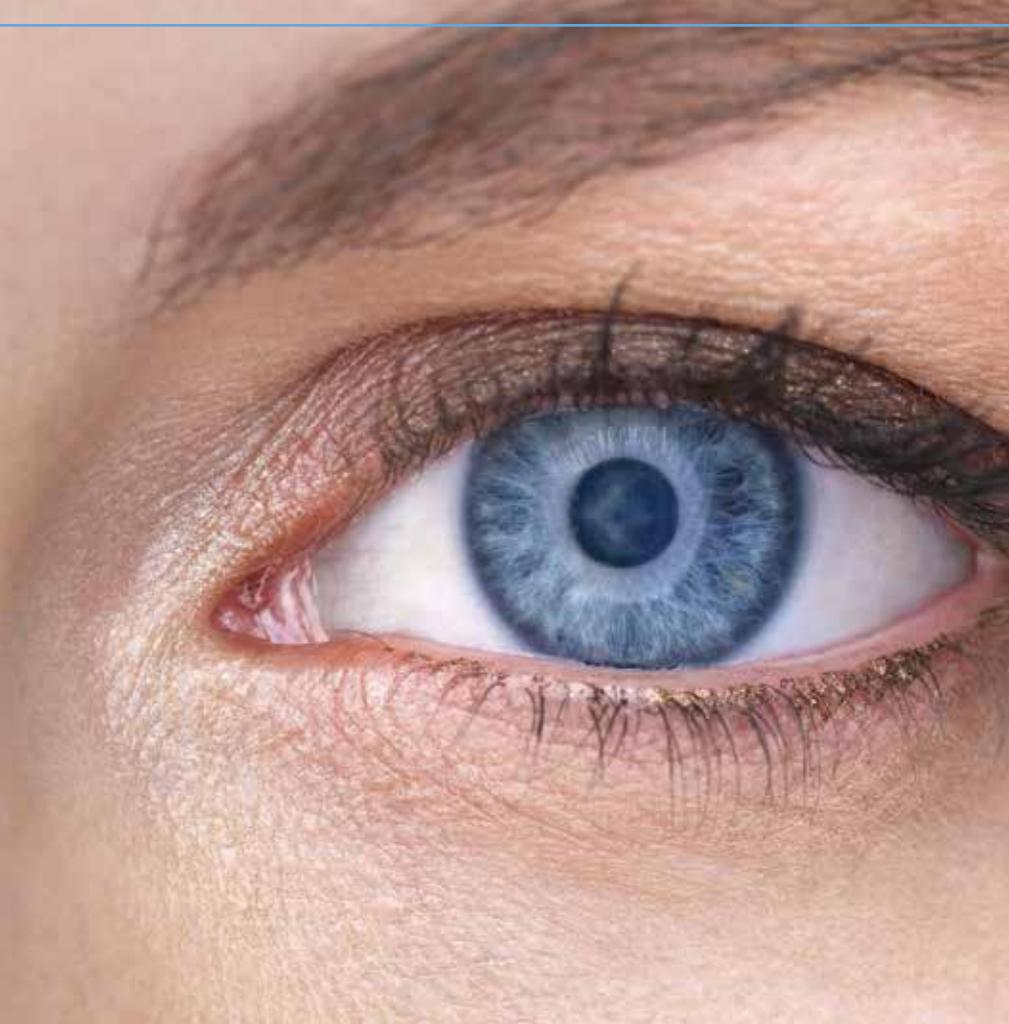
The simplest answer is, if you wear glasses or contacts—and you see well with those glasses or contacts—you are probably going to be a candidate.

It also helps to know who isn’t a candidate.

You should **NOT** undergo LASIK surgery if:

- You are pregnant or nursing;
- You have a collagen vascular, autoimmune, or immunodeficiency disease, such as rheumatoid arthritis, multiple sclerosis, lupus, or AIDS;
- You show signs of keratoconus or any other condition that causes a thinning of your cornea;
- You are taking isotretinoin (*Accutane®) or amiodarone (*Cordarone®).

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“LASIK is generally a safe and effective procedure. Someone inquiring about LASIK may experience what’s probably the most complete eye exam they’ve ever had. The testing that’s done ensures that the eye—particularly the cornea—is normal and healthy other than being nearsighted or farsighted or having astigmatism.”

—Lewis Groden, MD

Executive Medical Director,
LasikPlus Vision Centers
Tampa, Florida

“Laser vision correction can be used to treat myopia (nearsightedness), hyperopia (farsightedness), or astigmatism,” says Dr. Yoo, MD. “The goal is to reduce or eliminate the need for glasses or corrective lenses.”

So what exactly is LASIK?

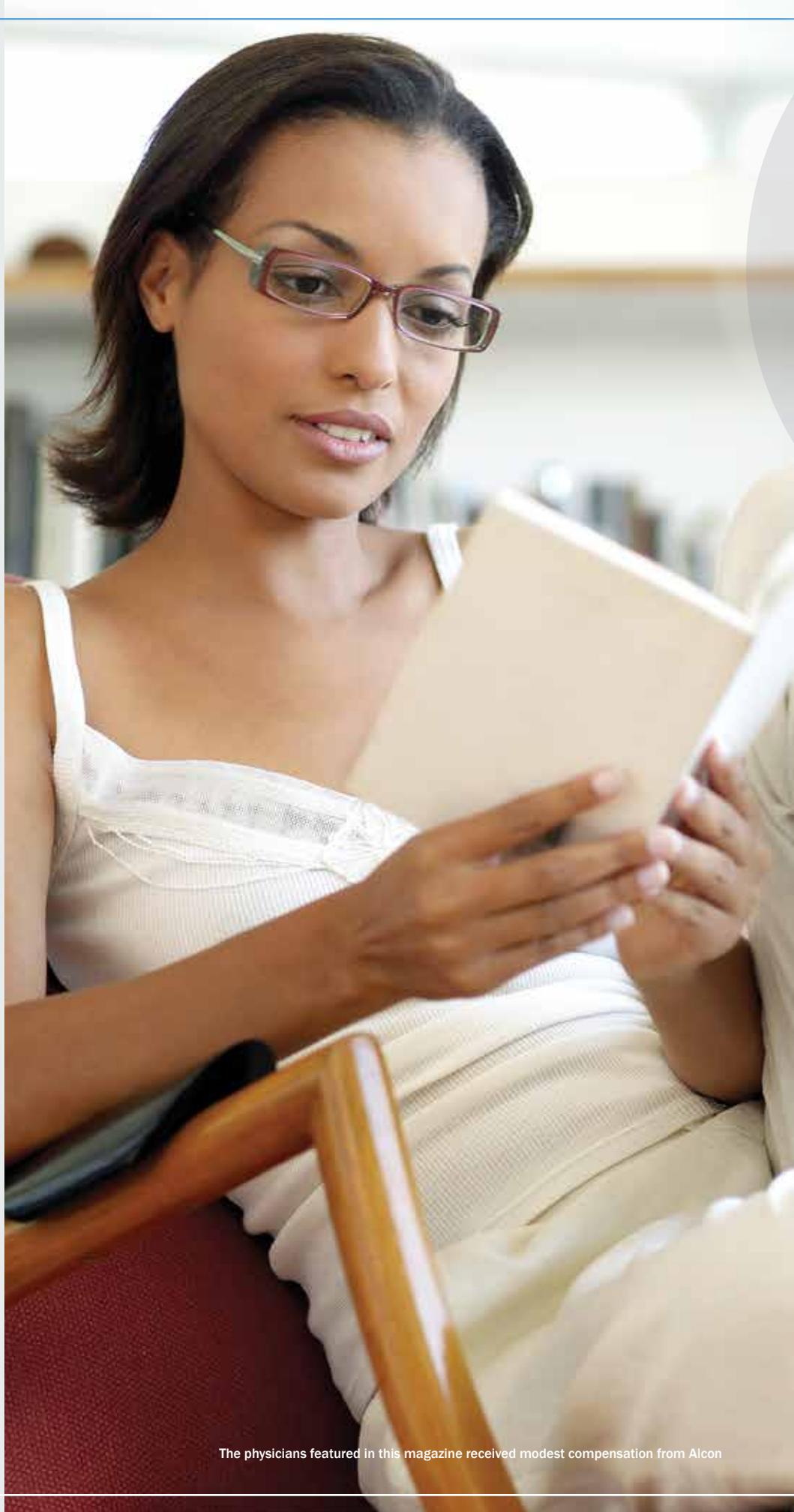
Most laser surgery patients have a LASIK procedure. LASIK stands for laser-assisted in situ keratomileusis. The eye surgeon uses a femtosecond laser, or an instrument called a microkeratome blade, to create a thin, hinged flap on the top layer of the cornea. The surgeon lifts the flap and then uses an excimer laser underneath to sculpt the cornea. At the end of the procedure, the surgeon lays the flap back down; the epithelium goes back into shape and knits together very quickly, giving the patient almost immediate improvement in vision.

Did you know?

Astigmatism is often especially well suited for laser surgery correction.

Contact lenses, even soft lenses, change the shape of your cornea. Don't wear contact lenses for at least a week (for soft lenses) and up to several weeks for semi-permeable lenses) before your initial laser surgery evaluation.

In the US, about 20% of people who undergo evaluation for laser vision correction are determined not to be candidates.



What is perfect vision?

What does 20/20 really mean?

The term “20/20” has become a common metaphor to imply clarity. From the literal visual standpoint, however, 20/20 is simply a normal standard of measurement. Think of that chart we’ve all seen on the exam room wall. It sits 20 feet from the patient’s eye, so 20/20 represents what an “average” eye would see clearly at 20 feet.

“A letter [on the eye chart] a typical person with good vision can see at 20 feet is 20/20,” Dr. Krueger explains. A change in the numbers implies a change from “average” vision. For example, if you can only see at 20 feet what a “typical person” sees clearly at 40 feet, that means your vision is 20/40. “So, you have to be twice as close to it to discriminate the size of the letter,” Dr. Krueger says, or the letter would need to be twice as big for you to see it. Likewise, if you can clearly see at 20 feet what a “typical person” can only see at 15 feet, your vision is 20/15.

“20/20 is a very arbitrary standard,” says Sanjay “Sonny” Goel, MD, Executive Medical Director, LasikPlus Laser Vision Centers, in Annapolis, Maryland. “It basically means that you can see a certain size letter from 20 feet away.”

“Some eyes are normal and can’t see 20/20. Other eyes are normal and see better than 20/20,” adds Dr. Groden. Because measuring vision is so subjective, there really is no such thing as “perfect vision” in the human eye, Dr. Yoo states.

LASIK is not for everyone. The most common risks of LASIK vision correction surgery with refractive lasers include dry eye syndrome; the possible need for glasses or contact lenses after surgery; visual symptoms including halos, glare, starbursts, and double vision; and loss of vision.

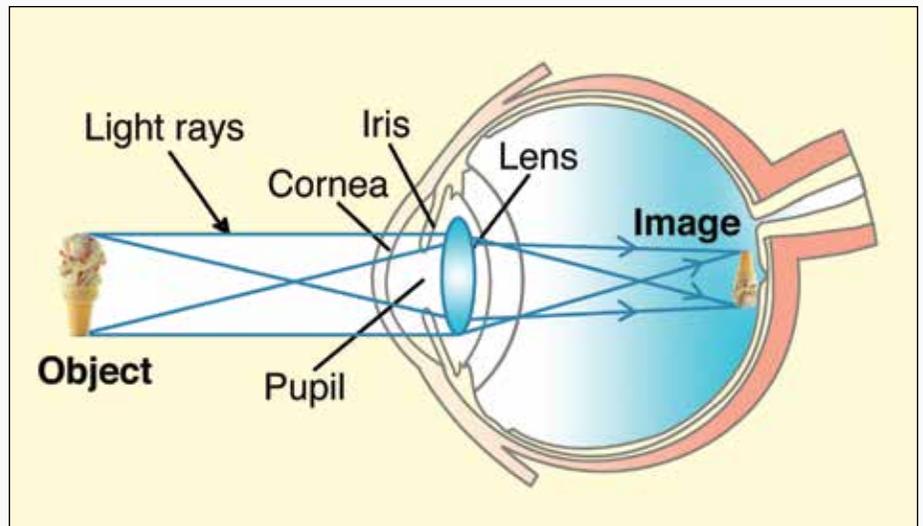
“The goal of laser vision correction is to give someone the vision they have with glasses or contacts. That may be 20/20, or it may be 20/25. Whatever their best corrected vision is before is what we want them to have after the surgery—just without glasses or contacts.”

— Lewis Groden, MD

“Don’t let price be what drives you. Go where you feel comfortable because you get a certain vibe when you walk into a doctor’s office. Talk to friends and family and coworkers and see if they have anybody that they recommend. I think if you do those things, you’ll find the right doctor.”

—Sanjay “Sonny”
Goel, MD

Executive Medical Director,
LasikPlus Laser Vision
Centers in Annapolis,
Maryland



This is the way light rays enter a normal, healthy eye.

What is astigmatism? And does that disqualify me from having surgery?

Astigmatism is when the cornea is not perfectly round but is more oval shaped, like a football or the back of a spoon. Because the shape isn’t perfectly round, it changes how light coming into the eye is focused.

Because laser surgery changes the curvature of the cornea to correct how light is focused, many people with astigmatism are particularly well suited to correction with laser surgery. In fact, Dr. Goel notes, “I love to treat patients with high levels of astigmatism because,” in many cases, “I know I’m going to have a measurable impact on the quality of life that they’re going to have without having to rely on glasses or contact lenses.” And while helping patients see better is always satisfying, Dr. Goel finds treating patients with “high prescriptions such as patients with significant nearsightedness or farsightedness” particularly rewarding, “because I know they’re going to be thrilled with the results.”

He and all surgeons stress, however, the importance of proper evaluation and screening. “You need to be evaluated prior to surgery to see if your particular astigmatism is amenable to treatment,” Dr. Yoo says.



Chirag Shah, MD, an ophthalmologist specializing in refractive surgery with LasikPlus Vision Centers in the Philadelphia area, says, “A lot of moms come in and say ‘I can’t see anything and what if I have to wake up in the middle of the night or my house is on fire and I have to run out with my baby? I don’t want to be looking for my glasses. I want to be able to get up and go.’ That’s a very common complaint that we’ll see from concerned parents.”

“I treated a deaf patient who relies on his eyes for two senses: for his seeing and for his hearing. And I was quite moved by the fact that he would trust me with his eyeballs for his two senses,” says Dr. Goel. “It was wonderful to see him get up off the table and be able to function without having glasses or contacts, to be able to see and ‘hear,’ if you will, after having had the LASIK done. That was pretty moving for me.”

What does it mean to be nearsighted? What does it mean to be farsighted?

If you’re nearsighted, you can see clearly up close, but objects farther away appear blurry. This is because the cornea’s shape focuses light in front of the retina. If you’re farsighted, you can see objects farther away more clearly than you can see up close (and often need corrective lenses to see up close as well) because the cornea’s shape focuses light behind the retina.

In either case, laser surgery changes the shape of the cornea so that the light focuses into the retina instead of in front of or behind it.

What is presbyopia?

As you age—usually starting at around age 40—you may begin to develop a condition known as presbyopia, begin to lose quality of up close vision, and may need to wear bifocals. Presbyopia isn’t a refractive error due to the shape of the cornea like nearsightedness or farsightedness. Instead, says Dr. Groden, “It is a normal change that comes with age in which the ability of the eye to change power to bring near objects into focus diminishes.” Items we could once hold in our hands and see clearly, “we hold out farther and farther because we can’t crank in that power to bring the image in focus. That’s a normal aging change.”





What is an aberration?

An aberration is a form of refractive error, Dr. Krueger says, that “has to do with an error in prescription or an error in refraction that is not typically correctable by glasses.”

There are “lower order” and “higher order” aberrations. Lower order aberrations are refractive errors that prescription lenses can help, and include nearsightedness, farsightedness, and astigmatism. Higher order aberrations are refractive errors that prescription lenses can’t fix, such as glare, halos, streaking of lights, and distortion, doubling, or ghosting of images. They’re usually due to very small irregularities in the cornea that change the way light enters the eye, and are “responsible for more subjective vision complaints,” Dr. Shah notes.

Newer generation lasers can be used to treat many aberrations.

“Nothing is guaranteed in medicine. No doctor will guarantee anything, including that the sun will rise tomorrow. So, there is no ‘guarantee,’ but if you want an enhancement and it’s medically indicated then, yes, you can have it.”

—Lewis Groden, MD

**Factors
influencing
price include:**

- The technology being used
- The surgeon's experience
- Current market forces



“Your flat screen TV can cost as much as, or more than, surgery...and if you can't see anyway, why have it?” —Stephen Slade, MD

How much does it cost?

LASIK procedure costs vary, but usually run anywhere between \$1,000 and \$3,000 per eye.

Because laser eye surgery is something people buy to enhance their lives, it has the element of a commodity, and “those prices vary pretty amazingly,” says Dr. Krueger.

Although Dr. Krueger’s practice charges just under \$5,000 for both eyes, the average cost for the procedure is approximately between \$1,000 and \$3,000 per eye. “Now, there might be some competitor down the street that charges \$1,750 an eye. For both eyes, that’s \$3,500. Somebody who wants to do everything based on price is going to look for the biggest discount. But that could be like saying ‘I’m going to buy the cheapest stereo.’ I always make the point: you can always throw away a stereo. You can’t throw away your eyes. So, you want to be making a decision that’s a smart decision that’s going to last you for your lifetime.”

Dr. Slade agrees, “If you think about it, the value delivered by this surgery is absolutely tremendous.”

Ultimately, of course, you’re the one to decide if you want laser surgical correction instead of wearing glasses or contacts—and how much that surgery is worth to you.

“In my practice, there is no charge for the consultation. The surgery usually ends up about \$1,800 an eye, give or take, and that includes lifetime refinements if needed at any offices in my group.”

— Lewis Groden, MD

“Insurance companies generally don’t cover [laser correction procedures] because they see it as elective surgery. And that’s part of what makes laser vision correction almost like a commodity because patients are now going to choose to spend out-of pocket money for something that they value and consider life enhancing.”

— Ron Krueger, MD

Is surgery covered by insurance?

Health insurance generally does not cover the cost of laser refractive surgery because it’s an elective surgery to treat vision problems that can be addressed with corrective lenses. Some companies do offer discounts, limited coverage through employee health plans, or coverage through contributions to the employee’s Flexible Spending Account. So, check with your individual insurance carrier(s) and benefits administrator.

If I need refinements, do I have to pay for those separately?

Generally, when you pay for LASIK, the price includes refinements for a certain length of time after the primary surgery, but this varies among practices. Most practices have a one-year to three-year window during which patients can return at no charge.

Most doctors agree that you go into the surgery with certain expectations. If you have an immediate need for fine-tuning, most doctors would say that’s covered under the original surgery because that’s your expectation level.

“The question is what about the timing of that?” Dr. Krueger notes. “Most surgeons would say that if you need to do any kind of refinement, that would be free within the first year of your surgery. But, if somebody has the surgery and walks away happy, and then, 10 years later comes back,” wanting additional surgery, it would probably not be covered under the original procedure.

Some practices have different policies. “At my practice, patients pay one fee and have what we call a lifetime commitment,” Dr. Goel says. As long as the patient’s original surgery was performed at another office in our group, “If they come back any time in the future for more LASIK, we do it at no charge to them.”

As with all else regarding laser eye surgery, find out your surgeon’s policy.



Did you know?

Laser surgery uses a “cool-beam,” high-energy laser that breaks the chemical bonds and vaporizes tissue without damaging anything below or adjacent to where the beam hits. This is how it so precisely reshapes the cornea.

The lasers used for eye surgery are the same lasers used to create semiconductor chips and computer chips. Few other mechanical systems today achieve this level of precision.

Refractive surgery reshapes your cornea to correct your refractive error. Think of your “refractive error” as the prescription for your glasses or contacts.

LASIK treats only problems with the cornea at the very front of the eye. It doesn't treat problems with the lens (like cataracts) or with the retina at the back of the eye.

Your cornea is about as thick as three sheets of newspaper.

WaveLight® Excimer Laser Systems Important Product Information

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRETTO WAVE®, the ALLEGRETTO WAVE® Eye-Q, and the WaveLight® EX500.

CAUTION: Federal (U.S.) law restricts the WaveLight® Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight® Excimer Laser System.

INDICATIONS: FDA has approved the WaveLight® Excimer Laser systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for:

- the reduction or elimination of myopia of up to -12.00 D and up to 6.00 D of astigmatism at the spectacle plane;
- the reduction or elimination of hyperopia up to +6.00 D with and without astigmatic refractive errors up to 5.00 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of +6.00 D;
- the reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 D at the spectacle plane; and
- the wavefront-guided reduction or elimination of myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane.

In addition, FDA has approved the WaveLight® ALLEGRETTO WAVE® Eye-Q Excimer Laser System, when used with the WaveLight® ALLEGRO Topolyzer® and topography-guided treatment planning software for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 D of myopia, or for the reduction or elimination of myopia with astigmatism, with up to -8.00 D of myopia and up to 3.00 D of astigmatism.

The WaveLight® Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism) with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.

CONTRAINDICATIONS: The WaveLight® Excimer Laser Systems are contraindicated for use with patients who:

- are pregnant or nursing;
- have a diagnosed collagen vascular, autoimmune or immunodeficiency disease;
- have been diagnosed keratoconus or if there are any clinical pictures suggestive of keratoconus;
- are taking isotretinoin (Accutane®) and/or amiodarone hydrochloride (Cordarone®);
- have severe dry eye;
- have corneas too thin for LASIK;
- have recurrent corneal erosion;
- have advanced glaucoma; or
- have uncontrolled diabetes.

WARNINGS: The WaveLight® Excimer Laser Systems are not recommended for use with patients who have:

- systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status;
- a history of Herpes simplex or Herpes zoster keratitis;
- significant dry eye that is unresponsive to treatment;
- severe allergies;
- a history of glaucoma;
- an unreliable preoperative wavefront examination that precludes wavefront-guided treatment; or
- a poor quality preoperative topography map that precludes topography-guided LASIK treatment.

The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

Topography-guided LASIK requires preoperative topography maps of sufficient quality to use for planning a topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the topography-guided LASIK treatment and may result in poor vision after topography-guided LASIK.

PRECAUTIONS: The safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for patients with:

- progressive myopia, hyperopia, astigmatism and/or mixed astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone;
- corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage;
- residual corneal thickness after ablation of less than 250 microns due to the increased risk for corneal ectasia;
- pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning;
- history of glaucoma or ocular hypertension of > 23 mmHg;
- taking the medications sumatriptan succinate (Imitrex®);

- corneal, lens and/or vitreous opacities including, but not limited to cataract;
- iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eye tracking; or
- taking medications likely to affect wound healing including (but not limited to) antimetabolites.

In addition, safety and effectiveness of the WaveLight® Excimer Laser Systems have not been established for:

- treatments with an optical zone < 6.0 mm or > 6.5 mm in diameter, or an ablation zone > 9.0 mm in diameter; or
 - wavefront-guided treatment targets different from emmetropia (plano) in which the wavefront calculated defocus (spherical term) has been adjusted;
- In the WaveLight® Excimer Laser System clinical studies, there were few subjects with cylinder amounts > 4 D and ≤ 6 D. Not all complications, adverse events, and levels of effectiveness may have been determined for this population. Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery.

ADVERSE EVENTS AND COMPLICATIONS

Myopia: In the myopia clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect.

Hyperopia: In the hyperopia clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

Mixed Astigmatism: In the mixed astigmatism clinical study, two adverse events were reported. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. UCVA was decreased due to this event. The second event involved the treatment of an incorrect axis of astigmatism. The axis was treated at 60 degrees instead of 160 degrees.

The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye.

Wavefront-Guided Myopia: The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. In the Control Cohort, one subject undergoing traditional LASIK had the axis of astigmatism programmed as 115 degrees instead of the actual 155 degree axis. This led to cylinder in the left eye.

The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort.

Topography-Guided Myopia: There were six adverse events reported in the topography-guided myopia study. Four of the eyes experienced transient or temporary decreases in vision prior to the final 12 month follow-up visit, all of which were resolved by the final follow-up visit. One subject suffered from decreased vision in the treated eye, following blunt force trauma 4 days after surgery. One subject experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

CLINICAL DATA

Myopia: The myopia clinical study included 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. Of the 782 eyes that were eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/40 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

Long term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

Hyperopia: The hyperopia clinical study included 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. Of the 212 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 69.4% were corrected to 20/20 or better. Subjects who responded to a

patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "much worse" at 6 months post-treatment: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

Long term risks of LASIK for hyperopia with and without astigmatism have not been studied beyond 12 months.

Mixed Astigmatism: The mixed astigmatism clinical study included 162 eyes treated, of which 111 were eligible to be followed for 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. Of the 142 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 97.3% achieved acuity of 20/40 or better, and 69.4% achieved acuity of 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline).

Long term risks of LASIK for mixed astigmatism have not been studied beyond 6 months.

Wavefront-Guided Myopia: The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 166 of the Study Cohort and 166 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.

Of the 166 eyes in the Study Cohort that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 166 eyes in the Control Cohort eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20.

In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

Long term risks of wavefront-guided LASIK for myopia with and without astigmatism have not been studied beyond 6 months.

Topography-Guided Myopia: The topography-guided myopia clinical study included 249 eyes treated, of which 230 eyes were followed for 12 months. Accountability at 3 months was 99.2%, at 6 months was 98.0%, and at 12 months was 92.4%. Of the 247 eyes that were eligible for the UCVA analysis at the 3-month stability time point, 99.2% were corrected to 20/40 or better, and 92.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "marked" or "severe" at an incidence greater than 5% at 1 month after surgery:

dryness (7% vs. 4% at baseline) and light sensitivity (7% vs. 5% at baseline). Visual symptoms continued to improve with time, and none of the visual symptoms were rated as being "marked" or "severe" with an incidence of at least 5% at 3 months or later after surgery.

Long term risks of topography-guided LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

INFORMATION FOR PATIENTS: Prior to undergoing LASIK surgery with a WaveLight® Excimer Laser System, prospective patients must receive a copy of the relevant Patient Information Booklet, and must be informed of the alternatives for correcting their vision, including (but not limited to) eyeglasses, contact lenses, photorefractive keratectomy, and other refractive surgeries.

ATTENTION: Please refer to a current WaveLight® Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects.

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