

seen[®]

magazine

Understanding LASIK Surgery



SEEN[®] magazine is an educational publication brought to you by Alcon, the global leader in eye care.

LASIK Gets Personal

Finding the right treatment
for your eyes.



LASIK Basics

Learn what to do before,
during and after.

Could LASIK be Right for You?

Find out with our
quick and easy quiz!

Compliments of:

She shoots, she scores.



Chelsea hasn't been able to see without glasses since the third grade. And while her vision may have improved, her lifestyle hadn't — especially on the basketball court. Discovering a solution that fit her needs, Chelsea chose to ditch the glasses and undergo LASIK surgery. Her results? Minimal discomfort, and almost immediate sharpness and clarity.

Visit YourLASIKSolution.com
to view Chelsea's personal story.

 **WaveLight**[®]
Lasers and Diagnostic Systems

*Realize your unique
vision potential.*

Consult with your doctor about the risks
associated with LASIK surgery.

3 Patient Profile: Spencer

From apprehensive to advocate, Spencer explains why he decided to get LASIK.

5 Could the LASIK Lifestyle be Right for **You**?

Seeing LASIK in your future, or not so sure you need it? Get an answer with our quick and easy quiz!

7 Loryn's Story

Learn how LASIK gave Loryn "the freedom to experience the world."



9 Your LASIK Surgery

The Before, During and After of LASIK

10 See the Light

Discover how WaveLight® can change your view.

Patients featured in this magazine received modest compensation for sharing their experiences. Although their results are typical, individual results may vary.

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See What You're Missing.

There's a whole wide world of unique things to see and do out there. And you? You're part of that. As unique as you are, you deserve every opportunity to experience life without compromise, to stand out from the crowd. Sometimes though, it can feel like something's holding you back. Maybe something as simple as a pair of contacts or glasses.

If you're looking for a way out from under contacts and glasses, LASIK surgery may be able to give you the freedom you need to do more of the things you've always wanted. Still, LASIK is more than just being free from glasses and contacts – it's about having the unique confidence to shine in every part of your life, and getting you in the spotlight where you belong.

You probably already know the gist of LASIK. But, no doubt you still have questions – about safety, about what to expect. And we'll answer those questions the easiest way we know how: by sharing stories of what most patients have experienced before, during and after LASIK. Once you've got the full story, you can decide if LASIK makes sense for you. And if it does, well, get ready to see what you're missing.



What is LASIK, anyway?

LASIK (laser-assisted in-situ keratomileusis) is a surgical procedure that involves reshaping your eyes with a laser to help improve eyesight. By creating a tiny door, or flap, in the surface of your eye, your surgeon can easily correct vision problems; this door is then closed, and your eyes heal up on their own. Although LASIK can provide benefits to your vision, it's still a surgical procedure and also carries some risks. Make sure to discuss the pros and cons of LASIK with your doctor so you can make an informed decision.

Remember: Although LASIK surgery has been shown to be safe and effective, it's still surgery; and like any surgical procedure, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor so you can make an informed decision about surgery.

To learn more about WaveLight® refractive technology, please see the Important Safety Information at the end of the magazine.



PATIENT PROFILE

Spencer



First he was apprehensive.

**Now he's a
LASIK believer.**

 **WaveLight[®]**
Lasers and Diagnostic Systems
*Realize your unique
vision potential.*

Considering LASIK? Visit YourLASIKSolution.com to learn more about what to expect during your LASIK surgery.

At first, Spencer wasn't so sure about LASIK. "Quite frankly, I was a little nervous to even consider it," he says, "because they're your eyes, and your eyes are all you have."

He had friends who had gotten the procedure, though, and decided to ask them about their experiences. "I got great responses," he says. "People were just blown away by the difference it made."

But, after talking to a surgeon, what really convinced Spencer was the personalized aspect of LASIK with **WaveLight**[®] refractive technology. "Everyone's eyes are different, so the **WaveLight**[®] technology was intriguing to me." And with that, he made an appointment to undergo surgery.

Spencer saw results right after his procedure. "I went home and slept for a few hours. When I woke up, I

remember being able to see my alarm clock for the first time without having to reach for my glasses. It was pretty neat."

And, as he describes it, things just kept getting better.

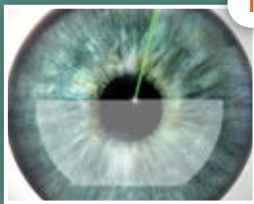
"As the weeks were going by, everything just crisped up and my eyesight got a little clearer every day."

Now, Spencer's the one telling people about LASIK with **WaveLight**[®] technology. And the advice he gives? "If your vision was as bad as mine, you've got to get it done. You've got to do it."

LASIK, Step-by-Step

We know LASIK can seem a bit scary at first, but with **WaveLight**[®] refractive technology, it doesn't have to be. While LASIK is still a surgical procedure, thanks to the advanced technology of the **WaveLight**[®] system, the entire LASIK process is fast, safe and precise. Plus, you'll finally have the opportunity for the vision you've always wanted.

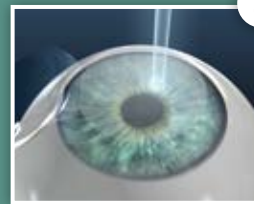
Here's how it works:



1 Step 1: Flap Creation

A thin flap, like a door, is created in the surface of the cornea and opened, exposing the underlying tissue so your surgeon can reshape the cornea from within. Now, you can finally have the opportunity for the vision you've

always wanted. Plus, thanks to new bladeless technology, you can take advantage of an all-laser LASIK procedure!



2 Step 2: Eye Reshaping

Your surgeon will work inside the cornea to carefully reshape the eye, removing small amounts of tissue with tiny, rapid bursts from a laser. Once the eye is a more ideal shape for clear, focused vision, the flap is put back into

place, where it acts as a natural bandage.

And that's it! The whole procedure takes a matter of minutes – and many people sit up noticing dramatically better vision!

Remember: LASIK surgery is not for everyone. You should not undergo LASIK surgery if you are pregnant or nursing; if you have a collagen vascular, autoimmune or immunodeficiency disease; if you show signs of keratoconus or any other condition that causes a thinning of your cornea; or if you are taking isotretinoin (Accutane*) or amiodarone hydrochloride (Cordarone*).

To learn more about **WaveLight**[®] refractive technology, please see the Important Safety Information at the end of the magazine.

* Trademarks are property of their respective owners.



How Effective Is LASIK

Obviously, safety is a priority with LASIK; but you want the procedure to work too, right? The same clinical evaluations used to determine the safety of a LASIK system are also used to determine its effectiveness. And the numbers are encouraging:

- 93%** of nearsighted patients see 20/20 or better.¹
- 95%** of farsighted patients see 20/40 or better.²
- 92%** of patients described their vision as "good" or "excellent."¹

1. FDA Clinical Trials: Wavefront Optimized® Wavefront Guide for Myopia plus astigmatism. [FDA.gov/scripts/cdrh/lfloc/cftopics/pma/cfm P0200505004](https://www.fda.gov/scripts/cdrh/lfloc/cftopics/pma/cfm P0200505004).
 2. Data on file. Alcon, Inc.

Seeing LASIK in your future, or not so sure you need it? Get an answer with our quick and easy quiz!

Do you want better vision?

- A) Absolutely.
- B) No. I'm hoping for a future in professional sports refereeing.

LASIK may be able to give you the vision you've always wanted – without the aid of contacts or glasses. Unfortunately, it can't do anything about the ref's latest bad call.

How would you describe your contact lens or glasses prescription?

- A) Dependably predictable. Sort of like the rising of the sun.
- B) Like a bad audition on "American Idol."** Up and down, back and forth – it's all over the place.

If you're looking to get LASIK, it's important that your prescription has been stable for around 1-2 years. Sometimes, change really isn't for the better.

Your date has taken you to see a foreign film. Can you read the subtitles?

- A) Subtitles? I can't even tell who's talking.
- B) Yes. But I still don't understand this movie.

Forget being nearsighted – or farsighted, for that matter. LASIK may be able to make it easier to see the big picture (or even a bad movie) much clearer.

Your best friend suggests an impromptu skydiving session. Your first reaction is to:

- A) Worry about the effect terminal velocity winds will have on your contacts (or worse, your glasses!).
- B) Search for your spare parachute.

Looking for the freedom to be adventurous, without having to worry about your contacts or glasses? LASIK may be able to help with that.

Could the LASIK Lifestyle be Right for You?



Continued...

How good are you at sitting still?

- A) I can handle short bouts of stillness.
- B) I fidget like a five-year-old who's eaten too many Pixy Stix**.

Good thing poise comes with age, because you need to be 18 (and sometimes 21) to undergo LASIK. The procedure itself is relatively simple on your end, however: all you really have to do is lie still for a few minutes and focus on a blinking light.

When you get a headache, it's typically induced by:

- A) Straining to see your computer.
- B) Last night's shenanigans.

Let's face it. Contacts and glasses can be a pain – literally. Bad prescriptions, ill-fitting glasses and dried-out contacts can cause all sorts of on-the-job discomfort. If you're tired of the torment, maybe LASIK is for you.

**American Idol® is a registered trademark of 19 TV Ltd. and FremantleMedia North America, Inc.
**Pixy Stix® is a registered trademark of Societe des Produits Nestlé S.A. Vevey, Switzerland

WaveLight® technology makes a difference in LASIK.

WaveLight® refractive technology combines newer surgical advancements into a LASIK procedure personalized for *your* ideal vision. If you're looking for LASIK that's as unique as you are, the WaveLight® system may be right for you — and we've got the stats to back it up!

- **93%** of nearsighted patients see 20/20 or better.¹
- **95%** of farsighted patients see 20/40 or better.²
- **92%** of patients described their vision as “good” or “excellent.”¹
- *Think 20/20 vision is impressive?* **75%** of Wavefront Optimized® treated nearsighted patients and **64%** of Wavefront-Guided nearsighted patients actually see better than 20/20.¹

Remember: 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.

To learn more about WaveLight® refractive technology, please see the Important Safety Information at the end of the magazine.

1. FDA Clinical Trials: Wavefront Optimized® Wavefront Guide for Myopia plus astigmatism. FDA.gov/scripts/cdrh/rlcloc/cftopics/pma/cfm P0200505004.
2. Data on file. Alcon, Inc.



PATIENT PROFILE

Loryn

Why Loryn says LASIK
with **WaveLight**[®] refractive
technology gave her
*“the freedom to
experience the world.”*

 **WaveLight**[®]
Lasers and Diagnostic Systems
*Realize your unique
vision potential.*

Loryn had long relied on glasses and contact lenses to correct her vision problems. And while they helped get her through college, contacts couldn't give Loryn the freedom she needed to dive into life's other adventures.

"I wanted to learn to surf," she says, "but contacts were just too uncomfortable to wear in the water." So Loryn's eyesight – and her surfing – suffered... until a friend recommended she look into LASIK.

Fed up with contacts and intrigued by the possibility of being free to try new things, Loryn opted to get LASIK with **WaveLight**® refractive technology. She quickly noticed results.

"I remember riding home from the procedure thinking, 'Oh my gosh, I can see!' I could see the hills and I could see the houses on the hills and all their little windows. I could experience the world without needing something on my eyes."

Now Loryn rides the waves like a pro. And her only regret about LASIK with **WaveLight**® technology? Not having it sooner. "If I could have done it ten years ago," she says, "I would roll back time and I would do it then. I've never experienced the world like I experience the world now."



Remember: 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.

To learn more about **WaveLight**® refractive technology, please see the Important Safety Information at the end of the magazine.

Considering LASIK? Visit YourLASIKSolution.com to learn more about what to expect during your LASIK surgery.



Your LASIK Surgery



Before LASIK Surgery

Evaluating Your Eyes

Once you have decided to get LASIK surgery, you will need to have an eye evaluation to determine which type of procedure is best for you. If you wear contact lenses, you may be asked to not wear them for up to two weeks before your evaluation so that your eyes return to their natural shape.

A thorough evaluation of your eyes will help determine if you are eligible for LASIK and if you have any conditions that may be problematic. The evaluation usually consists of:

- Testing your vision
- Mapping the shape of your cornea
- Screening for eye diseases, including glaucoma, cataracts or diabetic retinopathy
- Measuring corneal thickness, eye movement and pupil size
- Assessing the back of the eye

If you wear contact lenses between the evaluation and the surgery, you will need to stop wearing them again for up to two weeks prior to surgery.

During LASIK Surgery

What to Expect

Though the entire experience, from walking in to walking out, may take from two to three hours, the procedure itself typically lasts less than thirty minutes. Most patients feel little or no pain throughout the surgery. Each doctor's procedure will vary somewhat, but you can usually expect the following:

- Anesthetic drops will be placed in each eye.
- You will lie down on a patient bed under the laser system. Throughout the procedure, you will be asked to focus on a small blinking light.
- A flap is created by gently lifting a thin layer of tissue from the cornea. This makes the cornea easier to reshape.
- Pulses of laser energy precisely reshape your cornea. The corneal flap is then laid back into place and acts as a natural bandage to help your eye heal.

After LASIK Surgery

Immediately After the Procedure

Most LASIK patients notice improved vision immediately. Before you leave, your surgeon will most likely have you rest in a postoperative room for about an hour. You should also:

- Have someone drive you home, as most doctors will advise against you driving for 24 hours
- Stop on the way home to pick up any medications you may have been prescribed
- Keep your eyes clean and avoid rubbing them

Adjusting to LASIK Surgery

Some people experience minor problems such as watery or red eyes for the first few days after the procedure, but others are able to return to work the very next day. Your doctor will most likely schedule a follow-up appointment the next week to test your vision and ensure your eyes are healing properly. By this time, you are likely to see as good as or better than you did with contact lenses or glasses.

See the Light.

WaveLight® technology can change the way you view the world.

Everywhere you look, technology is constantly evolving.

Phones, cars, computers – new innovations are being developed all the time, pushing the limits of what the technology can do and the benefits it can provide. So why would LASIK be any different?

Alcon, the world leader in eye care technology, is constantly seeking new and better ways to help improve vision. Their latest effort? The **WaveLight® Workstation and Refractive Suite**, a one-two punch of LASIK performance, designed to provide outstanding results. The **WaveLight® FS200 Laser** was developed to make the process of flap creation – often the part of LASIK surgery patients worry about most – a little more predictable. Although flaps were originally created by hand, the **WaveLight® FS200 Laser** offers an all-laser, bladeless alternative, with fast, precise custom flap creation.

Flap creation is important, but it's reshaping the eye that provides the clear vision you've been looking for – and for that, you need the right combination of speed, precision and personalization. Designed to provide outstanding results, the **WaveLight® EX500 and ALLEGRETTO WAVE® Eye-Q Laser** combines high-speed excimer laser technology, precise beam positioning and the flexibility of personalized treatment options.

Exceptional LASIK performance starts with exceptional LASIK technology. To learn more about Alcon and the **WaveLight® Refractive Workstation and Refractive Suite**, visit reclaimyourvision.com

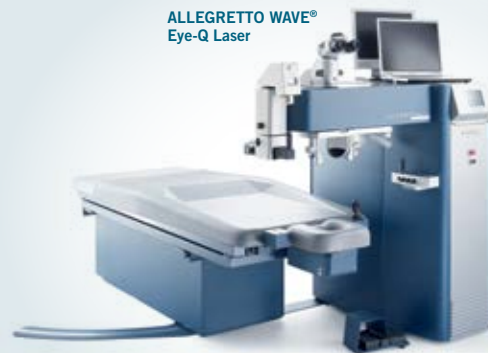
WaveLight® EX500



WaveLight® FS200



ALLEGRETTO WAVE® Eye-Q Laser



Remember: Although LASIK surgery has been shown to be safe and effective, it's still surgery; and like any surgical procedure, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor so you can make an informed decision about surgery.

To learn more about **WaveLight®** refractive technology, please see the Important Safety Information at the end of the magazine.

Driven to see clearly.

Jared can see just fine with his glasses, but, as a truck driver, navigating at night proved to be a different story. In the dark, light from the surrounding environment reflected off of his lenses making it difficult to see. Having heard positive reviews from his mother who had already undergone LASIK, Jared made the decision to follow suit. His result? A glare-free and active lifestyle of hiking and camping with his wife and five girls, as well as a little driving too.

Visit YourLASIKSolution.com
to view Jared's personal story.

Consult with your doctor about the risks associated with LASIK surgery.

To learn more about WaveLight® refractive technology, please see the Important Safety Information at the end of the magazine.

 **WaveLight**®
Lasers and Diagnostic Systems
Realize your unique vision potential.

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Important Safety Information about the WaveLight® Excimer Laser Systems

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 nearsightedness (myopia), farsightedness (hyperopia), and astigmatism, including mixed astigmatism. Astigmatism occurs if the shape of your eye causes light to bend and distort as it passes through your lens. With astigmatism, objects tend to appear blurry or unfocused. Mixed astigmatism occurs if you have symptoms of nearsightedness and farsightedness at the same time.

The WaveLight® Excimer Laser Systems are approved for the following specific LASIK treatments and ranges:

- Reduction or elimination of nearsightedness of up to - 12.00 diopters of sphere and up to 6.00 diopters of astigmatism at the spectacle plane.
- Reduction or elimination of farsightedness up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 diopters.
- Reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 diopters at the spectacle plane.
- Wavefront-guided reduction or elimination of nearsightedness of up to -7.00 diopters of sphere and up to 3.00 diopters of astigmatism at the spectacle plane. Wavefront-guided LASIK treatment takes into account small, complex imperfections in the shape of your eye that can affect your vision. Wavefront-guided LASIK is more highly customized than traditional LASIK procedures.

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), who have documented evidence that their refraction did not change by more than 0.50 diopters during the year before their preoperative examination.

ALTERNATIVES TO LASIK: LASIK is just one option for correcting your vision. Alternative options include eyeglasses, contact lenses, photorefractive keratectomy surgery (PRK), and other refractive surgeries. Be sure to talk to your doctor to find out if LASIK is appropriate for your condition.

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

- You are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment would improperly change the shape of your cornea.
- You have a collagen vascular, autoimmune or immunodeficiency disease, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS. These conditions affect the body's ability to heal.
- You show signs of keratoconus or any other condition that causes a thinning of your cornea. This condition can lead to serious corneal problems during and after LASIK surgery. It may result in the need for additional surgery and may result in poor vision after LASIK.
- You are taking medications with ocular side effects, such as Isotretinoin (Accutane*) for acne treatment or Amiodarone hydrochloride (Cordarone*) for normalizing heart rhythm, because they may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

WARNINGS: If you have any of the following conditions, you should have LASIK only if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk:

- Systemic diseases likely to affect wound healing. If you have a systemic disease such as a connective tissue disease, severe atopic disease or are immunocompromised, LASIK may be risky for you because it may affect the ability of your eyes to heal.
- Diabetes. If you have diabetes and depend on insulin, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- History of Herpes simplex or Herpes zoster infection that has affected your eyes. If you have had a Herpes simplex or a Herpes zoster infection that affected your eyes, or have an infection now, LASIK is riskier for you.
- Symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- Severe allergies. If you have severe allergies and take medicines for them, LASIK is riskier for you.

PRECAUTIONS: If any of the following conditions or situations apply to you, you should discuss them with your doctor:

- Your nearsightedness, farsightedness, astigmatism or mixed astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK.
- You have an eye disease. It is unknown whether LASIK is safe and effective under this condition.
- You have had a prior eye injury or eye surgery. If your eyes are injured or you have had surgery, it is unknown whether LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- You have a corneal abnormality (e.g., scar, irregular astigmatism, infection, etc.). An abnormal corneal condition may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- Your corneas are too thin. If your corneas are too thin to allow your doctor to cut a proper flap during the LASIK procedure, you can't have LASIK because it is necessary to have a flap.
- You have a history of glaucoma or high eye pressure. It is unknown whether LASIK is safe and effective for you.
- You take medicines that might make it harder for wounds to heal, such as sumatriptan succinate (Imitrex*) for migraine headaches. It is unknown whether LASIK is safe and effective for people who take these medicines.
- You are younger than 18 years of age (21 years for mixed astigmatism). It is unknown whether LASIK is safe and effective for you.
- Your doctor may modify the wavefront-calculated ablation program in order to give you a treatment that does not fully correct distance vision. You should discuss the risks in depth with your doctor for any LASIK corrections that do not fully correct for distance vision, especially if performed only in one eye.
- You have a cataract or other problem with the lens or vitreous of your eye. It is unknown whether LASIK is safe and effective under this condition.
- You have any problems with the iris (colored part) of your eye or have had previous surgery on this part of your eye. The eyetracker on the laser may not work properly and LASIK may not be safe and effective for you.

- You are taking prescription or over-the-counter medications that may affect the ability of your eye to heal after surgery, including antimetabolites.
- Your doctor plans to use a treatment zone with the laser < 6.0 millimeters or > 6.5 millimeters in diameter. It is unknown whether LASIK with these treatment zones is safe and effective for you.
- Your nearsightedness is worse than – 12.00 diopters, or with astigmatism that is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your farsightedness is worse than + 6.00 diopters, or with astigmatism that is worse than 5.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your mixed astigmatism is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you. Your mixed astigmatism is > 4.00 diopters to ≤ 6.00 diopters. Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.
- You have large pupils. Before surgery your doctor should measure your pupil size under dim lighting conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in conditions such as dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently when the entire prescription has not been fully corrected and perhaps in patients with pupil sizes larger than the treatment area.

Your doctor should evaluate you for dry eye before surgery. You may have dry eye after LASIK surgery even if you did not have dry eye before surgery. It is not known whether LASIK with a WaveLight® Excimer Laser System is effective over the long term (more than 12 months).

ADVERSE EVENTS AND COMPLICATIONS Common risks of LASIK procedures include:

- Developing dry eye syndrome, which can be severe;
- The possible need for glasses or contact lenses after surgery;
- Visual symptoms, including halos, glare, starbursts, and double vision, which can be debilitating; and
- The loss of vision.

The following adverse events and complications were reported in the clinical studies for the WaveLight® Excimer Laser Systems:

- **Nearsightedness Study:** In the myopia (nearsightedness) 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.
- **Farsightedness Study:** In the hyperopia (farsightedness) 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 Study:** In the mixed astigmatism clinical study, two adverse events were reported. One patient suffered from decreased vision in the treated eye following blunt trauma to the eye 6 days after surgery. The second event involved the treatment of an incorrect axis of astigmatism. 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 Nearsightedness Study:** No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. One subject undergoing traditional LASIK treatment was treated on the incorrect axis of astigmatism. 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.

CLINICAL DATA

Nearsightedness Study: Of the 782 eyes in the myopia (nearsightedness) study that were included in the analysis of effectiveness without wearing glasses, at 6 months after surgery, 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 3 months after surgery than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

Farsightedness Study: Of the 212 eyes in the hyperopia (farsightedness) study that were included in the analysis of effectiveness without wearing glasses, at 6 months after surgery, 95.3% were corrected to 20/40 or better, and 67.5% 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” 6 months after surgery: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

Mixed Astigmatism Study: Of the 111 eyes in the mixed astigmatism study that were eligible for the analysis of effectiveness without wearing glasses, at 6 months after surgery, 97.3% 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 at a “moderate” or “severe” level at least 1% higher 6 months after surgery 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).

Wavefront-Guided Nearsightedness Study: The wavefront-guided myopia (nearsightedness) clinical study compared patients treated with wavefront-guided LASIK (Study Cohort) to patients treated with traditional LASIK (Control Cohort). Of the 166 eyes in the Study Cohort that were eligible for the analysis of effectiveness without wearing glasses, at 6 months after surgery, 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, at 6 months after surgery, 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 3 months after surgery 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 3 months after surgery than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

ATTENTION: Please refer to a current WaveLight® Excimer Laser System Patient Information Booklet for a complete listing of the indications, complications, warnings, precautions, and side effects. Ask your doctor for a copy of the current Patient Information Booklet.

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