

# Is LASIK for me?

Part 3 of a 3-Part Series

A NEW VIEW  
ON LIFE

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.

## After Surgery— A New View On Life

After surgery, how you see life will change. Literally. Some ophthalmologists—who understand eyes and the possible risks/benefits better than anyone—have refractive surgery performed themselves.

“I developed contact lens intolerance and I was only able to wear my contacts socially on the weekends,” says Sanjay “Sonny” Goel, MD, executive medical director, LasikPlus Laser Vision Centers, Annapolis, Maryland. “And I found my glasses to be very uncomfortable. So, for me, it was an easy decision; I knew all the risks and benefits. I had the surgery in July of 1999, and in February of 2000—about eight months after surgery—I was able to snorkel and look in the water without glasses or contacts. I was seeing these incredibly beautiful, colorful fish and the sea life was just amazing. I didn’t know what I had been missing. It was unbelievable.”

### Will I still need glasses or contact lenses after surgery?

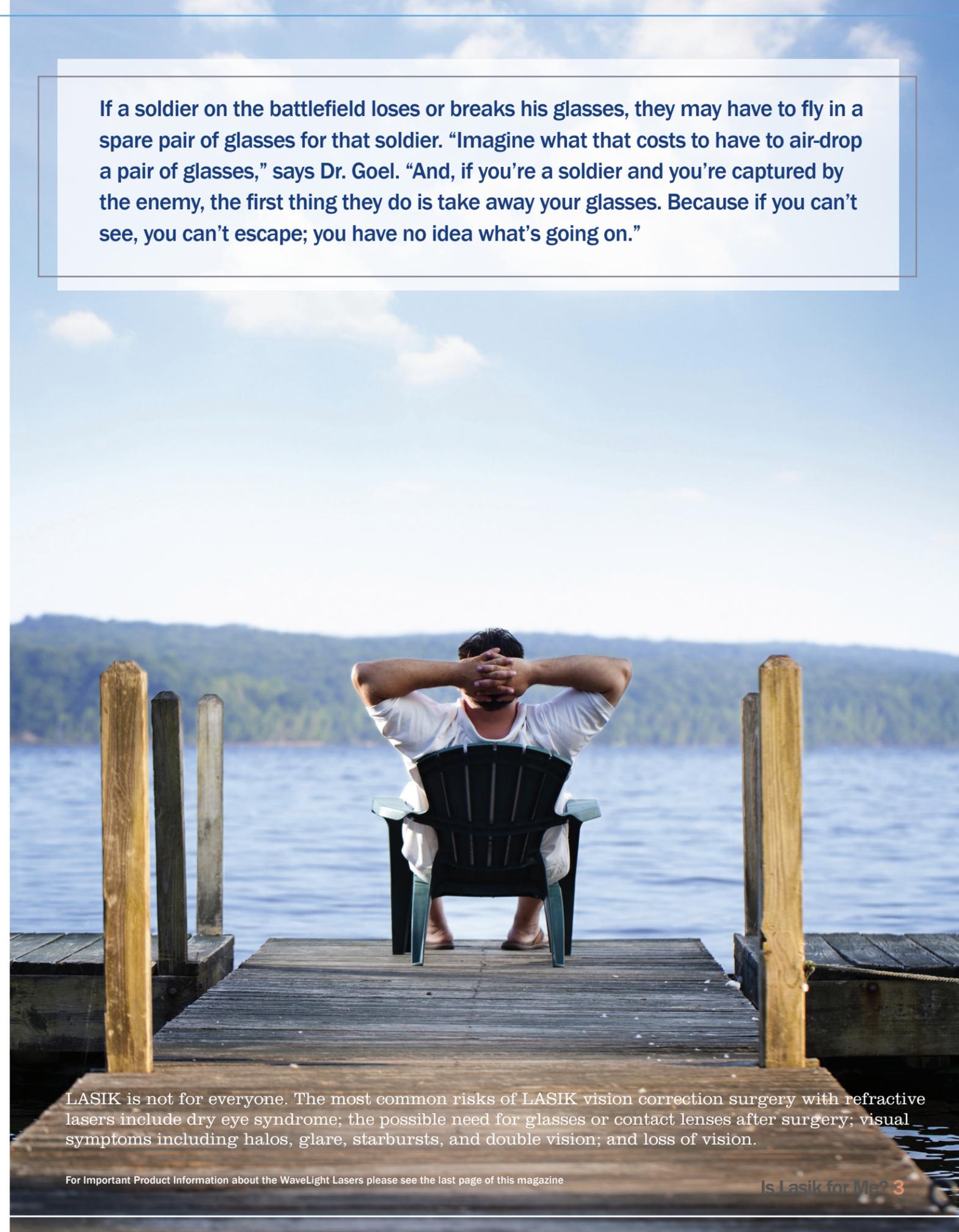
The less refraction you have going into the surgery, the greater the chance you’ll have 20/20 (or better) vision after surgery. If you have severe vision problems prior to surgery, you may still need to use glasses or contact lenses in some situations—for instance, for reading and/or driving.

If you have presbyopia and you wear bifocals before surgery, you may still need to wear reading glasses to see small print.

**“I developed contact lens intolerance and I was only able to wear my contacts socially on the weekends.”**

**— Sanjay “Sonny” Goel, MD**

If a soldier on the battlefield loses or breaks his glasses, they may have to fly in a spare pair of glasses for that soldier. “Imagine what that costs to have to air-drop a pair of glasses,” says Dr. Goel. “And, if you’re a soldier and you’re captured by the enemy, the first thing they do is take away your glasses. Because if you can’t see, you can’t escape; you have no idea what’s going on.”



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.

For Important Product Information about the WaveLight Lasers please see the last page of this magazine

# Is this the only surgery I'll need?

## “Will my surgery wear off?”

No, your surgery won't wear off. That said, you may wish to have additional surgery in the future to fine tune your vision or if your prescription changes. Sonia H. Yoo, MD, refractive surgeon with Bascom Palmer Eye Institute, and professor of ophthalmology, University of Miami Miller School of Medicine, Florida, says laser vision correction may last indefinitely when vision is stable at the time of the surgery. However, in cases of unstable vision, four to 10 percent of patients may require retreatment for under-correction.\*

Dr. Goel says his refinement rate is less than five percent.\* Those rare cases that do require retreatment often relate to differences in how individuals heal, he explains. “I tell patients the technology's wonderful, but everyone heals differently. And, even within the same individual, each eye could heal differently.”

Ron Krueger, MD, ophthalmologist, refractive surgeon with the Cole Eye Institute at the Cleveland Clinic in Cleveland, Ohio, says, “Your vision is not going to go back to where it started.” That said, he adds, we can't see into the future. “Anything can happen in 20 years. Maybe your eyes might grow, they might change. It's part of the nature of the living tissue which is your eye—that it may change.”

He has patients who had laser surgery 10 years ago, and when he examines their eyes, he sees that their prescriptions may have changed a little. “Then we talk about doing further surgery,” to address the change in prescription, he explains.

\*WaveLight® FDA Clinical Trials: Wavefront Optimized® and Wavefront-Guided for Myopia plus Astigmatism. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf2/P020050S004b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020050S004b.pdf), p.46, Accessed January 28, 2014.

## Does vision still deteriorate after LASIK?

Your eyes will continue to age after surgery, and this may eventually affect your near vision. Also, nearly everyone will develop cataracts as they get older. LASIK surgery doesn't treat—or prevent—cataracts. However, you can have cataracts removed if they develop after you've had laser eye surgery.

“Your eyes will continue to age and to change,” says Stephen Slade, MD, Slade & Baker Vision Center, Houston, Texas. “They may develop some cataracts or whatever else is going to happen to them, but the laser surgery's effect is permanent. It's really a lifetime of good vision.”

Chirag Shah, MD, an ophthalmologist with LasikPlus Vision Centers near Philadelphia says much the same. “Everyone will eventually develop cataracts. Everybody who has had LASIK will get cataracts. So will everybody who hasn't had LASIK. If you live into your 70s and 80s, you will get cataracts because it's a matter of aging. It's important to let your cataract surgeon know if you've had LASIK because it affects the type of implants or the power of the implant that you put in the eye. Your cataract surgeon will look at your data from before LASIK and calculate what size or power lens to put in the eye.”

## A Final Observation

Obviously, for a certain group of people, laser refractive surgery is a permanent, effective approach to seeing life more clearly. Whether LASIK or any of its iterations are an option for you is a decision that you and your ophthalmologist can make. If you need to wear glasses or contacts, however, and for any reason you'd rather not need corrective lenses, then it seems sensible to search out a skilled and reputable surgeon and undergo the pre-surgical assessment. Find out if you're even a candidate.



“I had my eyes done 10 years ago and it's still pretty amazing. After having worn glasses since third grade, it's very neat not to need them. That's pretty cool,” says Lewis Groden, MD, executive medical director, LasikPlus Vision Centers, Tampa, Florida. “I had an internal medicine doctor tell me he's really nervous about having LASIK because his eyes are important to him. Then he said he wears his contact lenses until they hurt. I told him LASIK would be safer for him than contact lens wear because he was abusing his contacts.”

Dr. Shah says, “Firefighters are running around, picking up people, their glasses get sweaty on their nose and they slide off and they're wearing masks on top of that—so they're under a lot of pressure to make sure that their vision is not compromising their safety. And, especially in the heat with the smoke, contacts get irritated. So, they're more interested in being less spectacle-dependent, too. We have soldiers getting it done before they deploy because they don't want to wear contacts or glasses in the middle of the desert; if they break them, they're in trouble.”



**Dr. Krueger performing LASIK on Karen**  
– Photo courtesy of Jack Shao, MD

# As I See It by Karen Donley-Hayes

A couple months ago, laser eye surgery wasn't on my bucket list, even though, as a writer and editor, I rely on my glasses to get the job done—literally. For me, glasses are a necessary nuisance. I don't like them, and forego them when I can. I work with horses, and avoid wearing my glasses if I'm riding, grooming horses, or just in the barn. I won't be able to read my watch or see anything clearly up close, but it's a trade-off: glasses

slide down my nose, get covered in dust and dirt, fog or frost up in cold weather, and are just one more thing to get broken or damaged. I tried wearing contacts, but they were irritating, and I often ended up rubbing them out of my eyes.

Wearing glasses has been an inconvenience and annoyance, but it's not like I'm totally blind without them. And frankly, I can be squeamish where eyes are concerned. When I was a paramedic, I would have preferred to be sent to a shooting than to a kid with something in his eye. Having lasers zap my eyes wasn't an attractive consideration.

Admittedly, I didn't know much about laser surgery—at least, not the things I wondered about. But working on this booklet, I talked to a lot of doctors regarding those things I wondered about. *Does it hurt? Am I awake? What will I see during the surgery? How much does it cost? How can lasers be safe?* The more I learned, the more interested I became. The surgeons' skills, the amazing technology, and the safety profile impressed me so much that I quickly decided it wasn't nearly as scary as I'd imagined. I thought about being able to work—to read and write—without glasses. I thought about being able to see the clock or caller ID on the phone in the middle of the night. Or seeing clearly in the barn, and being able to ride without my helmet squashing my glasses against my head. I thought about not having glasses pressing on the bridge of my nose, aggravating my sinuses, or irritating my temples and ears.

I decided I wanted to pursue it, and made an appointment with Ron Krueger, MD, ophthalmologist, refractive surgeon with

the Cole Eye Institute at the Cleveland Clinic in Cleveland, Ohio. Like all potential laser surgery patients, I underwent a very thorough examination to determine if I was a candidate, and, if so, which surgical approach would be best for me.

By the time I left the office a few hours after I'd arrived, I knew I was a candidate, and which procedure would be best for me. We discussed financing, and I was scheduled for a final preoperative visit/exam, LASIK surgery, and routine postoperative exams.

A year ago, I would not have believed it if someone told me I'd be doing this. Now, I can't wait to see my brave new world!

## My LASIK Surgery

The day prior to my procedure, I met with Dr. Krueger in his office for the final round of preoperative tests. They double-checked my prescription, dilated my eyes, conducted additional in-depth examinations, and Dr. Krueger and I again discussed my procedure. At the end of the meeting, I signed the consent form and made arrangements for payment.

On surgery day, Dr. Krueger and his assistants again discussed with me the exact procedure I would be having. I liked that we discussed this several times; it gave me confidence not only that Dr. Krueger and his team were completely focused on me and my case, but it also gave me time to think about and ask questions I may not have thought of without these longer discussions. By surgery time, I also felt I understood my specific LASIK procedure to the point I could explain it to someone else, and know what I was talking about.

In the operating suite, I got to look at all the equipment and computers. Dr. Krueger explained that he would create the flap (using the femtosecond laser) in both eyes first—this would take about 30 or 40 seconds per eye, and, although I wouldn't feel any pain, I would probably feel pressure when he made the flaps, during which time my field of vision would darken and I might see stars. This was often the most uncomfortable part of the procedure for most patients, he told me, but it would be over very quickly. After creating the flaps, Dr. Krueger would then use the excimer laser to sculpt each cornea. They showed me both lasers, explaining which was which—although I have to admit I wouldn't have recognized either as a laser; they just looked like components to the computers and other apparatus in the room.

I lay on my back on the operating table, my head resting in a cradle, and, much like with any eye exam, the equipment was very close to my face. Dr. Krueger put numbing drops in my eyes, and told me I'd be looking at lights of varying brightness. He placed gauze over my right eye, so only my left eye was open. Then he placed tape and small clamps on my eyelids to keep my eye open; this was not as irritating as I'd expected. He told me when he was about to create the flap with the femtosecond laser, and reiterated I might feel pressure and my vision would darken. He was right on both counts: I didn't have pain, but the pressure was uncomfortable; my vision darkened and I saw pinprick lights. In less than a minute, he was putting the gauze over my left eye, and working on creating the flap in my right eye. It was over very quickly, and I felt remarkably relaxed.

Having created the flaps with the femtosecond laser, Dr. Krueger switched to the excimer laser to sculpt first my right then my left cornea. I watched a green light in the center of another ring of lights. Sometimes the lights and colors blurred, sometimes they cleared. I didn't feel anything; I could smell the effect of the laser reacting with the oxygen in the room—sort of a singed hair smell—but otherwise it seemed I was looking at lights and colors through a kaleidoscope.



**A spectacle-less Karen with her horse, Indy.**  
– Photo courtesy of Karen Donley-Hayes

my vision would be clearer in a few hours. This information also proved accurate; I kept my eyes closed as my husband drove us home—about an hour-long trip—then I dozed at home for a while. Although I occasionally had a foreign-body feeling (like an eye lash), by dinnertime, my eyes felt almost back to normal, and my vision



**Karen with Dr. Krueger minutes after the completion of Karen's LASIK procedure.**  
– Photo courtesy of Jack Shao, MD

During the first week after my LASIK, I experienced some challenges and side effects. For example, I saw mild halos at night around lights (similar to what I'd seen when I wore contacts), and my eyes occasionally felt a little tired. For several nights, I wore the protective goggles so I didn't rub my eyes while I slept, but during the day, I really had to concentrate on not rubbing my eyes—a habit I'd had for years. I also had to be careful showering for the first week, concentrating on not rubbing my face or eyes or letting tap water run into my eyes. And the prescription eye drops I applied four times a day for the first week eventually worked through my sinuses and left a bad taste in the back of my mouth. Happily, I quickly discovered that eating chocolate took care of that small problem!

I admit that, before my LASIK procedure, I felt ambivalent about spending the money and going under the knife (well, the laser) merely because I didn't like dealing with glasses. It seemed frivolous and silly to spend so much money on a surgery that would give me what I already had with glasses. So, I didn't tell many people I was considering LASIK.

Within a couple days after the surgery, however, all that had changed, and I hardly stopped talking about it. Like that, within a day of the surgery, I already saw better—especially during close-up reading—than I had with my bifocals or even my “heavy duty” prescription reading glasses. I was surprised at the feeling of liberation. I love not having to juggle two or three pairs of glasses, depending on what I'm doing; I love being able to read whatever I want, whenever I want, without having to adjust my glasses or increase the size of the text on the computer monitor. I love being able to open the oven and not have my glasses steam up. I love not having them frost over when I go outside in the cold weather. And I love being able to see clearly when I groom my horse, fiddle around the barn, and ride; before, a lot of that was a blur—literally—because, as soon as I got to the barn, I'd stow my glasses in my locker.

I'm so happy that I didn't listen to that little voice inside fretting about LASIK being pricey and unnecessary. It was a gift from me to me, I decided. But, it wasn't until after I gave myself that gift that I could clearly see the beauty of it.

## Did you know?

**Research found that 87% of people who had undergone laser vision correction were happy with the results and would recommend the procedure.\***



**The computer monitor screen, showing the excimer laser's progress reshaping the cornea (the lighter grey area on the bottom has been treated).**

– Photo courtesy of Jack Shao, MD

had cleared almost completely.

As instructed, I wore the goggles to bed that night. The next morning, I drove myself to work—and spent the first half of the day reading, writing, and using the computer with no problems—and no glasses. In the afternoon, I drove myself into Cleveland for my first day post-operative evaluation. The exam showed both flaps to be in great condition. I thought I was seeing better than I had even with my glasses—turns out I wasn't just imagining it.

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These are real results from actual patients. Although results are typical, individual results may vary.

\*WaveLight® FDA Clinical Trials: Wavefront Optimized® and Wavefront-Guided for Myopia plus Astigmatism. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf2/P020050S004b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020050S004b.pdf), p.46. Accessed January 28, 2014. Disclosure: Ms. Donley-Hayes received no gratis or reduced fee consideration for her LASIK procedure.



## Important Product 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 System 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 of 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  $\leq 0.50$  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  $\leq 6$  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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