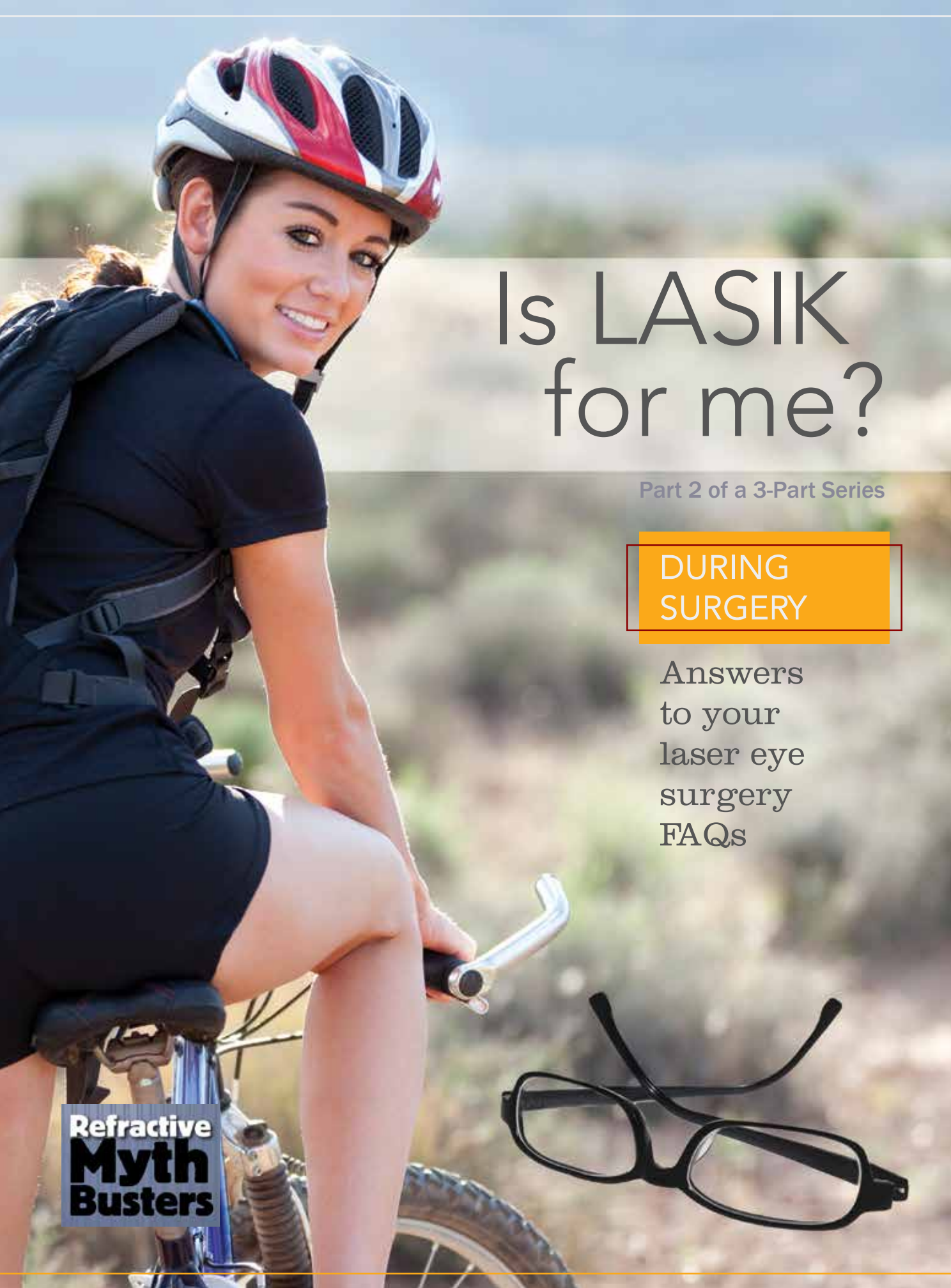


Is LASIK for me?

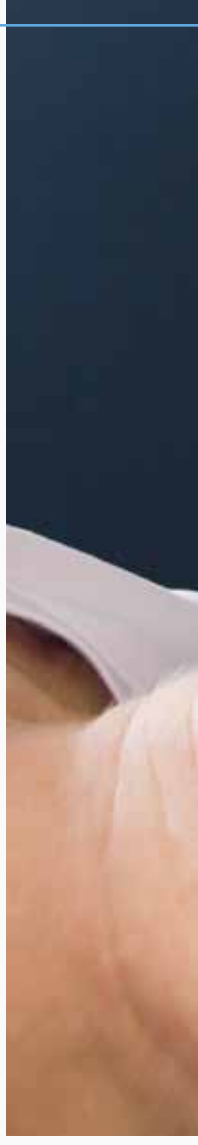
Part 2 of a 3-Part Series

DURING SURGERY

Answers to your laser eye surgery FAQs

Refractive Myth Busters

I'm ready to do this. What happens during surgery?



Now that you've decided to move ahead with laser eye surgery, you want to know what really goes on in the operating room. What happens between deciding to undergo laser eye surgery and when you leave the surgeon's office after the procedure?

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 femtosecond 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."

What are the risks and possible side effects?

The risks associated with laser eye surgery are very low, but potentially include:

- infection or issues with healing, resulting in follow-up treatment;
- permanent vision loss that cannot be corrected with glasses, contact lenses, or further surgery;
- debilitating visual symptoms, such as glare, halos, or double vision that can seriously affect nighttime vision;
- under- or over-treatment, necessitating further refinement to reach the intended correction;
- severe dry eye syndrome.

When patients express concerns about the possibility of getting infections within and/or losing their eyes, Dr. Krueger explains that LASIK doesn't go inside the eye, but rather treats the surface layers. So, any infection would affect the layers of the eye where it's more controllable. For these reasons, infections are rare.

Am I awake during the procedure?

Yes, you are awake during the procedure. Most surgeons prescribe medications to help calm and relax patients before the procedure.

Lewis Groden, MD, executive medical director, LasikPlus Vision Centers in Tampa, Florida, says he also talks to his patient during the entire procedure. "I'm the only one talking in the laser room during the procedure and I don't stop talking. It's just calming to the patient, and we want it to be a good experience."

Is there any pain?

You are given numbing eye drops, so you won't feel any pain. You will feel the doctor's hands around your face, and you may feel pressure, but it won't hurt.

Sanjay "Sonny" Goel, MD, executive medical director, LasikPlus Laser Vision Centers in Annapolis, Maryland, says, "The procedure itself is actually quite comfortable. When you make the flap, you feel pressure on the eye, but it's not pain. The other thing you feel are the eyelids being held open. You feel that, but it doesn't hurt; it just might feel a little different or odd."

After the LASIK surgery, when the anesthesia has worn off, you may feel some irritation. "You might feel like you have a piece of sand or an eyelash in the eye," Dr. Goel says. Some patients experience some dryness or burning sensation after surgery, he explains, which may "last for maybe three to four hours."

What will I see during the surgery?

During the procedure, you will see a flashing light, which is the target at which you are instructed to stare. You'll also see bright lights and shadows, and your vision may go dim or dark momentarily during the surgery. Otherwise, everything is too close for your eyes to focus, and you won't see much except flashing lights and shadows.

Laser eye surgery is fast—usually less than 10 minutes per eye. Dr. Krueger says, "Once you're in the laser room, you're done within half an hour."

"Even if you would start to look around during the treatment, the laser would detect the eye jumping too much. As soon as it cannot compensate for your movement it will stop, remember the point where the eye was last detected, store the information on how much of the treatment had already been done, and when the surgeon repositions you back into the treatment area, the system remembers the already-performed treatment, and just continues."

—Michael Mrochen, PhD

How much time does surgery take?

Laser eye surgery takes only about 10 minutes per eye.

What happens if my eye moves during the surgery?

One of the elements that makes laser eye surgery so safe and successful is the systems' precision. Michael Mrochen, PhD, researcher in medical physics and engineering, the Institute of Refractive and Ophthalmic Surgery, Zürich, Switzerland, says, "Laser systems have high-speed video imaging systems so they can measure your eye about 500 times per second. If your eye moves, the the laser follows it. It's actually measuring your eye's movement and the laser beam is corrected for that eye movement." The scanner is 10 times faster than your eye can move. Even if you were to jump away or move out of the laser beam, the system would detect that your eye was not in location, and would immediately switch off the laser.

Dr. Krueger says some patients ask, if they move, "is the laser going to drill a hole in the side of my head? The answer is no, because the tracking system will have been shut off and the laser will stop. And then, once you get your pupil back into alignment, the tracking system is engaged and you continue."

What happens if the doctor's hand shakes or moves?

Because much of laser eye surgery is computer-driven, there's less risk related to the doctor's movements or hand shaking.

Did you know?

A human has a reaction time of 20 or 30 milliseconds; the scanners on the laser systems are about 10 times faster.

What type of laser is it?

Usually, two different types of lasers are used:

- femtosecond laser
- excimer laser.

While a few practices still use a blade to create the flap in LASIK surgery, most surgeons use lasers for the entire procedure. "I would say, right now, 70% or more of LASIK surgeries in the United States are being done with a laser

making the flap instead of a blade,"* Dr. Krueger says.

In bladeless surgeries, two types of lasers work together: The femtosecond laser creates the flap and the excimer laser sculpts the cornea. Why two separate lasers? Each uses completely different technology to accomplish different things.

The femtosecond laser—the one used first to create the flap—uses an infrared wavelength and creates the flap by separating the layers of the cornea, cutting the tissue precisely with very, very short pulses.

The excimer laser then uses an ultraviolet wavelength to reshape the cornea so that light comes into focus on the retina on the back of the eye. And, regardless of the fact that it's a laser, it doesn't burn anything. Instead, it works by breaking bonds within and evaporating tissue. It removes microns of tissue without damaging anything below or to the side; that's how it reshapes the cornea so precisely.

How well does it work?

More than 93% of patients achieve at least 20/20 or better vision after LASIK,** says Sonia H. Yoo, MD, refractive surgeon with Bascom Palmer Eye Institute, and professor of ophthalmology, University of Miami Miller School of Medicine, Florida. This represents legal driving vision and it is good enough for most sports and activities.

Because today's lasers have tracking systems that follow the eye, the results have become more predictable, adds Dr. Shah. "The system compensates for movement, the pattern does not get affected, and you still get an accurate ablation on the eye. The results are a lot more accurate now because of that," he says.

*Market Scope 2012 Comprehensive Report on The Global Refractive Surgery Market

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

"The laser creates a new shape to the cornea with extreme high precision. There's no other mechanical system today that achieves that precision. That's why these lasers we are using for eye surgery are also the type used to create semiconductor chips and computer chips."

—Michael Mrochen, PhD

Dr. Krueger says it's critical that the laser systems are properly calibrated, "So, the right amount of treatment goes down, and also that it's well centered. If it's not well centered, then you're going to have some other distortions created. I tell patients that we calibrate before every patient to make sure the right energy is coming out onto your eye. The laser's tracking system locks onto and follows the movement of your pupil, so, when you're being treated the laser is following. Even if your eye moves, the tracking system follows it and the laser pulses go where they're supposed to go."

"The laser does not generate any heat. Nothing's burning, there's no heat with the laser at all. It may smell like something's burning, but that's simply the laser interacting with oxygen in the air to form ozone. Nothing's burning your eye. I could fire the laser on my hand and nothing would happen."

—Lewis Groden, MD

Even with this state-of-the-art technology, "there is still a human component to it," Dr. Groden says. "Honestly, probably the biggest input the surgeon has is the decision-making process. Who should and who shouldn't have it."

Policemen, firemen, even corrections officers in the prison system often express concern about wearing glasses or corrective lenses, says Chirag Shah, MD, ophthalmologist, LasikPlus Vision Centers near Philadelphia. "Prison correction officers and policemen come in saying that glasses or contacts can be a handicap.

If you get into a fight, the first thing they're going to do is to try and punch your glasses. If their glasses fall off, then they're really compromising their own safety and the safety of others, of their partners," he says.

The Air Force, NASA, and the Navy have studied LASIK flaps in great detail. They found that the force of a pilot ejecting out of a fighter plane would not dislocate the flap, so they permit their pilots and astronauts to have LASIK procedures performed.*

*Stanley PF, Tanzer DJ, Schallhorn SC. Laser refractive surgery in the United States Navy. Curr Opin Ophthalmol. 2008 Jul;19(4):321-4. doi: 10.1097/ICU.0b013e3283009ee3. Review. PubMed PMID: 18545015.

Do I have any restrictions?

How long is the recovery time?

Visual recovery occurs within the first several hours and days and is usually complete one to three months after the procedure. Your vision may fluctuate for several weeks as any inflammation and swelling subside.

For LASIK, the recovery is very rapid. When you walk out of the procedure room, you will already see better, but your vision may also probably have some haziness. That's due to minor swelling to the eyes' surface, and will improve within a few hours. Your eyes may feel uncomfortable—like a foreign body sensation of burning and tearing for the first two hours. Close your eyes and nap for a few hours. When you wake up, you'll feel and see better. Most LASIK patients return to their normal work and lifestyle the day after surgery.

Dr. Shah says, "I tell my patients they can go back to work the next day provided it's kind of a desk job. So, most patients can resume work; their main restrictions are no eye rubbing and don't get punched in the eye."

Most surgeons recommend a follow-up schedule of the first day after surgery, then again at one week, one month, and three months. These examinations watch for infection and monitor healing of the flap (for LASIK).

Did you know?

The less refractive error you have, the greater the chance of achieving 20/20 vision after surgery.

Do I have any restrictions?

You will have some minor restrictions after surgery, especially during the first few days. For example, your surgeon may recommend the following:

- Do not rub your eyes for the first week after surgery; wear an eye-shield at night to prevent inadvertent rubbing.
- When washing/drying your face, wipe the bony areas around the eye, not the eyelid.
- Go without eye make-up—especially mascara—for a week.

"I had this surgery done myself 13 years ago and I remember being able to sit up and see better right away." —Sanjay 'Sonny' Goel, MD

- You may shower the day after surgery, but avoid getting water in your eyes.
- Don't go swimming for the first 10 days.
- Wear sunglasses when in the sun for three to six months to protect against UV exposure.

In general, you won't have restrictions on your activities after one week to 10 days—during which time your eyes will be healing and stabilizing.

Dr. Groden says, "I've done the procedure on an awful lot of ophthalmologists. That probably says more about the safety and efficacy of LASIK, of laser vision correction; it's the first refractive surgery procedure that's widely accepted by ophthalmologists for their own eyes."

What if my vision is worse afterwards?

It will take a little time for your vision to recover after the surgery, although most patients can see better immediately. During the days and weeks after your surgery, your surgeon will examine how your eyes are healing and will repair any folds or shifts in the flap. If, after three months—when healing is usually complete—your vision isn't as sharp as it could be, you may be a candidate for a refinement.

In the extremely rare cases of infection, your vision might worsen, although "typically those things can be fixed," says Stephen Slade, MD, Slade & Baker Vision Center, Houston, Texas. Proper preoperative screening and following postoperative restrictions will help ensure that you obtain the best possible results.

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.

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 mangement 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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