The Pinnacle of Refractive Performance

CONTOURA® VISION

At 12 months, topography-guided lasik patients, **without the aid of glasses or contacts**, experienced the following results.[1]

98.4%
of patients said they would have the procedure again*

30.9%
of eyes gained 1 or more lines over baseline BSCVA

34.4%
could see 20/12.5 or better

64.8%
could see 20/16 or better

92.6%
could see 20/20 or better

Statistically significant improvements in the severity of these visual symptoms.[1]

- Decrease in light sensitivity.
- Decrease in complaints of difficulty driving at night.
- Decrease in reading difficulty.
- Reduction in complaints of glare.
- Reduction in complaints of halos.
- Reduction in complaints of starbursts.

WaveLight® REFRACTIVE PORTFOLIO | Advancing REFRACTIVE SURGERY

References: 1. Stulting RD, Fant BS; T-CAT Study Group. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. *J Cataract Refract Surg*. 2016;42(1):11-18.

Study Description: Prospective, Nonrandomized, multicenter study of 249 eyes with myopia or myopic astigmatism of 6.0D or less. Outcome measures included manifest refraction, UDVA, CDVA and visual symptoms up to 12 months.

*In a subset analysis of 124 patients, 122 responded that they would have LASIK again.

For Important Product Information about the WaveLight® Laser Systems please see back page.

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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 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.

In addition, the WaveLight® ALLEGRETTO WAVE® Eye-Q Excimer Laser System, when used with the WaveLight® ALLEGRO Topolyzer® and topography-guided treatment planning software, is approved for topography-guided LASIK treatments for the reduction or elimination of up to -9.00 diopters of nearsightedness, or for the reduction of elimination of nearsightedness with astigmatism with up to -8.00 diopters of nearsightedness and up to 3.00 diopters 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), 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 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.
- You show symptoms of severe 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.
- Your corneas are too thin. If your corneas will be too thin after your doctor has cut a flap and performed the LASIK treatment, you cannot have LASIK.
- You have recurrent corneal erosion. This condition can lead to serious corneal problems during and after LASIK surgery.
- You have advanced glaucoma. It is unknown whether LASIK is safe and effective for you.
- You have uncontrolled diabetes. LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.

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 more risky 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 more risky for you. These medicines may change the wetness level in your eye. If the medication changes the moisture of your eye, the accuracy of your refractive results may be affected, and topography-guided LASIK is more risky for you.
- History of glaucoma, increased pressure inside your eyes, have been diagnosed with ocular hypertension, or are being followed for possible glaucoma, because it is unknown whether LASIK is safe and effective for you.
- Your doctor is unable to obtain preoperative topography maps that are of good enough 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.
- Taking the medication isotretinoin (Accutane*) for acne treatment, because this may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

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.
- 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 certain types of cancer drugs (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 are considering topography-guided LASIK treatment for nearsightedness that is worse than – 9.00 diopters, or nearsightedness with astigmatism that is worse than – 8.00 diopters of nearsightedness or 3.00 diopters of astigmatism. It is unknown whether topography-guided LASIK is safe or effective for you.
- 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.
- You have any other medical condition that is likely to increase the risk of LASIK surgery or make you an unsuitable candidate for LASIK surgery. Tell your doctor about all your medical conditions.
- You have a history of crossed eyes (strabismus). It is unknown whether LASIK is safe and effective under this condition.
- If you have a decreased vision in one eye, it is unknown whether LASIK is safe and effective under this condition.
- If there is an infection or problem with healing after the surgery, it is more likely that both eyes will be affected if both eyes are treated at the same session. If only one eye is treated, the difference in vision between the treated eye and the one without treatment might make vision difficult. In such a case, you might not have functional vision unless the second eye is treated with LASIK or by wearing glasses or contact lenses that compensate for the difference.

Your doctor should evaluate you for dry eye symptoms before surgery. You may have dry eye after LASIK surgery even if you did not have dry eye symptoms 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: The wavefront-guided myopia (nearsightedness) clinical study compared subjects treated with wavefront-guided LASIK (Study Cohort) to subjects treated with traditional LASIK (Control Cohort). 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.
- Topography-Guided Nearsightedness Study: There were six adverse events reported in the topography-guided nearsightedness 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:

Nearsightedness Study: 782 eyes in the myopia (nearsightedness) study were included in an analysis of effectiveness at 6 months after surgery. Of these, 98.3% were corrected to 20/40 or better without wearing glasses, and 87.7% were corrected to 20/20 or better without wearing glasses. 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: 212 eyes in the hyperopia (farsightedness) study were included in an analysis of effectiveness at 6 months after surgery. Of these, 95.3% were corrected to 20/40 or better without glasses, and 67.5% were corrected to 20/20 or better without glasses. 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: 111 eyes in the mixed astigmatism study were included in an analysis of effectiveness at 6 months after surgery. Of these, 97.3% were corrected to 20/40 or better without glasses, and 69.4% were corrected to 20/20 or better without glasses. 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 subjects treated with wavefront-guided LASIK (Study Cohort) to subjects treated with traditional LASIK (Control Cohort). 166 eyes in the Study Cohort and 166 eyes in the Control Cohort were included in an analysis of effectiveness at 6 months after surgery. Of the 166 eyes in the Study Cohort, 99.4% were corrected to 20/40 or better without glasses, and 93.4% were corrected to 20/20 or better without glasses. Of the 166 eyes in the Control Cohort, 99.4% were corrected to 20/40 or better without glasses, and 92.8% were corrected to 20/20 without glasses.

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).

Topography-Guided Nearsightedness Study: 247 eyes in the topography-guided nearsightedness study were included in an analysis of effectiveness at 3 months after surgery. Of these 247 eyes, 99.2% were corrected to 20/40 or better without glasses, and 92.7% were corrected to 20/20 or better without glasses. 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.

Attention: Please refer to a current WaveLight® Excimer Laser System Patient Information Booklet for your procedure 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 for your procedure.

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