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Cataract & Refractive Surgery Today



Taking LASIK to the Next Level: CONTOURA Vision

Implementation Recommendations for Your Clinic

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OPTIMIZING OUTCOMES WITH CONTOURA VISION

Implemented correctly, this major advancement in refractive surgery enables better outcomes for patients.

BY MARK LOBANOFF, MD



The CONTOURA Vision (Alcon) system is changing LASIK. The technology enables surgeons to treat each cornea's unique topographic irregularities in a broad range of LASIK patients, which may produce a better quality of vision.

By removing each cornea's topographic irregularities CONTOURA Vision treatments also benefit patients by reducing night vision problems such as glare and halos.¹ That is unique to CONTOURA Vision; a LASIK technology that creates vision higher in quality than anything that has come before. Vision for many patients that is superior to what glasses, contacts, or traditional LASIK can offer. Today, CONTOURA Vision is a practice differentiator, garnering high patient satisfaction and referrals for surgeons who use it.

Outcomes with CONTOURA Vision can be spectacular. In FDA clinical trials and today in open use, CONTOURA Vision outcomes are measurably superior and show noticeably better patient satisfaction compared to standard LASIK. After the procedure in 249 eyes, 92.6% of patients have 20/20 or better uncorrected visual acuity—better than preoperative best-corrected visual acuity in more than 30% of eyes.² An astounding 1 in 3 patients achieved 20/12.5 or better uncorrected vision. CONTOURA Vision also has lower rates of symptoms associated with LASIK, such as light sensitivity, night driving problems, reading difficulty, glare, halos, and starbursts.¹ Given the higher quality of vision that CONTOURA Vision delivers to patients, in a survey of 124 patients, 98% said they would have the procedure again.²

WAVELIGHT® TOPOLYZER™ VARIO

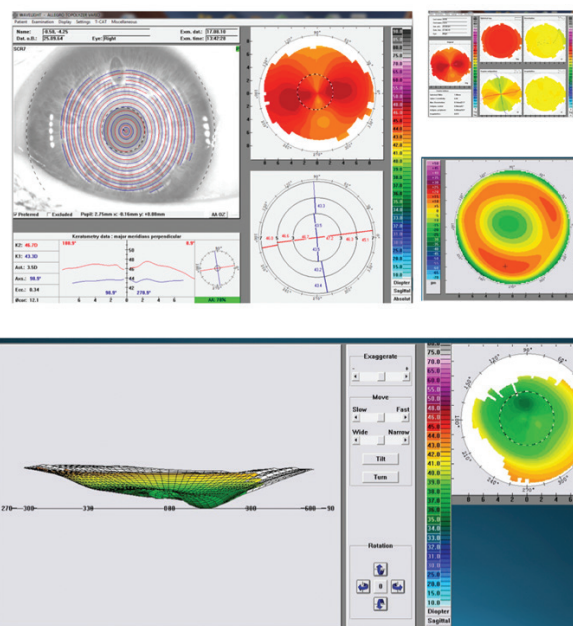


Figure 1. The WaveLight Topolyzer VARIO Diagnostic Device.

NEXT-LEVEL TECHNOLOGY WITH BROAD APPLICATION

CONTOURA Vision takes customized refraction a step further by addressing very specific problems related to corneal topography that had never been fully addressed before. New cutting-edge topography must be meticulously

CONTOURA VISION ALSO HAS LOWER RATES OF SYMPTOMS ASSOCIATED WITH LASIK, SUCH AS LIGHT SENSITIVITY, NIGHT DRIVING PROBLEMS, READING DIFFICULTY, GLARE, HALOS, AND STARBURSTS.¹ GIVEN THE HIGHER QUALITY OF VISION THAT CONTOURA VISION DELIVERS TO PATIENTS, IN A SURVEY OF 124 PATIENTS, 98% OF PATIENTS SAID THEY WOULD HAVE THE PROCEDURE AGAIN.²

CONTOURA VISION IS NOT A PREMIUM SURGERY FOR JUST A FEW PATIENTS. PATIENT SELECTION IS SIMILAR TO LASIK OR PRK, AND ANYONE WHO FALLS WITHIN THE ESTABLISHED GUIDELINES CAN POTENTIALLY BE A CONTOURA VISION PATIENT.

accurate, without shadows, tear film disruption, or other factors that could impair its quality. What used to be an assessment tool is now a surgical guide because the topographic corneal data are sent to the Alcon WaveLight laser and actually used to improve the accuracy of the excimer laser treatment. That's a true paradigm shift—topographic data not just examined by the surgeon but actually sent directly to the laser as part of the treatment. And as always, the quality of the outcomes starts with the quality of input into the laser.

Once practices master capturing WaveLight Topolyzer VARIO Diagnostic Device (Alcon) images, the rest of the CONTOURA Vision process is seamless (Figure 1). Through a highly visual process, the software helps technicians and surgeons evaluate the quality of the images, so it is easy to pick the four images required for surgery. We can now look at exquisitely detailed corneal topography, isolate the impact of any topographic aberrations on the cornea, and decide how to integrate those aberrations into the refraction. Finally, the laser will have the actual 22,000 topographic data points for each eye's treatment, a huge improvement over simply imputing a steep K and a flat K. The 22,000 keratometric data points are much better than 2 simple K readings.

CONTOURA Vision is not a premium surgery for just a few patients. Patient selection is similar to LASIK or PRK, and anyone who falls within the established guidelines (up to -8.00 D sphere, up to -3.00 D cylinder, and a spherical equivalent no greater than -9.00 D) can potentially be a CONTOURA Vision patient. Even patients with low refractions benefit from CONTOURA Vision, because everyone has topographic aberrations in the cornea that affect visual performance. However, we sometimes need to rule out patients if we think that corneal scarring or another challenge will make it impossible to acquire reliable images. I use CONTOURA Vision for all of my eligible patients and on most days 80% to 90% of my patients are treated with CONTOURA Vision. Yet 100% of my

patients benefit from it. How so? Because even if a patient can't have CONTOURA Vision, we are still able to capture iris recognition data, which is sent to the WaveLight laser's tracker. This allows perfect axis placement of astigmatic treatments in WAVEFRONT OPTIMIZED treatments. Hyperopic patients benefit because the Topolyzer VARIO data can identify the true corneal vertex with nearly perfect precision. Hyperopic treatments can thus be centered on the pupil center or the corneal apex depending on surgeon preference for each eye. Tangible benefits from having your diagnostic technology "talk" directly to your laser.

CAPTURE THE HIGH-QUALITY MEASUREMENTS YOU NEED

To optimize the outcomes of refractive surgery with CONTOURA Vision, we need to capture high-quality images with minimal shadowing and healthy tear film. My staff and I follow these five steps:

- 1. Ensure the ocular surface is clear and consistent.** Because the Topolyzer VARIO is a Placido disc measurement that relies on rings reflected onto the corneal surface, it is important to have a healthy, uncompromised ocular surface. In preparation for these measurements, we have patients stop wearing soft contact lenses for 1 week, or gas permeable lenses for 3 weeks. We also perform the Topolyzer VARIO measurements first, before any other testing is done that requires staring or other actions that can disrupt or distort the tear film or corneal surface.
- 2. Position and coach the patient.** Patients have a role in capturing the best CONTOURA Vision images, so our technicians give patients a 30-second overview of what to expect before they begin. Technicians explain that nothing uncomfortable or surprising (no puff of air) will take place during the measurements.



Figure 2. A technician using the Topolyzer VARIO system with a patient.

PATIENTS CAN HELP OPTIMIZE THEIR OCULAR SURFACE BY KEEPING THEIR EYES CLOSED BETWEEN MEASUREMENTS. WHEN THE TECHNICIAN IS READY TO CAPTURE A MEASUREMENT, THEY INSTRUCT PATIENTS TO DO THREE QUICK BLINKS, OPEN THEIR EYES WIDE WITH THEIR EYEBROWS UP, AND FOCUS IN THE CENTER OF A LITTLE YELLOW “DONUT” (FIXATION TARGET).

Body positioning is very important, because if patients are uncomfortable, they will move a lot, which makes it difficult to capture a good image. Patients should be sitting upright in a comfortable position, and we do not want them to sit back in between measurements (Figure 2). Patients can help optimize their ocular surface by keeping their eyes closed between measurements. When the technician is ready to capture a measurement, they instruct patients to do three quick blinks, open their eyes wide with their eyebrows up, and focus in the center of a little yellow “donut” (fixation target). If it takes longer than 4 to 5 seconds to capture an image, technicians tell the patients, “blink, blink, blink, and brows up,” and they try again.

3. Position the eyes for optimal image capture. The right positioning helps ensure that we get the most data possible for CONTOURA Vision treatment. First, we adjust the table height so patients are comfortable because uncomfortable patients naturally shift around and need to be repositioned. To prevent shadowing from the nose, we measure the right eye with the head turned (never tilted) slightly to the left, and measure the left eye with the head turned slightly right. Using the forehead spacer is also important because it helps push the forehead back ever so slightly for better superior

exposure. Technicians do a quick eye-to-eye test before taking the first measurement on the right eye or left eye, in order to help ensure there is no cyclotorsion related to head tilt. Sometimes having a second technician lift the eyelid from the side helps as well (Figure 3).

4. Capture six images for the CONTOURA Vision procedure. Optimally, we need four images to perform the CONTOURA Vision procedure. For patients whose measurements fall within the criteria for CONTOURA Vision surgery (up to -8.00 D sphere, up to -3.00 D cylinder, and a spherical equivalent no greater than -9.00 D), my technicians aim to capture six images. This allows me to rule out outliers, such as images with variations from compromised tear film or missing data (lids, lashes, or nose shadows) during the comparison process. However, I will still proceed with CONTOURA Vision in many cases if we capture fewer than 6 images but those that are captured are of a high quality.

5. Gather measurements for other refractive surgeries. When patients fall outside the CONTOURA Vision indication, the Topolyzer VARIO measurements are still valuable. Iris registration can be used for other procedures. I also export data from the Topolyzer VARIO (patient

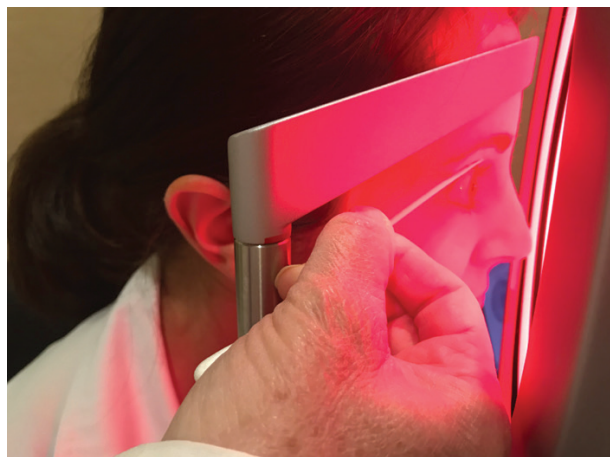


Figure 3. The right positioning helps ensure that we get the most data possible for CONTOURA Vision treatment.

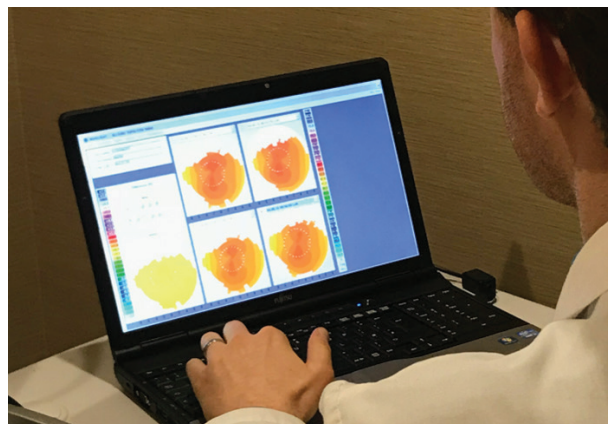


Figure 4. Once we capture images for the CONTOURA Vision procedure, my technicians follow an interactive image analysis process, eliminating outliers and verifying that measurements are consistent and reliable.

demographics, iris registration, keratometry, and corneal vertex measurement) for any WAVEFRONT OPTIMIZED procedure I perform using the WaveLight EX500 Excimer Laser (Alcon). This increases our efficiency on OR days as the data will not need to be entered into the laser “on the fly.”

ANALYZE AND SELECT THE BEST IMAGES

Once we capture images for the CONTOURA Vision procedure, my technicians follow an interactive image analysis process, eliminating outliers and verifying that measurements are consistent and reliable (Figure 4). From the patient’s six captures, they select four high-quality images for either the CONTOURA Vision procedure or for iris registration alone.

First, we compare measurements for consistency and reliability of ± 0.75 D. Using comparison maps of the treatment area in the Compare Images Display on the Topolyzer VARIO, we look at four images on the screen. We choose the scan with the best tear film/topography image as a baseline for comparing Topolyzer VARIO images. To compare other images to that baseline, we check from the pupil to the mid-periphery to make sure that the difference is less than 0.75 D. After discarding the outliers, we pull up additional scans and make the same comparison.

Next, the Analyzer Area tool helps us ensure we have the data we need. It calculates the data available for 5.50 mm and 6.50 mm optical zones. The Optical Zone Analyzer section on the Overview page shows the optical zone for the eye, split into inferior, superior, temporal, and nasal quadrants (Figure 5). The software marks each quadrant in red or green. Green check marks tell us that there is enough data in the optical zone for CONTOURA Vision and iris registration. In addition, a green “P” means preferred (for the CONTOURA Vision procedure) and a green “R” indicates good iris registration.

If the examination is less than perfect, the screen will

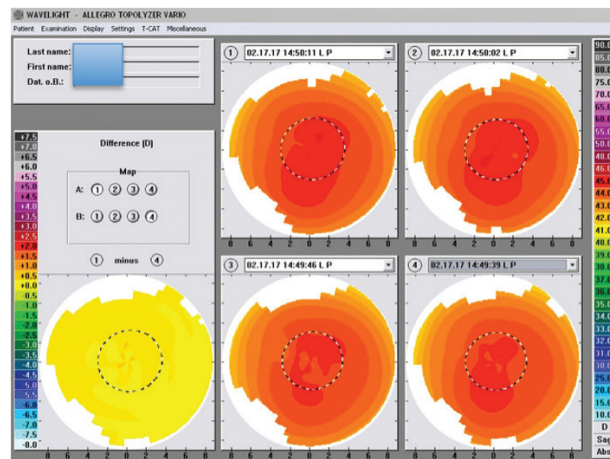


Figure 5. The Optical Zone Analyzer section on the Overview page shows the optical zone for the eye, split into inferior, superior, temporal, and nasal quadrants.

display a red “X” and show which quadrant or quadrants have insufficient data. For example, data may be missing from the superior region if the eyelashes cast a shadow, or the nose may have a shadow in the nasal quadrant.

Images should have 90% or higher AA OZ in the 6.50 OZ and pupil border recognition within 0.1 mm or 100 μ m of the baseline image. Patients typically will have several scans with sufficient data, but if, for example, the 5.50 mm optical zone has 100% of the data, while 6.50 mm is missing data but is still over 90%, we can manually change the image to “preferred” for the CONTOURA Vision procedure. Any scans below those thresholds are not usable. Alcon’s trainers are excellent and can help explain all of this thoroughly. In practice, it is not difficult.

CALCULATE CONTOURA VISION TREATMENT

Once the technicians have a good set of images for surgery, I calculate the laser refractive treatment for the CONTOURA Vision procedure. It begins with checking the reproducibility of imported measurements. Once my technicians send the selected scans to the laser, I have the opportunity to double-check them for accuracy. At the planning station, I look at the images in the Raw Data Sagittal view, comparing the appearance of the corneal topographies and eliminating any extreme outliers. Inspect the K values, axes, Q values, and pupil sizes, if necessary. This usually takes me about 30 seconds or less.

I can dig deeper into the data behind the images if needed, but generally, this simplified approach is very effective. Once I approve the scans and removed any scans that the technician may have missed, I am ready for the next step.

Advancing to the next screen, I input the patient’s specific treatment data: manifest refraction, vertex distance, K values, pupil size, and pachymetry results (Figure 6). The third page in the planning process is where I can calculate the patient’s final treatment. In the table at the top of the page, the top line displays the manifest refraction that was inputted on the previous screen. The second line shows the highly accurate measured refraction and cylinder axis of the astigmatism found by

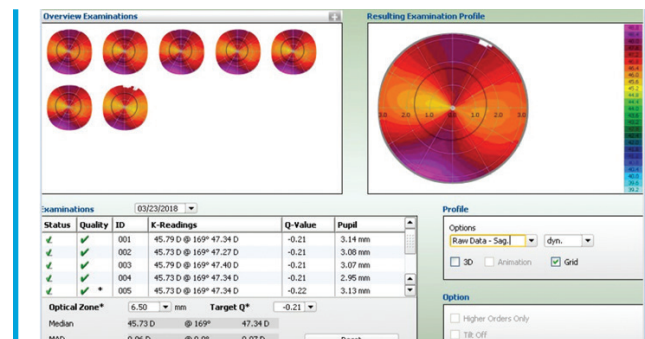


Figure 6. This screen shows the patient’s specific treatment data: manifest refraction, vertex distance, K values, pupil size, and pachymetry results.

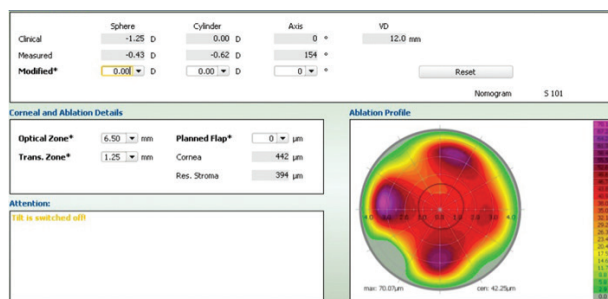


Figure 7. This ablation profile shows only the anterior corneal topographic aberrations.

the Topolyzer VARIO. (Note: the Topolyzer VARIO is incapable of determining the sphere, so this figure should be disregarded.) On the third line, known as the “Modified” line, I enter the final, nomogram-adjusted treatment chosen for the eye.

In making my final choice for treatment, I consider which nomogram to use and whether I should make an age adjustment. I can also dig deeper into the topographic pattern found on the cornea and think about how this can affect the refraction. To see how the CONTOURA Vision procedure will remove these aberrations to provide a smoother, more regular corneal surface, I enter 0 in the modified sphere and cylinder boxes. The resulting ablation profile shows only the anterior corneal topographic aberrations (Figure 7). Understanding how the aberrations in this profile can influence vision, I feel confident in treating patients with CONTOURA Vision.

Because I have been using CONTOURA Vision for more than 2 years, and we track our outcomes, I am able to individualize patients’ treatment calculations, when needed, based on various criteria. This is the “art” of working with CONTOURA Vision, and it comes with experience. However, for surgeons who are new to the procedure, I recommend following the straightforward calculations given by Alcon, which are based on the company’s most current data. Start simple and straightforward, then advance with more complex treatments as you gain experience and confidence with the technology.

CONTOURA VISION TRAINING AND IMPLEMENTATION

With CONTOURA Vision, there are some additional steps versus standard WAVEFRONT OPTIMIZED LASIK, where we simply enter refractions and two K values into the laser to guide surgery. We are going from using 2 K values to 22,000 to achieve our better results. Our technicians have to take quality, reproducible images, and surgeons have to take a more in-depth look at the corneal topographic irregularities. Once we began using this approach in my practice, my staff and I quickly became confident, and now it adds only a little extra time. But that extra time and effort are worth it in my practice, because

THE ALCON TRAINER SPENT A FULL WORKDAY WITH OUR TECHNICIANS, TRAINING THEM TO CAPTURE AND ANALYZE SCANS, OBSERVING THEIR WORK WITH PATIENTS, AND ANSWERING QUESTIONS.

better outcomes with higher quality of vision leads to happier patients and more referrals. We take pride that we are offering excellent refractive treatments for our patients. It is how we separate ourselves in a competitive market.

Like any paradigm shifting technology, CONTOURA Vision required a period of transition. The Alcon team trained our surgeons and staff very thoroughly and conveniently. The Alcon trainer spent a full workday with our technicians, training them to capture and analyze scans, observing their work with patients, and answering questions. Next, Alcon practiced surgical planning for CONTOURA Vision procedures with our surgeons, and they were there on surgery day to make sure everything went smoothly. The trainers are available to answer questions, visit additional surgery days, or do refresher training for technicians and new staff. The instruction and support helped us implement the CONTOURA Vision measurement process and procedure very quickly and confidently.

After just a few weeks of practice, CONTOURA Vision did not have a major impact on patient flow at the clinic or surgery center. Because CONTOURA Vision is a practice differentiator, Alcon has also given us some pointers so we could position ourselves to turn patient satisfaction into referrals for the procedure. CONTOURA Vision helps us deliver a game-changing procedure that reduces side effects commonly associated with LASIK, and we want patients in our community to know that we offer those advantages.

1. Stulting RD, Fant BS, The 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;42:11–18.
2. At 12 months: Summary of safety and effectiveness data, WaveLight ALLEGRETTO WAVE Eye-Q Excimer Laser System and the ALLEGRO Topolyzer. September 27, 2013. Available online: http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020050S012b.pdf

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

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

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

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

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

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

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

- are pregnant or nursing;
- have a diagnosed collagen vascular, autoimmune or immunodeficiency disease;
- have been diagnosed with 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 mm Hg;
- 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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