Selecting Candidates for CONTOURA Vision, Topography-Guided LASIK

Five experienced surgeons discuss indications, as well as their own recommendations for early cases as surgeons adopt CONTOURA Vision.

This is CONTOURA Vision topography-guided ablation. Can you talk about how topographies help you identify candidates for CONTOURA Vision? Does that differ at all from wavefront candidates?

Kerry D. Solomon, MD: Because CONTOURA Vision addresses corneal irregularities instead of the collective aberrations neutralized by wavefront, it is an excellent option when it is difficult to acquire wavefront measurements, but topography is accurate and shows significant corneal aberrations. After surgery, these patients can have clear corneas, in addition to fewer induced aberrations, uncorrected distance vision better than best spectacle-corrected vision before surgery, and improved visual symptoms.

Daniel S. Durrie, MD: I would say that the best candidates for CONTOURA Vision are patients for whom you can get absolutely perfect topography. That is where you want to start. Patients who have a prominent brow or nose obstructing the reflection and preventing you from acquiring the data are not good candidates for CONTOURA Vision. You want to be very careful to make sure that the measurements guiding the procedure are highly accurate—if not, I imagine the outcomes could be equally problematic. As they say, “garbage in, garbage out.” However, if we use CONTOURA Vision on label, with healthy, nondry eyes, the data show that our patients will do extremely well.

Ronald R. Krueger, MD: I agree. If we make sure to acquire accurate data before surgery, then, in my experience, we will get good outcomes comparable to or better than the clinical study. Surgeons see the clinical study results and get excited about this procedure. It shows at 1 year that 93% of eyes achieved 20/20 or better UCVA, with nearly two-thirds seeing 20/16 and one-third seeing 20/12.5. Also, more than 30% gained one or more lines of UCVA compared to their best preoperative acuity. If we want to get outcomes like those achieved in the clinical study, we need to follow the same guidelines, which include meticulous topographies, multiple images (at least four to eight per eye), and good coordination of data.

I think that surgeons who are new to CONTOURA Vision should...
look for previously untreated eyes that have mildly irregular topographies with consistent refractive and topographic astigmatism. Those will be perfect cases, where the small topographic irregularities can be treated to achieve the best possible vision.

If a patient is in the indicated range of myopia astigmatism and has highly accurate topography, what additional characteristics should surgeons seek or avoid in a potential CONTOURA Vision candidate?

Dr. Stonecipher: One thing we noted when we evaluated patients for CONTOURA Vision is that a typical dry eye patient may be harder to measure. In fact, you may not be able to get a good topography for these patients, which disqualifies them from the procedure. We cannot base a procedure on inaccurate measurements. Like Dr. Durrie, I think that deep-set eyes also present a challenge for topography, making them another disqualifying factor for some patients. I just explain that I cannot get a good measurement and why, and we choose another option.

Dr. Krueger: Like Dr. Stonecipher, I consider ocular surface disease to be an important factor, which can either contraindicate the procedure or lead to preoperative treatment so as to get the most accurate topographic measurements. The resulting accurate topographies ultimately lead to the best results.


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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 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 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 catactarct;
- 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) antimalabsites.

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;

The WaveLight® Excimer Laser System clinical studies, there were several subjects with cylinder amounts ≥ 4.0 D and ≤ 6.0 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 trial, two adverse events were reported.

The first event involved a patient who postoperatively was subject to blunt trauma to the treatable 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). 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 93.1%. 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, 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 Hyperopia:** 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 93.1%. 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, 94.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. 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 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: 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 (4% vs. 3% 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 kerectomy, 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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