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January 2016

Right Patients, Exceptional Outcomes[1]

With Topography-Guided LASIK Custom Treatments

Adoption Strategies and Patient Selection With Topography-Guided LASIK

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One of the most important things to remember when discussing the topography-guided LASIK custom treatment procedure on the WaveLight Excimer Systems (Alcon) is that there is no such thing as a "normal" topography-guided refractive surgery procedure.

In my experience, delivering successful topography-guided LASIK custom treatments requires a detailed knowledge of the technology, the physicians' personal involvement in the patient's evaluation and treatment from start to finish, and the acquisition of pristine topographic images.

DETAILED KNOWLEDGE OF TOPOGRAPHY

Because topography-guided LASIK custom treatments are created from the patient's own topographic data, surgeons must have a solid understanding of how to capture high-quality images with the WaveLight Topolyzer VARIO (Alcon). Then, they must know what to look for on those topographic images in order to build a customized treatment plan for the patient. Furthermore, the WaveLight Topolyzer VARIO includes software for conducting pupilometry, something that many topography units lack and with which surgeons may need to familiarize themselves.

PERSONAL INVOLVEMENT IN EVALUATION AND TREATMENT FROM START TO FINISH

Topography-guided LASIK custom treatments require the surgeon to personally plan and execute the treatment, because its successful execution depends on the accuracy of the topographic examination and image capture. The WaveLight Topolyzer VARIO must be able to capture at least 70% of the corneal surface and 100% of the imaged pupil in order for the surgeon to successfully execute the procedure. Therefore, when capturing the patient's initial topographic image, surgeons must be careful to guard against centering errors, inadequate coverage, issues with pupil tracking or mires recognition, and shadows from the eyelashes or nose that will degrade the quality of the map. Because this information is gathered in analog form, it must be accurate before it is digitized, compressed, and transferred onto the computer.

THE SURGEON'S ACQUISITION OF HIGH-QUALITY TOPOGRAPHIC IMAGES

Because of the high-quality topography maps necessary to perform topography-guided LASIK custom treatments, surgeons may have to take a few extra steps that are not necessary with standard topographical screening tests. He or she may have to place a speculum or tape the eyelids away from the visual field. In some cases, long eyelashes may need to be trimmed. The patient must be looking directly at the fixation target to capture a good Topolyzer VARIO map, although the surgeon may need to decenter the head position so that the nose is farther away. It is also important that the mires are clear and well defined.

The goal is to capture a reproducible topographical image of the corneal irregularity. In the FDA clinical trial of the topography-guided LASIK custom treatments, we investigators used four acceptable topographic pictures. We ensured that the pupil accurately identified and tracked 360°. We also checked to make sure the mires were as crisp and clear as possible.

Even with the best methodology, however, screening failures can occur. There are some patients for whom the surgeon may not be able to acquire adequate diagnostic information to qualify the patient for the topography-guided LASIK custom treatments. Individuals with irregular corneas, small optical zones, ectasia, or early keratoconus need to be informed that they may need more than one topography-guided LASIK custom treatment. Preoperative education is necessary so that patients understand the process of trying to restore visual function to an abnormal cornea and do not expect same-day results like normal LASIK recipients enjoy.

THE DECISION TO TREAT

Once the surgeon is able to capture reliable, high-quality topographic images, the he or she can determine a treatment plan and decide whether there is adequate tissue to perform LASIK versus PRK. This, too, is a surgical decision that requires the surgeon's active involvement. Surgeons who cannot commit their time to topography-guided LASIK custom treatments may not be the best candidates for using this technology.

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BENNET CHOTINER, MD

CASE STUDIES

Case 1

In 2009, our office manager (female, age 37) asked to undergo a topography-guided LASIK custom treatment because she was impressed by the outcomes she was seeing in our study patients. Preoperatively, she had -5.50 D of sphere in the right eye with a BCVA of 20/20 with spectacles, and 20/20 UCVA in the left eye (Figure 1). After my staff and I performed the topography-guided

Please see page 4 for important product information.

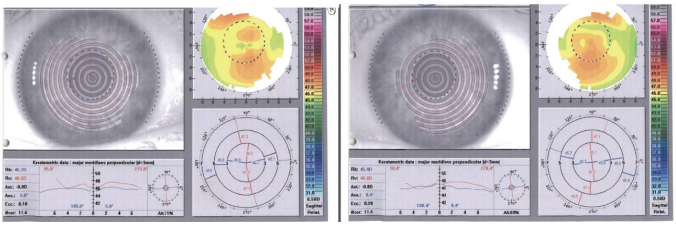

Figure 1. Case 1: Right and left eyes preoperatively; November 2009.

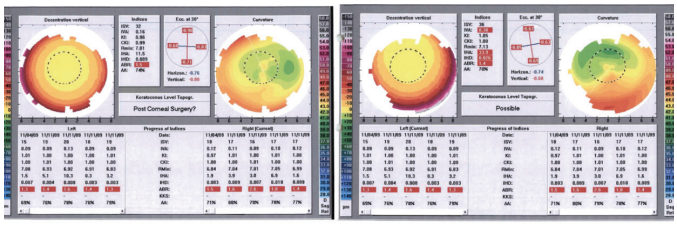

Figure 2. Case 1: Right and left eyes postoperatively; October 2010.

LASIK custom treatment in the patient's right eye, its refraction was -0.25 +0.25 x 180, which gave her a UCVA of 20/20 +2 (Figure 2). The left eye after treatment was -0.25 +0.25 x 015, for a final acuity of 20/20 +1. She prefers the vision in the right eye, which received the topography-guided LASIK custom treatment.

Case 2

A 31-year-old high astigmat presented with a preoperative refraction of -8.75 0.25 x 135, BCVA of 20/20 in the left eye, and -9.00 +0.50 x 060 in the right eye, giving her a BCVA of 20/20 (Figure 3). The right eye received the topography-guided LASIK custom treatment. Postoperatively, her UCVA was 20/15+ in the right eye and 20/16 in the left (Figure 4).

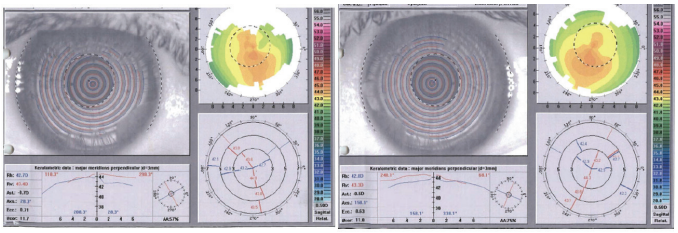

Figure 3. Case 2: Right and left eyes preoperatively; January 2010.

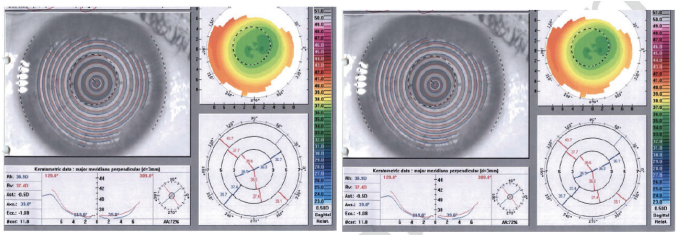

Figure 4. Case 2: Right and left eyes postoperatively; January 2011.

Bennet Chotiner, MD, was a clinical investigator for topography-guided LASIK custom treatments and is the founder and medical director of the Memorial Eye Institute in Harrisburg, PA. Dr. Moore may be reached at (713) 984-9777; crm@texaslasik.com.

1. Summary of Safety and E ectiveness Data. P020050S012d

RONALD KRUEGER, MD

Acquiring Topographic Information

Patients must stop wearing contact lenses before their screening examination, and they should not wear them again before the LASIK surgery. Wearing contact lenses can change the shape of the cornea and affect the surgery's outcome. The length of time to remove contact lenses before the screening examination depends on the type of lenses the patient is wearing (Table).

Type of Contact Lens	Minimum time to stop wearing before screening
Soft	3 days or longer
Rigid gas permeable	3 weeks or longer

Patients who currently wear contact lenses or have worn them in the past few months will be required to complete one or more additional screening visits to assess their eyes' stability for surgery. Unstable eyes are not good candidates for topography-guided LASIK custom treatments. As part of the screening tests, physicians should capture the following:

- Visual acuity
- Manifest refraction and cycloplegic refraction
- Topography, keratometry, aberrometry, pachymetry
- Intraocular pressure (IOP)
- Slit-lamp examination
- Pupil size
- Dilated funduscopic examination
- Contrast sensitivity and low-contrast acuity

Surgeons should obtain a minimum of four (4) topography images for each eye with the ALLEGRETTO Topolyzer, which will be used to create a treatment plan. In addition to the tests and measurements discussed above, others may be required based on the patient's anatomy.

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TOPOGRAPHY-GUIDED REFRACTIVE SURGERY

Topography-Guided LASIK Custom Treatments With the WaveLight Excimer Systems

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 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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