Right Patients, Exceptional Outcomes
With Topography-Guided LASIK Custom Treatments
Adoption Strategies and Patient Selection With Topography-Guided LASIK

BY CHARLES R. MOORE, MD, AND BENNET CHOTINER, MD

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.

Charles R. Moore, MD, is a paid consultant for Alcon and was a clinical investigator for topography-guided LASIK custom treatments. Dr. Moore may be reached at (713) 984-9777; crm@texaslasik.com.

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
TOPOGRAPHY-GUIDED REFRACTIVE SURGERY
Topography-Guided LASIK Custom Treatments With the WaveLight Excimer Systems

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).

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.

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.

Ronald Krueger, MD, is a paid consultant for Alcon and the medical director of the Department of Refractive Surgery at the Cole Eye Institute of the Cleveland Clinic Foundation in Cleveland. Dr. Krueger may be reached at (216) 444-8158; krueger@ccf.org.

Table 1: Summary of Safety and Efficacy Data

<table>
<thead>
<tr>
<th>Type of Contact Lens</th>
<th>Minimum time to stop wearing before screening</th>
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</thead>
<tbody>
<tr>
<td>Soft</td>
<td>3 days or longer</td>
</tr>
<tr>
<td>Rigid gas permeable</td>
<td>3 weeks or longer</td>
</tr>
</tbody>
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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).

1. Summary of Safety and Efficacy Data. P020050S012d
Important Product Information about the WaveLight® Excimer Laser System

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRO, the WaveLight® ALLEGRO Topozer™, and the WaveLight® EX500.

Caution: Federal (U.S.) law restricts this WaveLight® Excimer Laser System to sale by or on the order of a physician. Only practitioners who have been appropriately experienced in the performance of 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 for the performance of laser-assisted in situ keratomileusis (LASIK) procedures 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 myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane;
- the wavefront-guided elimination of myopia of up to -7.00 D and up to 3.00 D of astigmatism at the spectacle plane;
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In addition, FDA has approved the WaveLight® ALLEGRO Topozer™ Eye-Q Excimer Laser System, when used with the WaveLight® ALLEGRO Topozer™ and the WaveLight® EX500.

Topography-Guided LASIK Custom Treatments With the WaveLight® Excimer Systems

In addition, safety and effectiveness of the WaveLight® Excimer Laser System, including the WaveLight® ALLEGRO, the WaveLight® ALLEGRO Topozer™, and the WaveLight® EX500, were confirmed in the following long-term follow-up studies:

- Wavefront-Guided Myopia: The wavefront-guided myopia clinical study included 374 treated eyes, of which 290 were eligible for 12 months. Accountability of 112 was 96.4%, and at 3 months was 96.6%, and at 6 months was 96.9%.
- Wavefront-Guided Hyperopia: In the Wavefront-Guided Hyperopia study, 188 treated eyes were followed for 12 months. Accountability of 184 was 99.7%, and at 3 months was 94.6%, and at 3 months was 94.6%, and at 6 months was 94.6%.
- Wavefront-Guided Mixed Astigmatism: In the Wavefront-Guided Mixed Astigmatism study, 162 treated eyes were followed for 12 months. Accountability of 155 was 95.1%, and at 3 months was 95.2%, and at 12 months was 95.2%.
- Wavefront-Guided Mixed Astigmatism: The wavefront-guided myopia clinical study included 249 treated eyes, of which 230 were followed for 12 months. Accountability at 1 month was 99.2%, at 3 months was 98.0%, and at 12 months was 99.2%. Of the 247 that were eligible for the UCVA analysis at the 3-months stability time point, 99.2% were corrected to 20/20 or better, and 98.8% were corrected to 20/20 or better.
- Wavefront-Guided Mixed Astigmatism: In the Wavefront-Guided Mixed Astigmatism study, 162 treated eyes were followed for 12 months. Accountability of 155 was 95.1%, and at 3 months was 95.2%, and at 12 months was 95.2%.
- Wavefront-Guided Mixed Astigmatism: The wavefront-guided myopia clinical study included 249 treated eyes, of which 230 were followed for 12 months. Accountability at 1 month was 99.2%, at 3 months was 98.0%, and at 12 months was 99.2%. Of the 247 that were eligible for the UCVA analysis at the 3-months stability time point, 99.2% were corrected to 20/20 or better, and 98.8% were corrected to 20/20 or better.
- Wavefront-Guided Mixed Astigmatism: In the Wavefront-Guided Mixed Astigmatism study, 162 treated eyes were followed for 12 months. Accountability of 155 was 95.1%, and at 3 months was 95.2%, and at 12 months was 95.2%.

Adverse Events and Complications

Topography-Guided LASIK. In the Wavefront-Guided LASIK study, there were 559 treated eyes, and 500 were eligible for 6 months. Of the 500 eligible eyes, 436 were followed for 6 months. There were 82 adverse events reported in 71 eyes, with an incidence of at least 5% at 3 months or later after surgery. The most common adverse events were:

- Dryness (11 of 500 treated eyes, 2.2%); visual symptoms including halos, glare from bright lights (3.0%); discomfort (3.4%); blurred vision (3.4%); glare (3.0%); dryness of the eye (3.0%); and light sensitivity (3.0%).
- Subjective complaints of inability to drive (2.4%); difficulty with night vision (2.4%); glare (2.4%); halos (2.4%); glare from the lights (2.4%); and light sensitivity (2.4%).
- One subject suffered from decreased vision in the treated eye, follow-up astigmatism, ocular disease, previous corneal or intraocular surgery, progressive myopia, hyperopia, astigmatism and/or mixed astigmatism; or a history of Herpes simplex or Herpes zoster keratitis; or have a diagnosed collagen vascular, autoimmune or immunodeficiency disease; or have uncontrolled diabetes.
- The complications were reported 6 months after LASIK: 0.9% (7/788) had ghosting or double images in the operative eye; 0.1% (1/186) had a corneal epithelial defect. Hyperopia. In the hyperopia clinical study, 0.5% (1/186) of the eyes had a retinal detachment or retinal vascular abnormality 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 epithelial.

Long term risks of wavefront-guided LASIK for myopia with and without astigmatism, and with and without astigmatism have not been studied beyond 12 months. Information for Patients: Topography-Guided Myopia. The wavefront-guided myopia clinical study included 901 treated eyes, 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 95.2%. Of the 812 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 93.3% were corrected to 20/40 or better, and 98.9% were corrected to 20/20 or better.

Attention: Please refer to the current WaveLight® Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects. * Trademarks are property of their respective owners.