The procedure achieved a 98.4% satisfaction rate in the clinical trial.¹
Successful Planning With Topography-Guided LASIK Custom Treatments

BY R. DOYLE STULTING, MD, PhD, AND DAVID W. FRIESS, OD, FAAO

Topography-guided LASIK custom treatments (Alcon) incorporate corneal higher-order aberrations using the preoperative topography, so topography acquisition has to be accurate. Accurate topographic maps are achieved through carefully acquiring and reviewing the images obtained and then comparing those images to each other to make sure their findings are consistent (Figure 1). The investigators in the clinical trials of topography-guided LASIK custom treatments were required to obtain at least four consistent topographic images within a minimum-sized coverage area for each patient. Incorporating several image acquisition techniques and screening methods into planning for topography-guided LASIK custom treatments is recommended to help ensure the most accurate patient outcomes.

SCREENING METHODOLOGY

Obtaining accurate maps can sometimes be challenging, either because the orbital or facial structure makes imaging difficult (e.g., deep-set eyes), or because the tear film is not stable. Eyes with marginal dryness and tear-film breakup can produce artifactual information in topographic mapping.

Screen Failure

In the clinical trial for topography-guided LASIK custom treatments, screen failure referred to individuals who did not meet the inclusion criteria for the study. These clinical study subject enrollment criteria are described in the safety and effectiveness portion of the study results.

WHEN TO PERFORM TOPOGRAPHY-GUIDED LASIK CUSTOM TREATMENTS VERSUS WAVEFRONT-GUIDED PROCEDURES

From the clinical findings of the prior FDA study, Table 1 illustrates the efficacy of Wavefront-Optimized and wavefront-guided corneal ablations in terms of the amount of higher-order aberrations (see the vertical axis of the chart). The horizontal axis shows the amount of attempted correction. The findings demonstrate that Wavefront-Optimized treatments work better for lower degrees of higher-order aberrations and higher degrees of refractive error. As described previously, wavefront-guided treatments can create a certain amount of noise, or variabilities within the final refraction. If the cornea has a lot of higher-order aberrations, then the noise becomes minimal compared to the benefit of the treatment. If a cornea contains minimal higher-order aberrations, then the noise becomes large compared to the benefit gained from the treatment. This is why Wavefront-Optimized treatments are more beneficial for lower amounts of higher-order aberrations. The same is true for the amount of myopia. With high degrees of myopia, the noise generated by a wavefront-guided treatment is high compared to the benefit it imparts, versus a Wavefront-Optimized treatment, which is based on a simple refraction and creates less noise.
Based upon the clinical study, properly screened eyes within the approved treatment range are expected to benefit from a personalized topography-guided LASIK custom treatment while adhering to the methods used during the study. Topography-guided LASIK custom treatments do require significantly more planning than Wavefront-Optimized procedures and attention to diagnostic topographic scans.

**CAPTURE ERRORS**

Errors in the capturing of topographic data can include inadequate coverage and problems with pupil tracking and mire recognition. The software draws a line where it identifies the pupil’s border, and sometimes, it does not correctly recognize the margins of the pupil or the edge of the Placido mires. Figure 1 demonstrates inadequate coverage due to interference from a patient’s eyelid. Improvements that have been made to the software since the clinical study can help this process, but it is important for surgeons to review the topographic images and pupil recognition to ensure accuracy. Incorrect images must be thrown out and repeated. Also, patient fixation can be a source of error when patients do not sight perfectly under the eyepiece of the topographer.

**SELECTION CRITERIA FOR ADEQUATE TOPOGRAPHIC IMAGES**

Investigators in the clinical trial of topography-guided LASIK custom treatments used general criteria to review and evaluate captured Topolyzer images (Figure 2) for adequate Placido ring (mires) quality and data prior to image selection and export. These criteria were developed from prior international experience with the procedure and included:

1. **Analyzed Area**: ≥ 68% unless due to peripheral ring artifact.
2. **Coverage**: Measuring from the center of the pupil, there should be at least 3 mm of ring coverage in all directions that is free of artifacts and has only minor ring breaks.
3. **Rings**: Rings should be regular with minimal breaks.
4. **Pupil Tracking**: Ensure that the software accurately identifies the pupil border.
5. **Pupil Diameter/Shape**: Evaluate the pupil’s shape and diameter for consistency among selected topographic maps (Figure 3).
6. **Repeatability**: A difference map of the selected topographies should be performed, and there should be ≤ 1.00 D of difference within the area of the pupil diameter among the selected topographic elevation maps (Figure 4).

**ERRORS IN TREATMENT AND REFRACTIVE CORRECTION**

In the clinical study, no treatment delivery errors were detected specific to the topography-guided LASIK custom treatments of the ALLEGRETTO WAVE laser. Of course, as with any laser treatment, it is possible for surgeons to make errors in treatment and refractive correction. In the clinical study, no treatment delivery errors were detected specific to the topography-guided LASIK custom treatments of the ALLEGRETTO WAVE laser. Of course, as with any laser treatment, it is possible for surgeons to make

**TABLE 1. WFO/WFG PATIENT SELECTION BASED ON PREOPERATIVE HIGHER-ORDER ABERRATIONS (HOAs)**

<table>
<thead>
<tr>
<th>Preop RMSH</th>
<th>Treatment Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.2 µ</td>
<td>WG/WO</td>
</tr>
<tr>
<td>0.2 – 0.3 µ</td>
<td>WG/WO</td>
</tr>
<tr>
<td>0.3 – 0.4 µ</td>
<td>WG</td>
</tr>
<tr>
<td>&gt; 0.4 µ</td>
<td>WG</td>
</tr>
</tbody>
</table>

Table 1. Treatment recommendations based on preoperative spheroequivalent and RMSH values. (WG = Wavefront-Guided LASIK; WO = Wavefront-Optimized LASIK; WG/WO = both equally safe and effective).
Important Product Information about the WaveLight® Excimer Laser Systems

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRO Topolyzer®, the ALLEGRO WAVE®, and the ALLEGRETTO WAVE® Eye-Q Excimer Laser. Dr. Friess may be reached at dwfriess@wolffeye.com.

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

TOPOGRAPHY-GUIDED REFRACTIVE SURGERY

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Treatment refraction error entries, but following sound protocols for surgery planning should help minimize these errors.

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TOPOGRAPHY-GUIDED REFRACTIVE SURGERY

Summary of Safety and Effectiveness Data: WaveLight® WVL15012JS-B

Attention:

- Long term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

- Long term risks of LASIK for hyperopia without and with astigmatism have not been studied beyond 12 months.

- Long term risks of LASIK for mixed astigmatism clinical study included 162 eyes, 103 of which were followed for 6 months and 14 of which were followed for 12 months.

- The mean preoperative cylinder was 3.78 D and the mean postoperative cylinder was 1.81 D at 12 months post-treatment.

- The following complications were reported after wavefront-guided LASIK: 0.2% (2/876) of the eyes had a lost, misplaced, or mislabeled flap reported at the 3-month examination.

- In addition, FDA has approved the WaveLight® ALLEGRO WAVE® Logo-Q Excimer Laser System. Only practitioners of the topography-guided LASIK treatment and may result in poor vision.

- Mixed Astigmatism: In the mixed astigmatism clinical study, the mean postoperative cylinder was 2.32 D at 12 months post-treatment.

- Hyperopia: The hyperopia clinical study included 374 eyes treated, 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). In the Study Cohort, the mean postoperative cylinder was 0.57 D at 12 months post-treatment. In the Control Cohort, the mean postoperative cylinder was 0.99 D at 12 months post-treatment.

- Myopia: In the myopia clinical study, the mean postoperative cylinder was 0.71 D at 12 months post-treatment.

- Mixed Astigmatism: In the mixed astigmatism clinical study, the mean postoperative cylinder was 1.63 D at 12 months post-treatment.

- Hyperopia: The hyperopia clinical study included 374 eyes treated, 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). In the Study Cohort, the mean postoperative cylinder was 0.57 D at 12 months post-treatment. In the Control Cohort, the mean postoperative cylinder was 0.99 D at 12 months post-treatment.