Moving from Rx to measured

Exciting new learnings for Contoura Vision treatment results. How to calculate surgical treatment using the Vario measurement information!
Vario Data: After receiving the height data from the Topolyzer Vario (a device that is specifically selected to provide benchmark performance in centration and resolution in topography measurements), the Contoura Vision topography-guided ablation design begins with the calculation of the reference body. The median of the flat meridian (although both keratometry values are displayed at the planning screen of the WaveLight EX500) is used to shape the reference body. Additionally, the asphericity of the dataset imported is determined and used. If various datasets are imported, the median calculation will only include exams of the same day.

The actual corneal shape is now fitted to the reference body. Differences in this calculated reference body are analyzed by a proprietary algorithm based on Zernike polynomials used for the later ablation profile calculation, and the difference of radii of the main meridians are translated to C3 and C5 polynomial amplitudes.

Exams containing at least 90% or more data within the optical zone will be activated by the algorithm and will be used for the reference body median calculation. To include exams containing less than 90% of data points, the user may reduce the optical zone (e.g., from 6.5 mm to 6.0 mm). This decrease of optical zone will potentially result in surpassing the 90% criterion and will allow Contoura Vision surgery for patients where patients' anatomy might shadow the Placido ring projection.

If desired, at this stage, the asphericity used for fitting the reference body can be modified. However, modifying the asphericity will affect the spherical aberration and potentially the achieved spherical correction.

To eliminate obvious outliers, the general visual impression of the individual exams, but also some ancillary criteria such as the keratometry and its axis, the asphericity, and with lower importance the pupil-size, can be used as criteria to identify outliers.

Overview of imported exams
Advanced Eye-Tracker options for the later treatment will only be available if an exam with good forecast status indication (✓) is used. At this stage, the software will select one infrared image from the dataset, and that image will be marked with an asterisk (*). This identified infrared image is the closest to the median of the selected dataset imported. The image chosen may also be of red forecast status (✗) (registration not possible); therefore, it is important to only export infrared images with a green forecast status if registration is desired or indicated.

The imported examinations and the resulting Examination Profile can be displayed in various maps:
Getting the most out of the Vario algorithm

by Sissimos Lemonis

After entering the subjective refraction and other required information, the ablation profile is displayed.

Treatment Planning Pearls: The parameters for treatment planning include the following:
• The line “Clinical Refraction” displays the entered subjective refraction Vertex Distance (VD).
• The line “Measured Refraction” is the refraction calculated by the Contoura Vision algorithm for the chosen optical zone and entered VD.
• The line “Modified Refraction” is the correction for sphere and cylinder (selectable in 0.01-D steps) to be applied to higher-order aberrations (HoAs).
• The optical zone is adjustable in 0.50-mm steps.
• The transition zone is adjustable in 0.25-mm steps.

The ablation profile display assists the surgeon in predicting the residual stroma after ablation by selecting the flap thickness.

Setting the sphere and cylinder (at the modified column) to Plano refraction will expose the ablation profile addressing all corneal irregularities.

The ablation algorithm is based on Zernike polynomials and uses the WaveLight proprietary correction algorithm to compensate for loss of the ablation efficiency towards the periphery. This ablation efficiency correction algorithm is applied for all Zernike polynomials and is based on the preoperative corneal curvature and to the corneal asphericity. This customized addition/reduction of laser energy to compensate for efficiency losses related to the angle of incidence (for every position of the cornea based on the individual preoperative curvature and asphericity) would qualify the topography-guided ablation as a custom treatment, more so than wavefront-guided ablations that don’t consider the true preoperative corneal curvature and asphericity.

The necessary ablation to balance irregularities is calculated automatically and consists of flattening (visible as ablation within the optical zone) and/or steepening (shown as ablation out of the optical zone, similar to hyperopic ablation profiles) elements.

All known customized ablation profiles efficiently correcting HoA will affect sphere and cylinder. The effect to sphere and cylinder will depend on the shape of the related aberration. The following figure demonstrates the effect of spherical aberration on the corrected sphere. In this example, we are demonstrating the C12 value amplitude and compensate the additional flattening/steepeing caused by C12 with spherical correction (c4) (while sphere and cylinder both have been set to Plano refraction previously). In doing so, the resulting ablation profile is assumed to be sphere correction neutral.

To estimate the amount of spherical compensation needed to neutralize the applied ablation profile, the C4 value is brought close to the C12 value (Zernike button).
The result of the spherical compensation could now be added to target spherical correction and to any eventual individual nomogram adjustment applied.

Astigmatism management: To understand Contoura Vision guided ablations, the forecast of the effect of a Contoura Vision ablation without any correction for sphere and astigmatism would result in a corneal shape that corresponds to the reference body and the selected corneal asphericity (within the selected optical zone). Because the astigmatism was not corrected, the expected appearance of the postoperative astigmatism is predicted to be symmetric. This would suggest that the correction of this astigmatism with glasses would now be possible for all categories of preoperative irregular asymmetrical astigmatism. Ideally, the predicted power and axis should in this case (where only sphere and HoA aberrations are correct) confirm the measured astigmatism by the Contoura Vision algorithm.

The earlier mentioned projection might lead to the following models of understanding astigmatism correction:

• The contribution of coma-like aberrations to the visual impression of the patient. Keratoconus is well known to be a mostly horizontal-oriented coma aberration (the Contoura vision system is contraindicated for treatment of eyes with keratoconus). However, because of the lack of coma-correcting lenses, patients will instead accept cylinder correction. Coma aberration of considerable amplitude might interfere with both the power and axis of the subjective astigmatism accepted by the patient. Following is an example of a patient with an obvious predominant coma-like aberration who accepts astigmatism following the axis of the coma. The patient accepts –0.75 x 88 degrees, while the Fourier display and the Sim Ks don't show any relevant astigmatism. Interestingly, the coma axis (black circles that resemble a pearl necklace) at the Fourier display coincides with the axis selected by the patient.

• The following figures demonstrate the influence of difference of asphericity of the two meridians. The below example depicts regular astigmatism power along the corneal diameter for a spherical cornea for the two main meridians. The distance between the two meridians can be translated to corneal astigmatism. For astigmatism example 1, the distance between the two meridians (blue and red line) is parallel and straight (Example 1 below). In this or similar cases, the patient will experience no changes in astigmatism power during different lighting conditions.

A prolate astigmatic cornea with dissimilar asphericity (Example Astigmatism 3) of the two main meridians depicts varying astigmatic power. In this case, the patient's visual impression and the Contoura Vision algorithm calculated astigmatism will differ for various lighting conditions and optical zones.
Corneas with corneal coma will depict various refractions for the half meridians and might be positive or negative.

- Influence of other HoAs or a combination of aberrations

  Setting the Modified Refraction for cylinder and sphere to plano will depict the HoA ablation profile: Oval-shaped central ablations and, therefore, irregular refraction of the incoming light might equalize for the existing corneal astigmatism and lead to reduced or increased manifest astigmatism power and changing astigmatism perception by the patient. Likewise, an auto-refractometer device (that usually measures the central ray of light) might get biased by the HoA and deliver deviating astigmatism power and axis results.

**Case study: Corneal aberration cancellation of manifest astigmatism**

Preop manifest refraction: –1.50 with BCVA of 20/20
Preop auto-refraction: –2.00
Measured Contoura Vision astigmatism: –0.77 x 121
Postop refraction and vision at 1 week: Plano; 20/15

Conceivable reasons for the discrepancy between corneal and subjective astigmatism:

The lens might accommodate for corneal astigmatism. Wavefront examinations during accommodation showed that the accommodation of the lens can also compensate for astigmatism or generate new HoAs.

Lenticular astigmatism might comprise astigmatism, coma, and higher-order astigmatism. Lenticular astigmatism in conjunction with coma-like aberration might further complicate the situation. Therefore, it is important to locate where the cylinder is originating and conclude the preferred ablation for such seldom-appearing cases.

It is theorized that patients might accept with-the-rule astigmatism better than against-the-rule or oblique astigmatism (neurological interpretation of information). Therefore, it is understandable that some patients may not request full correction for with-the-rule astigmatism but may request against-the-rule astigmatism correction.

The astigmatism correction and axis provided by the topography-guided algorithm calculation (at the measured column) are comprised of Zernike polynomials C3 and C5 only and are not biased by HoAs. With the above-mentioned details and considerations, the ablation profile to be applied is designed and stored.

As a side note, there is a specific advantage of topography-guided ablations when compared to wavefront-guided ablations. The goal of topographic ablations is to target the aberration at their source, which is the anterior surface of the cornea. Consequently, ray-tracing issues as shown below are less likely to appear.

**Performing ablation on the eye**

Therefore, the ablation sequence does not differ from a standard LASK application. The biggest difference is that the treatment is applied on the corneal apex. Consequently, the pupil size during treatment should not differ (too much) from the pupil size during the examination. One needs to consider flap-centration for patients with large angle kappa in order to accommodate the ablation within the flap borders.

Registration requires improvements regarding timing during the procedure and how to fit registration into the routine of the surgeon.
Topographic-guided LASIK is available in the United States as Contoura from Alcon. It is a versatile and powerful new tool for refractive surgery. However, it does require refractive surgeons to rethink their treatment calculations and to consider the patient’s total refractive error in a new way. In the past, LASIK surgeons would simply target the patient’s astigmatic axis and magnitude off the patient’s manifest refraction. As surgeons begin to become more precise and target the small topographic imperfections of the cornea, they must treat the astigmatic axis and magnitude that the advanced Contoura topographer detects. It becomes disconcerting when the Contoura astigmatism differs from the manifest. At this point, the surgeon needs to resist his or her experience-based knowledge and trust the technology, treating measured and not the refraction axis.

This case highlights these issues. The patient is a 23-year-old woman. Pre-LASIK MRx is \(-5.00 \pm 0.50 \times 35\) 20/15. Wavefront PPR is in good agreement with this at \(-4.99 \pm 0.31 \times 34\). However, Contoura is detecting astigmatism along an axis of 10 degrees. (Figure 1). Double checking the Contoura against another topographer, the Orbscan, shows it too detects corneal astigmatism along axis of 10 degrees. (Figures 2 and 3). The surgeon now faces a decision: choose the astigmatic axis based off manifest or measured? Figure 4 shows that there is a 48 degree difference between these two and an 0.62 D difference in magnitude. A lot of difference! Why are they so different? What should be treated?

The answer lies in the influence that the topographic abnormalities have on how light is being focused. The manifest is the optical image as it strikes the retina. It is the sum total of the effects of the smaller topographic abnormalities and the true corneal astigmatism. Figure 5 shows just the topographic correction for this eye after removing the cylinder and sphere from treatment. It is the effect of these smaller topographic abnormalities that “bend” the manifest cylinder away from the true corneal measured astigmatism. Once you remove these abnormalities, the true corneal cylinder measured by Contoura is at 10 degrees. This is the cylinder that should be treated with Contoura topographic LASIK.

By treating all of the corneal abnormalities, vision sharpness and better than normal manifest results can be obtained. It seems to be a leap of faith for the surgeon at first to treat a different axis than manifest refraction but the optical physics here are real and can and should be trusted to gain the best possible results.
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 and with 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 not 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;
• severe dry eye that is unresponsive to treatment;
• 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) antimalabiles.

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;
• 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% (7/781) 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
increased 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).

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 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). 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: 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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