Interview Series

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Perspectives on Vision: A Detailed Look at the Phorcides Analytic Software and the Benefits it Brings to Topography-Guided LASIK

Featuring:

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Introduction

Topography-guided laser-assisted in-situ keratomileusis (LASIK) considers the shape of the anterior corneal surface and uses corneal curvature data from preoperative corneal topography measures. These treatment profiles help reduce higher order aberrations (including spherical aberration) by compensating for cosine effect and by normalizing the overall surface of the cornea. This is done by flattening elevations and relatively steepening flatter areas by ablating around them.

Determining the correct sphere magnitude, cylinder magnitude and cylinder axis for treatment with topography-guided LASIK has been a dilemma among surgeons. With the recent introduction of the Phorcides analytic software, treatment planning can be simplified and the treatment accurately calculated with the exact treatment profile required without further calculations by the surgeon.[1,2]

Mark Lobanoff, MD, Stephen Wexler, MD and Doyle Stulting, MD discuss Phorcides technology and the clinical benefits it brings to topography-guided LASIK.

Mark Lobanoff, MD

North Suburban Eye Specialists,
Minneapolis, MN

What is topography-guided LASIK?

Topography-guided LASIK is treatment based on the unique corneal topography of an individual's eye. It not only treats sphere and cylinder, but also treats corneas differently than any other prior laser refractive technology by essentially smoothing topographical irregularities on the corneal surface. By reducing the surface irregularities and creating a more uniform corneal surface, better vision can be achieved.

How do surgeons complete surgical planning for topography-guided LASIK?

The specific treatment planning approach for topography-guided LASIK is dependent on the laser platform and manufacturer, but all generally use similar clinical data to guide the treatment. For example, the Contoura® Vision platform is a topography-guided LASIK procedure approved in the United States where the following treatment planning approaches have been used: 1) manifest refraction, 2) TMR, 3) 50/50, and 4) Phorcides software. Treatment planning on this platform was originally based solely on the manifest refraction astigmatism; however, this method did not provide optimal results. The topographic irregularities on the cornea contribute to the manifest refraction measured by manual refraction at the phoropter. This means that removal of the topographic irregularities will affect the resulting manifest refraction. By ignoring the refractive effect of eliminating the topographic irregularities, surgeons did not see visual outcomes as good as they expected. Additionally, if the topographic irregularities are large, the astigmatic axis resulting from treating the manifest could result in significant residual errors.[1] A contrasting method, topography-modified refraction (TMR), based treatment on the anterior corneal astigmatism measured by topography, ignoring the manifest refraction.[3] Overall, the results of TMR were better than treating based on the manifest refraction.[4] However, there were cases in which this strategy led to the astigmatic axis being "flipped" after surgery. In other cases, residual astigmatism remained that kept patients from achieving their best vision. Over time, the 50/50 method was developed by Dr. Wexler. This method used 50% of the difference in magnitude between manifest and topography measured along with the axis measured by topography. This method yielded good results and almost never flipped an astigmatic axis. However, it often left behind some untreated astigmatism and thus resulted in some residual refractive errors that reduced the overall uncorrected distance visual acuity (UDVA).

Why was the Phorcides analytic software created?

Given that so many treatment planning methods have been utilized for topography-guided LASIK, it was clear that a more standardized and objective approach was needed – one based on logic, mathematics, and optical physics. And this led to the development of the Phorcides analytic software. Phorcides was created to provide a definitive treatment calculation to make topography-guided LASIK planning easier and more accurate for surgeons.

What is the Phorcides analytic software?

Phorcides is a program that uses geographic imaging software to analyze the anterior topographic profile of an individual's cornea (Figure 1 and 2). It takes into account anterior topographic data from the Placido Disc-based Topolyzer® Vario, along with anterior and posterior corneal astigmatism data from a Scheimpflug topographer. The Phorcides software measures the radius of each topographical feature, or talus, and uses all this information to determine the true anterior corneal astigmatism (Figure 2). The software compiles a series of refractive vectors: one vector for each raised topographic feature on the corneal surface, one for the anterior corneal astigmatism, one for the posterior corneal astigmatism, and one for any internal lenticular astigmatism (Figure 3). Finally, it uses a series of advanced computer algorithms to determine an optimized sphere and cylinder magnitude and orientation for the treatment. Of course, starting with a good manifest refraction and quality topography images are essential for calculating the correct treatment.

Figure 1: Anterior corneal topographic treatment image from the Contoura® Vision planning laptop.

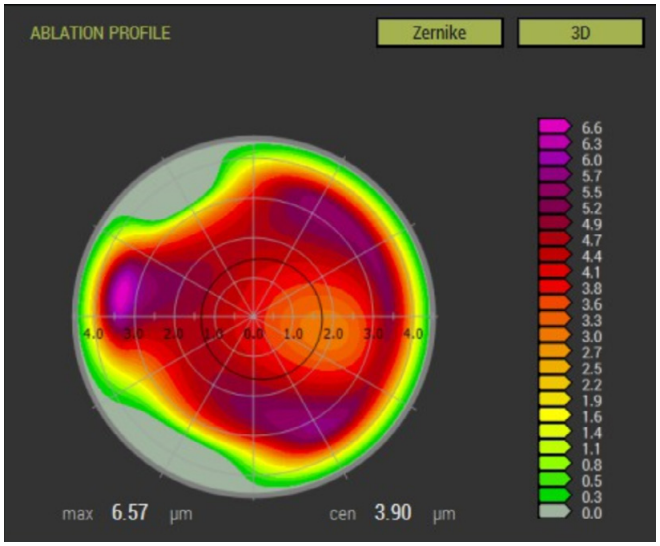


Figure 2: The Phorcides analytic software uses geographic imaging software (GIS) to analyze the corneal topographic treatment image produced by the Contoura® Vision planning laptop. Each talus radius is measured, and its refractive effect is analyzed.

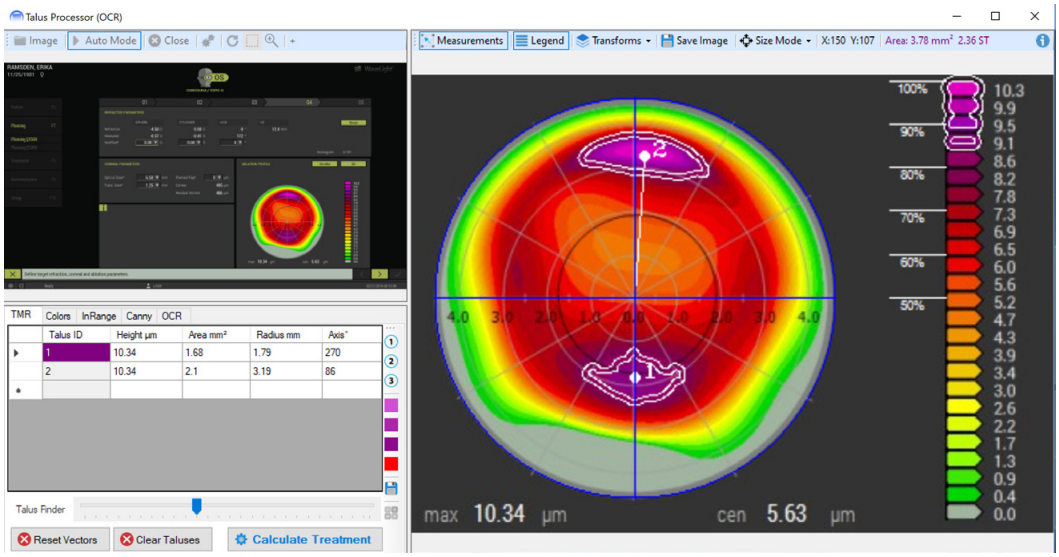
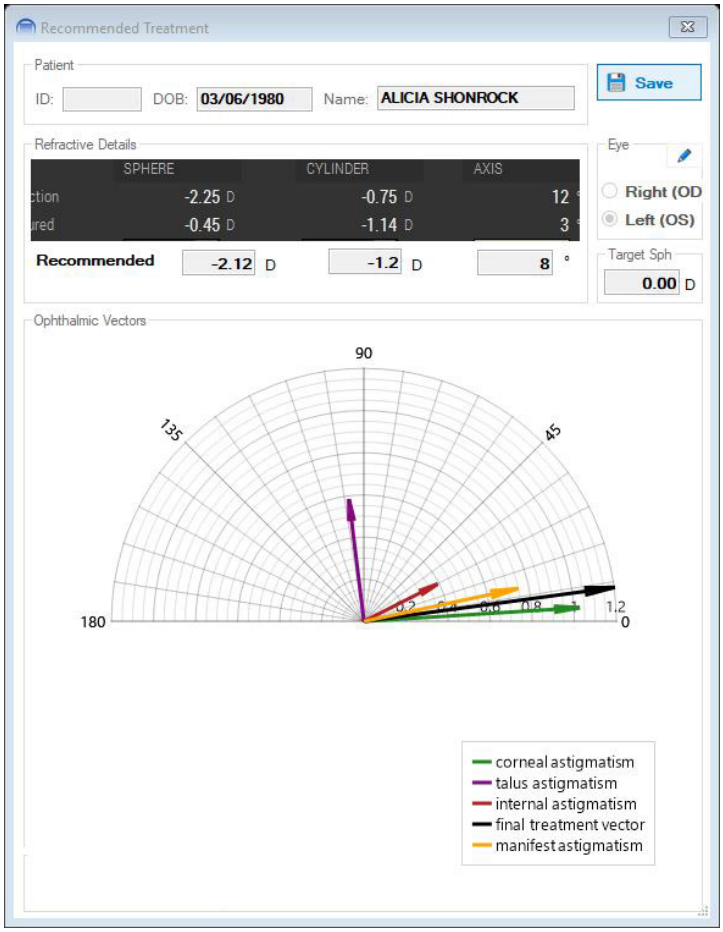


Figure 3: The Phorcides analytic software determines the low-order astigmatic vector created by all sources (anterior cornea, posterior cornea and lenticular) and uses vector addition to calculate the final astigmatic vector.



How does planning topography-guided LASIK treatments with Phorcides software compare to planning treatment with other methods (manifest, TMR, 50 / 50)?

The Phorcides software uses more data and takes the analysis of each eye further than other methods currently allow. For example, none of the other methods currently take into account posterior corneal astigmatism or internal (lenticular) astigmatism the way that Phorcides does. The other methods also do not use a mathematical model to determine the optical effects of removing topographic irregularities from the cornea. Finally, the Phorcides software removes some of the subjective decision-making required by the other methods (i.e. determining the correct balance between manifest and topography cylinder) and allows for a more objective and calculated approach to treatment.

Stephen Wexler, MD
TLC Laser Eye Center,
St Louis, MO

Doyle Stulting, MD
Woolfson Eye Institute,
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How do you decide if topography-guided LASIK is the right treatment for a patient?

Dr. Wexler: I consider using topography-guided LASIK on all my routine refractive surgery patients. My main criterion for using topography-guided LASIK is whether I get good corneal topography measurements or not (Figure 4 and 5). If I get good scans, and Phorcides can calculate a treatment, then I use topography-guided LASIK programmed with Phorcides.

Dr. Stulting: I recommend topography-guided LASIK for all refractive surgery patients that we are able to treat with this technology. There are times when I have to opt for a different treatment (e.g. WFO) such as when the refraction is outside of the FDA approved treatment range for Contoura or when adequate topography scans cannot be obtained. Scans are sometimes difficult in patients with deep-set eyes or difficulty opening their lids. For many of them, these difficulties can be overcome by using an assistant to help with the lids or a change in the position of the head. Ocular surface disease can cause an unstable tear film, which can interfere with the capture of an acceptable corneal topography image (Figure 5). In these cases, it is important to manage the ocular surface disease before performing LASIK.

Figure 4: Example of a good quality image with Topolyzer® Vario.

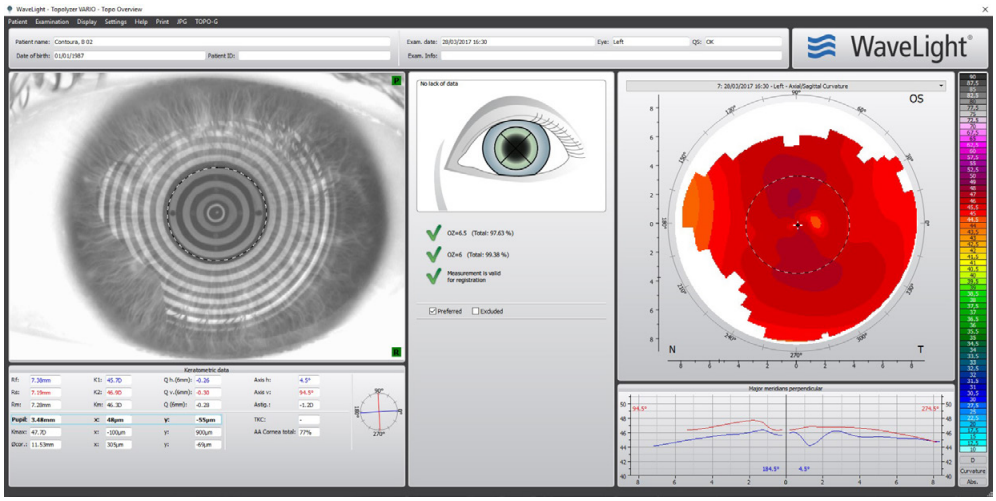
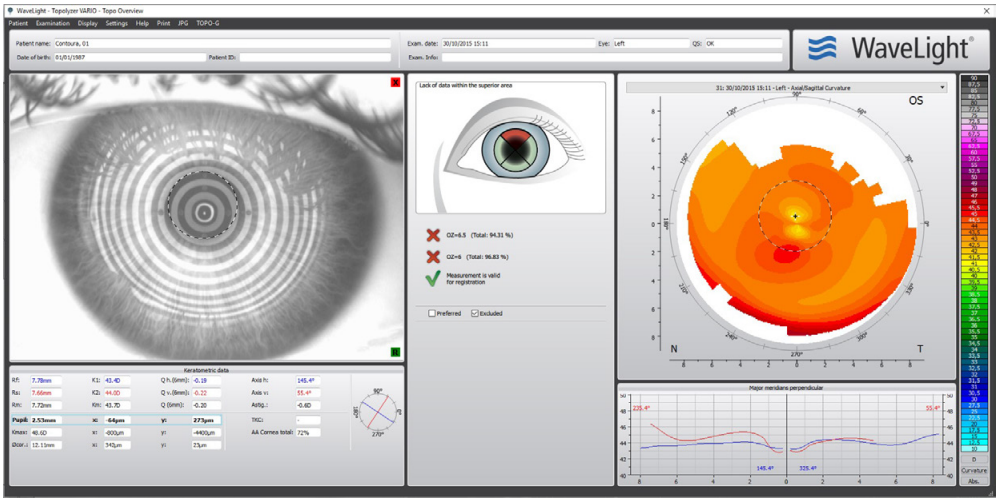


Figure 5: Example of a poor quality image with Topolyzer® Vario due to central dryness and upper lid interference.



How does using the Phorcides software impact your confidence in the final treatment plan for topography-guided LASIK?

Dr. Wexler: It is just impossible to look at a higher order aberration map and know exactly how much influence the irregularities will have on the treatment, and I used to struggle with how to incorporate these into the treatment plan. Before Phorcides, I often used a combination of manifest cylinder and corneal cylinder but never really knew if it would be the optimal treatment amount, particularly when there were large disparities between the manifest- and topography-measured astigmatism. Phorcides takes the guesswork out of topography-guided LASIK treatment planning. I am much more confident now with the definitive calculation that it provides! One of the great things about using Phorcides is that we rarely see a flipped axis anymore, whereas we used to see it on occasion with manifest refraction and TMR.

Dr. Stulting: Treatment with topography-guided LASIK is state-of-the-art, but Phorcides takes us a step beyond what manifest and topography measured treatment planning can offer. Phorcides not only takes into account the effect of localized aberrations in the anterior topography, but also the posterior corneal surface. It allows calculation and incorporation of internal astigmatism into the treatment plan. This allows for an accurate determination of the low-order astigmatism magnitude and axis needed for treatment planning. With this, I am much more confident that the final calculated result will be the optimal treatment and give my patients the best possible visual outcome.

What are the differences between the Phorcides analytic software and other nomograms?

Dr. Wexler: Phorcides is different than a nomogram in that it provides a calculated treatment strictly based on data from that individuals eye rather than averaged data from other patient eyes. I do keep track of all my outcomes on IBRA and have a sophisticated nomogram based on thousands of eyes. While I do use this to adjust sphere and cylinder for wavefront optimized treatments, I don't need to do this for topography-guided LASIK. I can just go with the Phorcides calculated numbers and know that I will get great results. I still alter my target goals based on age, and Phorcides allows me to easily do that.

Dr. Stulting: Nomograms calculate the average result of past treatments, compare it to the desired outcome, and adjust treatments accordingly. These adjustments are based on average outcomes obtained from large databases. Phorcides, on the other hand, makes corrections in the treatment plan based on factors that are characteristic of the individual, rather than database averages. So Phorcides provides an accurate, individualized plan that nomograms alone cannot provide.

What does the clinical data show for Phorcides versus manifest / TMR?

Dr. Wexler: Outcomes are similar and speak to the fact that Contoura® Vision is a very effective treatment. However, we just published a retrospective study that showed a higher percentage of patients achieving postoperative 20/15 by planning with Phorcides, rather than the manifest refraction (Figure 6).[1] That study also showed that more patients gained 1 or more lines of UDVA compared to their preoperative corrected distance visual acuity (CDVA) with Phorcides (Figure 7).

Dr. Stulting: Along with other users of Contoura® Vision, we retrospectively studied the actual and calculated refractive cylinder outcomes of Contoura® Vision programmed with the manifest refraction, topographically measured refraction (TMR), and Phorcides. This study showed that the best outcomes were obtained with Phorcides.[2] A prospective study is currently underway to confirm these findings and analyze subjective quality of vision obtained with Phorcides.

Figure 6: Postoperative uncorrected distance visual acuity (UDVA) by group (n=317 manifest, n=323 Phorcides; p<0.002; X2 test).

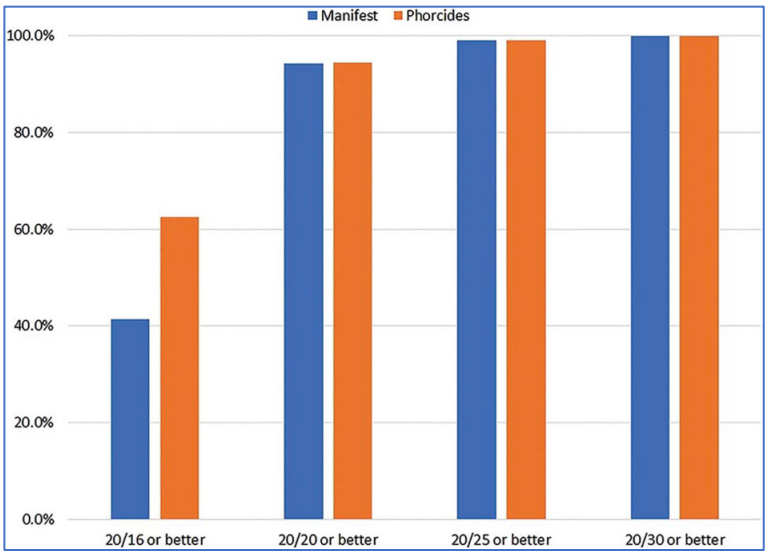
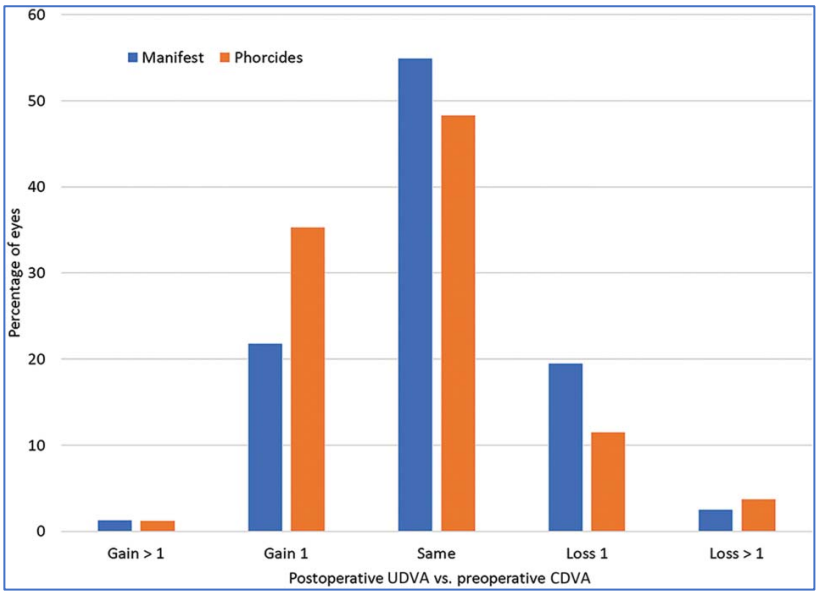


Figure 7: Difference between the postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA) (n=317 manifest, n=323 Phorcides; p<0.002; X2 test).



What does visual acuity data show for Phorcides (or Contoura® Vision in general) versus other treatment options (WFO / WFG)

Dr. Wexler: Wavefront optimized (WFO) and topography-guided LASIK routinely get great results -especially at the 20/20 level. However, there are two large head-to-head studies that showed a higher percentage of patients achieving 20/15 or better with Contoura® Vision versus WFO treatment (Figure 8 & 9).[4,5] Stonecipher (2018)[4] also showed that Contoura® Vision allowed for a higher percentage of both 20/20 and 20/15 or better, compared to wavefront-guided (WFG) treatment (Figure 8).

Dr. Stulting: While WFO generally provides great outcomes, recent studies have shown that more patients can achieve 20/15 or better with Contoura® Vision (Figure 8 & 9).[4,5] The addition of Phorcides makes the treatment even more accurate with higher rates of 20/15 or better (Figure 6).[1]

Figure 8: Postoperative uncorrected distance visual acuity (UDVA) among various treatment types4 (n=27 WFG; n=430 WFO; n=416 Contoura manifest).

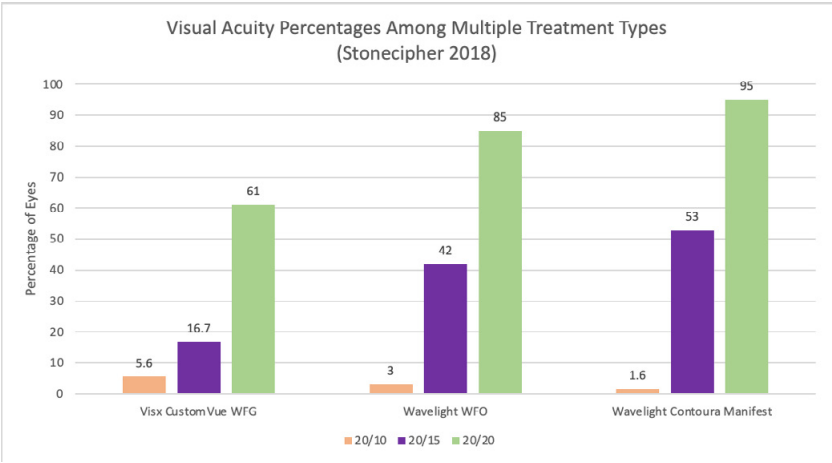
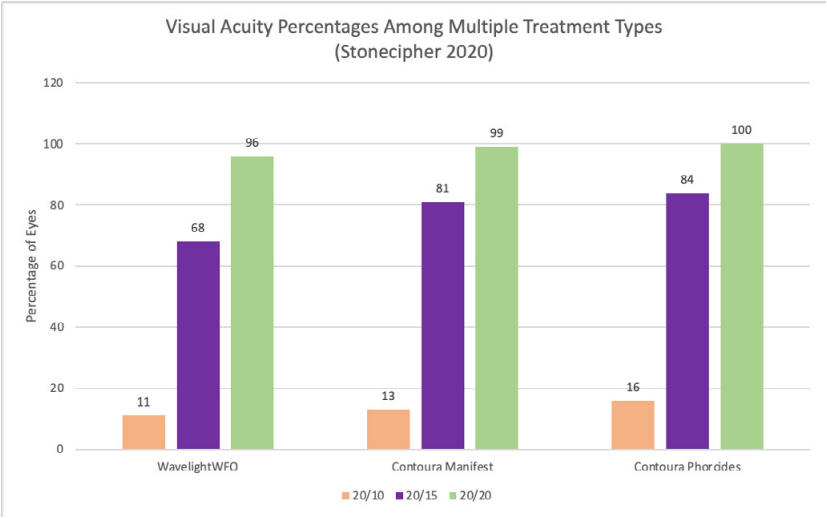


Figure 9: Postoperative uncorrected distance visual acuity (UDVA) among various treatment types5 (n=788 WFO; n=1027 Contoura manifest; n=338 Contoura Phorcides).



Are there any data that show an effect of topography-guided LASIK on ocular aberrations and quality of vision?

Dr. Wexler: There is a large study by Zhang et al (2019)[6] that showed that total higher order aberrations and coma were significantly lower with Wavelight Contoura® Vision vs WFO at 1 and 6 months postoperatively ($p<0.05$). There are several other smaller studies with similar findings,[7–9] but more research is needed in this area.

Dr. Stulting: The FDA study for Contoura® Vision showed a reduction in total RMS magnitude for 2nd through 5th order corneal aberrations which reflects the overall effect of topography-guided LASIK on corneal irregularities. This study also showed that pre-op visual symptoms of light sensitivity, difficulty with night driving, reading difficulty and glare, significantly improved postoperatively.[10] These data allow us to tell our patients truthfully that the quality of their vision after treatment may be better than it was before treatment with the best glasses that could be prescribed.

Are there any data to indicate that using the Phorcides software would improve ocular aberrations or quality of vision more than other treatment planning options (manifest, TMR, etc)?

Dr. Wexler: So far, we don't have much data on this for Phorcides. As mentioned earlier, there is improvement in post-op UDVA, compared to the pre-op CDVA, and this may be a result of reduced aberrations producing better visual quality. We are currently starting a prospective study using Phorcides and will be looking at this. So, we will have more data soon.

Dr. Stulting: Specific data on aberration profiles and quality of vision specific to Phorcides are currently limited; however, our upcoming prospective study will provide this information.

What impact does the Phorcides software have on your approach to implementing topography-guided LASIK in your practice)?

Dr. Wexler: It just takes the guess work out of programming the laser. It really helps increase your confidence level because it is easy to use and gives great results. I could not go back to NOT using it! I would recommend Phorcides for anyone using Contoura® Vision.

Dr. Stulting: Contoura® Vision with the addition of the Phorcides software allows surgeons to feel confident that the calculated cylinder magnitude and axis are the optimal treatment and provides surgeons with the opportunity to give patients better vision than they have ever had.[1,5] Before Phorcides became available, we performed extensive calculations to determine the correct refractive input for treatment planning. We were always concerned that we might make a calculation error and end up with a bad result. I would recommend topography-guided LASIK with Contoura® Vision using Phorcides to all other surgeons. I expect those who are dedicated to providing their patients with the best possible outcomes will adopt this technology.

Conclusion

Topography-guided LASIK, specifically using Contoura® Vision with the Phorcides analytic software, allows for a higher percentage of patients to reach 20/15 or better. Phorcides takes into account the effects of not only anterior astigmatism, but also posterior and lenticular astigmatism, where other treatment planning options do not allow for this. Phorcides helps surgeons avoid the need to determine the sphere and cylinder components and, it allows them to feel confident that the calculated result is the optimal treatment plan for each individual patient.

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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 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 compormising 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 N. ot 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 (219% 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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