White Paper

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Wavefront Optomized versus Topography Guided Corneal Ablations with WaveLight® Platform: A Summary of Visual Outcomes

Jessica Mathew, OD, PhD, FAAO[1]
Karl Stonecipher, MD[2]

1. Alcon Medical Affairs, North America, Fort Worth, TX
2. TLC Laser Eye Centers Greensboro, NC

Key Takeaways:

- Modern corneal refractive ablation profiles have evolved over time with increasing sophistication to neutralize spherical aberration, treat higher order aberrations and smooth the contour of the corneal surface
- WFO treatments and Contoura® Vision are both effective at the 20/20 level; However, Contoura® Vision can provide even better visual outcomes overall, with more patients reaching 20/15 and 20/10
- The Phorcides Analytic Engine software offers an objective, user-friendly approach to treatment planning making it appealing to surgeons

Introduction

Two corneal refractive ablation procedures that have been widely adopted and compared are wavefront optimized (WFO) treatments and topography guided treatments. The WaveLight® Excimer laser platform was originally approved for WFO treatments and was later approved for use for topography guided treatments.[1-5] Some surgeons have generally preferred the ease of WFO compared to newer, more advanced laser refractive treatment options. While WFO generally provides good vision for most patients, topography guided ablation has shown visual acuity advantages.

Corneal Refractive Ablation Profile Types

Laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) treatments have evolved over time with increasingly sophisticated profiles typically aimed at addressing the perceived shortcomings of their predecessors. The following summary briefly describes the most commonly used treatments in order to demonstrate the key differences among each treatment type.

Early conventional ablation profiles for LASIK and PRK generally created small optical zones, changed the corneal asphericity and caused abrupt transitions in the peripheral treatment zone. These conventional approaches often induced high order aberrations, particularly increased negative spherical aberration, which may reduce visual quality and contrast sensitivity especially in dim light. Some factors that contributed to this were the small optical zone size and peripheral under-correction due to the cosine effect, which is the loss of laser energy as a result of both beam reflection and the increased angle into the peripheral cornea also causing beam ovalization (Figure 1).[6,7]

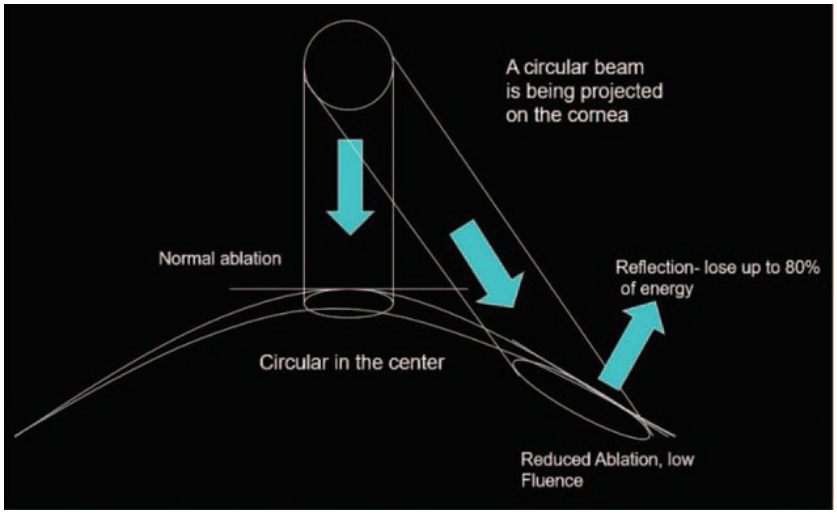

Figure 1: Conventional ablation showing loss of laser energy due to peripheral cosine effect: beam ovalization, increased angle of incidence into the peripheral cornea, and increased beam reflectivity. (Use of figure with permission from Michael Mrochen, PhD)

The development of wavefront-optimized (WFO) treatment and specifically the aspheric ablation profiles commonly used today, resulted in a more prolate corneal shape (versus traditional ablation) and compensated for cosine effects. This was accomplished by increasing the laser energy in the periphery allowing for improved peripheral treatment efficacy and better peripheral blending which helps minimize induced spherical aberration.[7] One important factor to highlight with this treatment is that preoperative spherical aberration of the eye is not treated directly, and the goal is to avoid inducing new spherical aberration during treatment versus eliminating it. Furthermore, the treatment is based on the spherocylindrical refraction, not preoperative aberrometry measurements, and does not aim to correct or reduce any other higher order aberrations. An important distinction between WFO and Wavefront-guided (WFG) ablation profiles is that WFG treatments are designed to correct not only lower order aberrations (sphere and cylinder) but also higher order aberrations. The treatment profile is based on preoperative aberrometry measurements of the whole eye (not just the cornea). Therefore, the goal with wavefront-guided treatment is to directly treat and reduce higher-order aberrations in addition to lower order refractive error.[8-10]

More recently, topography guided ablation profiles have been developed that consider the shape of the anterior corneal surface and use corneal height data from preoperative corneal topography measures. These treatment profiles help reduce higher order aberrations (including spherical aberration) resulting from the cornea (not the entire eye) by compensating for cosine effect and by normalizing or 'smoothing' the overall surface of the cornea to improve regularity. In these treatments, the ablation profile flattens elevations and relatively steepens flatter areas by ablating around them. Topography-guided treatments are not dependent on pupil size and allow for large treatment zones. This also allows for measurement and treatment of peripheral corneal irregularities, which can be responsible for visual disturbances in some patients.[9] Topography-guided treatments can be modified by the surgeon to include consideration of individual refractive error, if desired, or the surgical planning can be simplified by using special software that accurately calculates the exact treatment profile required without manual input from the surgeon.[11,12]

WaveLight® Treatments: Wavefront Optimized vs. Topography Guided Contoura® Vision

Clinical Implications

WaveLight® treatments for both WFO and topography guided Contoura® Vision LASIK are performed using the Allegretto Wave EyeQ 400Hz excimer laser or WaveLight® EX500 excimer laser. Both treatments rely on sphere and cylinder input from the surgeon, while Contoura® Vision also requires Topolyzer® Vario measures for anterior corneal height data. The topography-guided treatment profile provided by the Contoura® software is not adjustable and is designed to treat all corneal topographic aberrations. However, the sphere and cylinder correction can be user-specified. Originally, Contoura® Vision was performed on patients whose manifest sphere and cylinder matched closely with the topography measured amounts from the Topolyzer® Vario, as this was the protocol followed for FDA approval. As surgeons gained experience with Contoura® Vision, they began treating eyes with larger differences between topographic astigmatism and manifest cylinder. How to determine the actual sphere and cylinder treatment power using either the topographic or refractive information became a frequent question among surgeons. This uncertainty led to various different surgeon specific treatment approaches which included maintaining the use of the subjective manifest refraction, using the topographic astigmatism and axis, and various combinations and/or variations of both (the latter including Kanellopoulos, Motwani, and Wallerstein).[13-15] In this regard, Contoura® Vision treatment planning has been somewhat subjective, and this resulted in a surgeon led development of a standardized approach for treatment planning using the Phorcides Analytic Engine software. This software objectively determines the treatment required and considers the topography of the cornea, not only in terms of astigmatism, but in terms of its varying elevation profile.[12] It takes into account the anterior corneal astigmatism, topographic irregularities that create higher order aberrations, posterior corneal astigmatism, and lenticular astigmatism.[12] This more objective approach allows the treatment planning to be more efficient and appealing to surgeons.

Visual Outcomes

The prospective FDA study on normal eyes showed excellent visual outcomes after Contoura® Vision, with uncorrected distance visual acuity (UDVA) of 20/20 or better in 92.6% of eyes and 20/16 or better in 63.8% of eyes, 20/12.5 or better in 34.4%, and 20/10 or better in 15.7% (at 12 months). These results were achieved when the manifest refraction was used, and in eyes where the difference between the topographic astigmatism and manifest refractive cylinder were nominal. Additionally, 30.9% of eyes gained 1 or more lines of UDVA compared with preoperative corrected distance visual acuity (CDVA). Visual acuity improvements from 3 months to 12 months was also shown.[5]

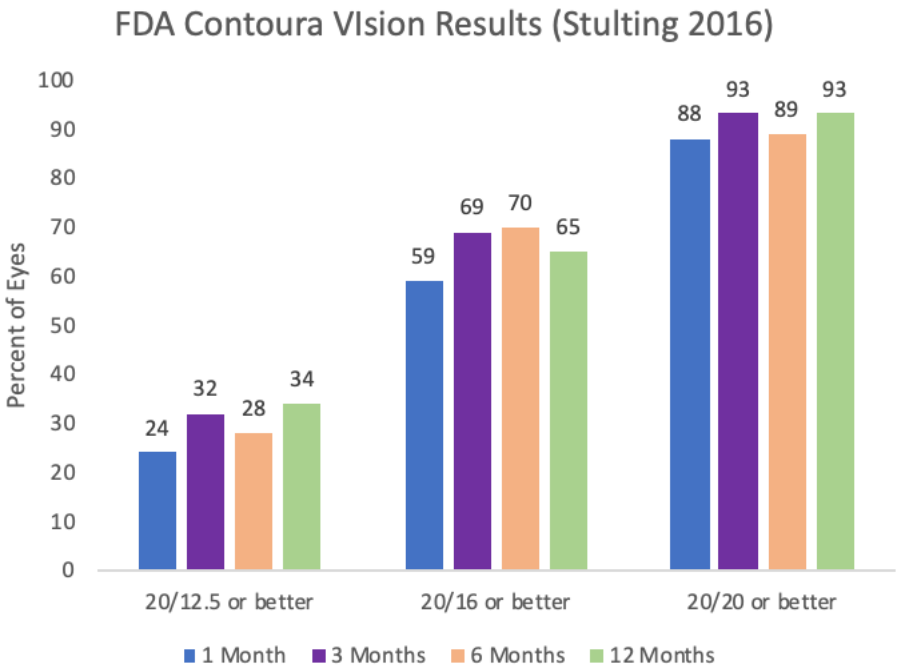

Figure 2: FDA clinical trial showing uncorrected distance visual acuity (UDVA) at each post-operative visit following Contoura® Vision treatment.[5]

Study results listed below include only those studies where Contoura® Vision was used consistent with the approved FDA indications for use, the manifest refraction was used for the surgical planning and 20/15 visual outcomes were provided. In general, all treatments were equally effective at the 20/20 level, but differences at 20/15 and 20/10 were shown. Additionally, residual refractive error among all treatments was similar across the studies mentioned unless stated otherwise.

WFO vs Topography Guided

Stonecipher et al. (2018)[9] conducted a large prospective study on 846 eyes comparing WFO (n=430) to topography guided Contoura® Vision (n=416) using manifest refraction for treatment planning. The study showed that more patients achieved better than 20/20 vision with Contoura® Vision than with WFO: 81.0% vs 73.0% had UDVA of 20/15 or better and 17.0% vs 10.0% had 20/10 or better. These visual acuity percentages did not reach the levels seen in the FDA study. However, this study included all patients with normal corneal parameters and was not restricted by differences in corneal and refractive astigmatism as was the case in the FDA study. They also found in this study that the post-operative spherical equivalent refraction and the residual cylinder were slightly worse in the wavefront-optimized group.

One study by Kim et al. (2019)[16] showed that the number of patients with post-op UDVA was numerically higher at 20/16 with WFO (versus Contoura® Vision); however, this difference was reported as not being statistically significant. They also showed that topography-guided LASIK with Contoura® Vision induced fewer total corneal HOAs (p=0.13) and less coma (p=0.003). Notably, this study was substantially smaller (n=86 eyes) than the other studies reported here.

Contoura® Vision: Manifest Refraction vs Phorcides

Several retrospective analyses on Contoura® Vision using manifest refraction versus Contoura® Vision using the Phorcides software for treatment planning have recently been published. These studies show that the two treatment profiles are equivalent at 20/20. However, more patients are able to achieve 20/15 and 20/10 acuities with the use of Phorcides.[12,17] Lobanoff et al. (2020)[12] showed that a significantly higher percentage of patients reached 20/16 vision with Phorcides versus manifest refraction based Contoura® Vision (62.5% vs 41.3%; p<0.001). The number of patients in this study with UCVA better than their preoperative BCVA was significantly higher in the Phorcides group (36.5% vs 23.0%; p < 0.001), and significantly more eyes in the Phorcides group gained 1 or more lines of BCVA (42.7% vs 30.3%; p = 0.001). Importantly, these studies showed 20/20, 20/15, and 20/10 results that are very similar to the percentages in the FDA study results which selected for eyes with tight agreement between the manifest astigmatism and the measured anterior corneal astigmatism, whereas these studies were not selective in this way and represented the true clinical population better.[12,17]

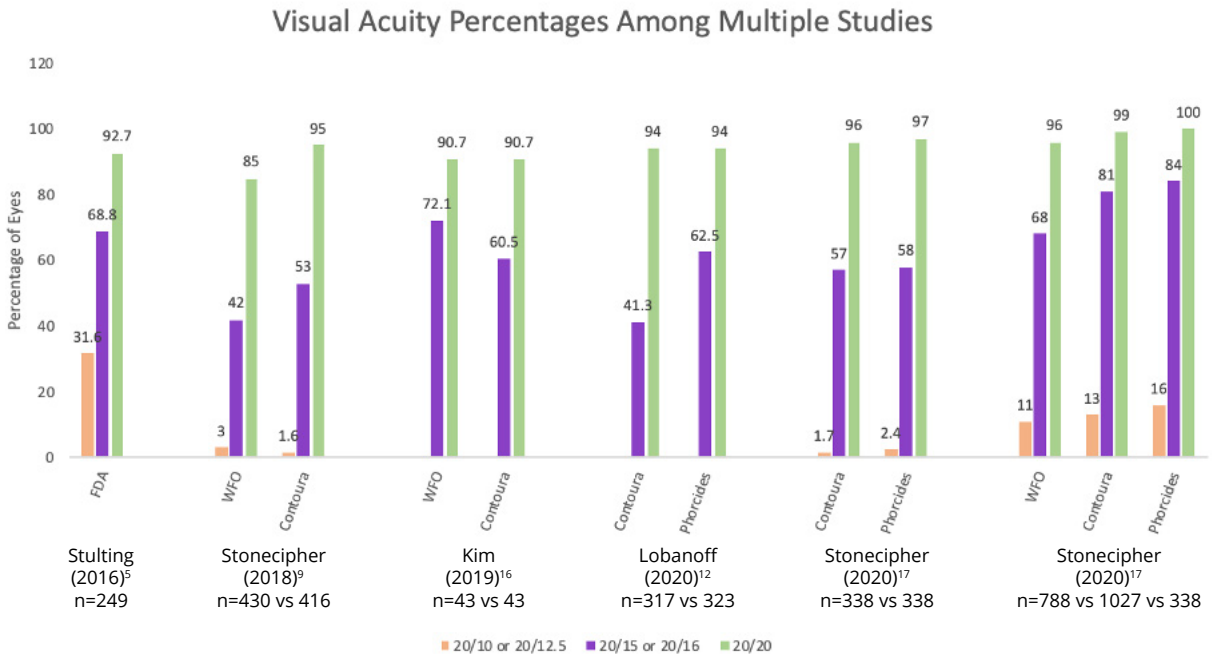

Figure 3: Visual acuity percentages among multiple studies where the manifest refraction was used for Contoura®Vision. ***Note: those with missing 20/10 or 20/15 were not provided within the manuscript***

In addition to the studies already presented, there are several publications by Wallerstein et al. and others using a manifest refraction-based nomogram that also show that Contoura® Vision treatment can be highly effective.[11,13,15,18,19] However, these studies did not provide direct head to head comparisons of their approach to either WFO or Phorcides.

Which treatment is right?

WFO and Contoura® Vision treatments both provide excellent visual outcomes especially at the 20/20 level. While both treatments can also deliver 20/15 visual acuity, Contoura® Vision has shown, overall, that a higher number of patients can achieve 20/15 or better.[12,17] Further, the use of the Phorcides Analytic Engine software has consistently delivered higher percentages of 20/15 over the standard manifest refraction based Contoura® Vision planning, even in patients whose manifest and topography astigmatism do not match.[12,17]

While Contoura® Vision has the potential for better visual outcomes and has been used successfully on a wide range of patients, there are a few instances where WFO treatments would be preferred.

1. When several good quality topography images are not obtainable, as this will limit the ability to accurately define the anterior corneal elevations.
2. When the clinical refraction is outside of the FDA approved parameters for Contoura® Vision (ex. Hyperopia, myopia > -8.00D, cylinder > 3.00D, MRSE > -9.00D)

In conclusion, WFO treatments and Contoura® Vision are both effective at the 20/20 level; however, Contoura® Vision, and specifically the use of the Phorcides Analytic Engine software, provides even better visual outcomes overall, with more patients reaching 20/15 and 20/10. The Phorcides software helps surgeons avoid the subjective nature of Contoura® Vision that can require determining the right balance of cylinder magnitude and axis and it provides a more objective, user-friendly approach that makes it more appealing to surgeons.

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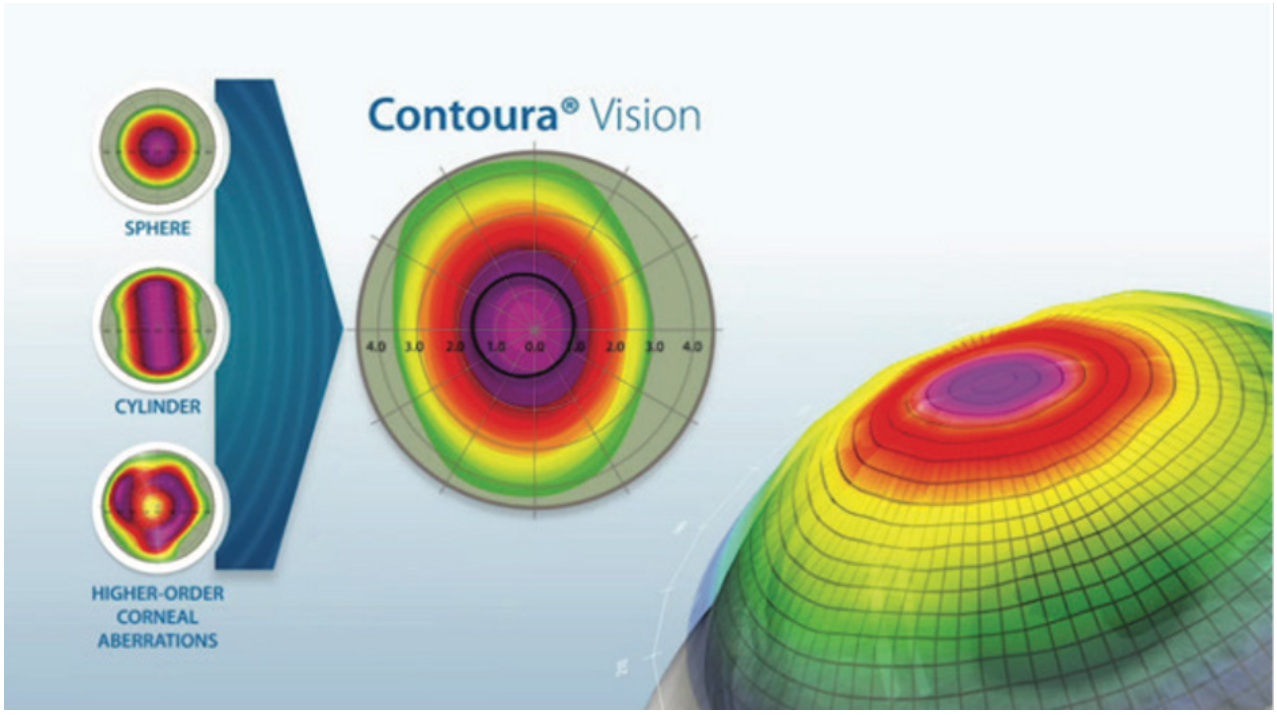

Important Product Information about the WaveLight® Excimer Laser Systems

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 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 for use in laser-assisted in situ keratomileusis (LASIK) treatments for:

- the reduction or elimination of myopia of up to - 12.00D and up to 6.00D of astigmatism at the spectacle plane;
- the reduction or elimination of hyperopia up to + 6.00D with and without astigmatic refractive errors up to 5.00D
- at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00D;
- the reduction or elimination of naturally occurring mixed astigmatism of up to 6.00D at the spectacle plane;

and

- the wavefront-guided reduction or elimination of myopia of up to -7.00D and up to 3.00D of astigmatism at themspectacle 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 -9.00D of myopia, or for the reduction or elimination of myopia with astigmatism, with up to -8.00D of myopia and up to 3.00D 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 ≤ 0.50D 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 7.0mm after mydriatics where applied for wavefront-guided ablation planning;
- history of glaucoma or ocular hypertension of > 23mmHg;
- 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 < 6.0mm or > 6.5mm in diameter, or an ablation zone > 9.0mm 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 > 4D and ≤ 6D. 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.

Alcon Medical Affairs