

Wavefront Optimized vs. Topography-Guided Corneal Ablations with WAVELIGHT Platform: A Summary of Visual Outcomes



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INTRODUCTION

Two corneal refractive ablation procedures that have been widely adopted and compared are wavefront optimized (WFO) treatments and topography-guided treatments. Some surgeons have generally preferred the ease of WFO compared to newer, more advanced laser refractive treatment options, and while WFO generally provides good vision for most patients, topography-guided ablation has shown visual acuity advantages. The WAVELIGHT Excimer Laser Platform (Alcon) was

originally approved for WFO treatments¹⁻⁴ and was later approved for use for topography-guided treatments.⁵

VISUAL OUTCOMES

The prospective FDA study on normal eyes showed excellent visual outcomes after CONTOURA Vision (Alcon), with uncorrected distance visual acuity (UDVA) of 20/20 or better in 92.6% of eyes, 20/16 or better in 64.8% of eyes, 20/12.5 or better in 34.4% of eyes, and 20/10 or better in 15.7% of eyes (at 12 months) (Figure 1). These

results were achieved when the manifest refraction was used, as well as in eyes where the difference between the topographic astigmatism and manifest refractive cylinder were nominal. Additionally, 30.9% of eyes gained one or more lines of UDVA compared with preoperative corrected distance visual acuity (CDVA). Visual acuity improvement from 3 to 12 months was also shown.⁵

Study results listed below include only those studies where CONTOURA Vision was used consistently 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 ABLATION

Stonecipher et al⁶ 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 (Figure 2). The study showed that more patients achieved better than 20/20 vision with CONTOURA Vision than with WFO: 54.6% versus 45.0% had UDVA of 20/15 or better. These visual acuity percentages did not reach the levels seen in the FDA study. However, this study included all

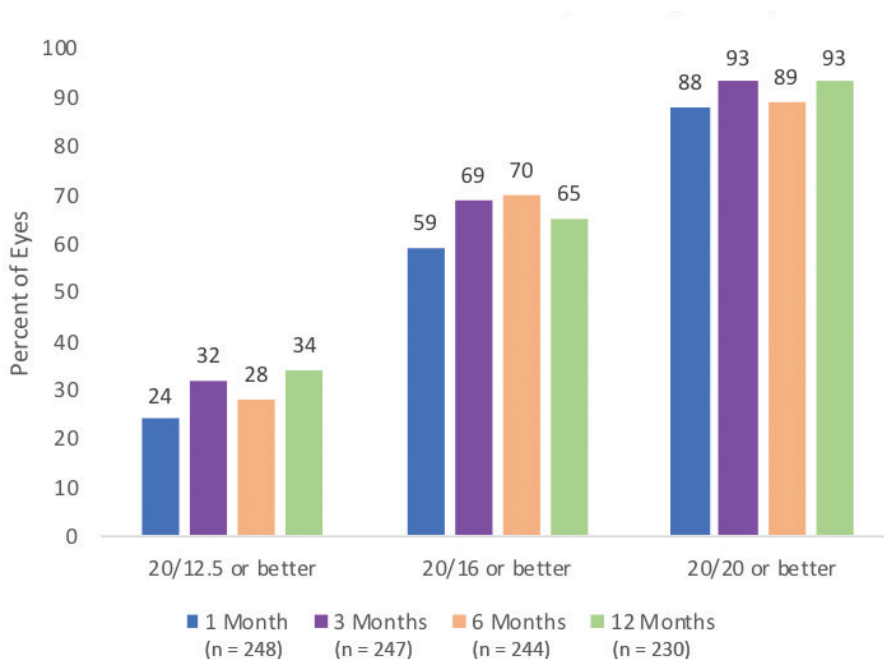


Figure 1. FDA clinical trial showing UDVA at each postoperative visit following CONTOURA Vision treatment.⁵

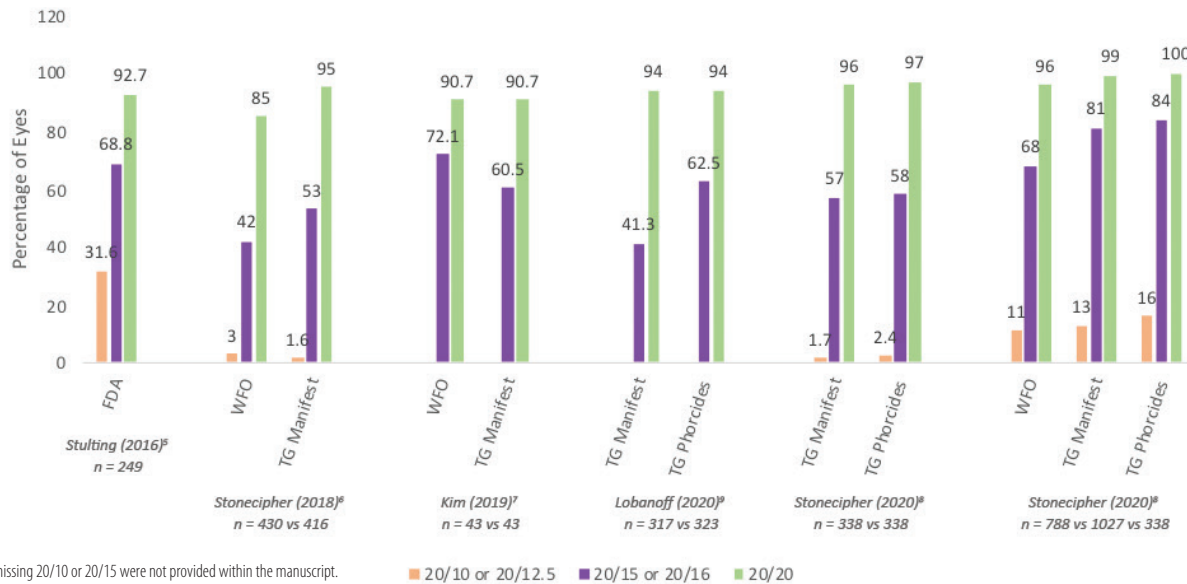


Figure 2. Visual acuity percentages among multiple studies where the manifest refraction was used for CONTOURA Vision. Postoperative UDVA: Stulting at 3 months;⁵ Stonecipher at 1 day;⁶ Kim at 3 months;⁷ Lobanoff at 2-5 months;⁹ Stonecipher at 1 day;⁸ Stonecipher at 1 day.⁸

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 postoperative spherical equivalent refraction and the residual cylinder were slightly worse in the wavefront-optimized group.

One study by Kim et al⁷ showed that the number of patients with postoperative UDVA was numerically higher at 20/16 with WFO (versus CONTOURA Vision); however, this difference was reported as not statistically significant. The study also showed that topography-guided LASIK with CONTOURA Vision induced fewer total corneal HOAs ($P = .013$) and less coma ($P = .003$). Notably, this study was substantially smaller ($n = 86$ eyes) than the other studies reported here.

CONTOURA VISION: MANIFEST REFRACTION VERSUS PHORCIDES

Several retrospective analyses on CONTOURA Vision using manifest refraction versus the PHORCIDES Analytic Engine software (Alcon) 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.^{8,9} Lobanoff et al⁹ showed that a significantly higher percentage of patients reached 20/16 vision with PHORCIDES ($n = 323$ eyes) versus manifest refraction-based ($n = 317$ eyes) CONTOURA Vision (62.5% vs. 41.3%; $P < .001$). The number of patients in this study with UDVA better than their preoperative CDVA was significantly higher in the PHORCIDES group (36.5% vs. 23.0%; $P < .001$), and significantly more eyes in the PHORCIDES group gained 1 or more lines of CDVA (42.7% vs. 30.3%; $P = .001$). 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 better represented the true clinical population.^{8,9}

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.¹⁰⁻¹³ However, these studies did not provide direct head-to-head comparisons of their approaches to either WFO or PHORCIDES.

WHICH TREATMENT IS RIGHT?

WAVELIGHT 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.^{8,9} 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.^{8,9}

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 high-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 (e.g. Hyperopia, myopia > -8.00 D, cylinder > 3.00 D, MRSE > -9.00 D)

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, can provide even better visual outcomes overall, with more patients reaching 20/15 and 20/10. The PHORCIDES software helps surgeons avoid the subjective nature of determining the right balance of cylinder magnitude and axis when manually planning CONTOURA Vision treatments, and it provides a more objective, user-friendly approach that makes it more appealing to surgeons. ■

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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® EK500. **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 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 (Cordaron®); have severe dry eye; have comeas 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 (Miltrex®); 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) anti-inflammatories. 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. No or 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 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.