Contoura® Vision Topography-Guided Ablation

Clinical Science Compendium

Summary of peer-reviewed clinical research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our surgical medical device products, such as the WaveLight® suite for Contoura® Vision, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community.

High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for Contoura® Vision, a topography-guided ablation technology, designed to provide surgeons with the ability to perform more personalized laser procedures for patients with myopia, or myopia with astigmatism, based on the unique corneal topography of each eye.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—AlconScience.com—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

The 19 articles summarized in this compendium were identified using the PubMed and Google Scholar databases incorporating the search terms "Contoura Vision", "topography-guided LASIK, topography-guided ablation", "WaveLight Topolyzer", and "WaveLight Topolyzer VARIO". Articles were included when they were published between January 1, 2011 and May 31, 2020 and contained research relevant to Contoura® Vision (including use of 1] WaveLight® 400 Hz excimer laser or WaveLight® EX500 excimer laser and 2] WaveLight® Topolyzer or WaveLight® Topolyzer VARIO) for reduction or elimination of up to -9.00 D of spherical equivalent myopia or myopia with astigmatism, with up to -8.00 D of spherical component and up to 3.00 D of astigmatic component at the spectacle plane and on normal, previously unablated eyes. Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

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Results of Topography-Guided Laser in situ Keratomileusis Custom Ablation Treatment with a Refractive Excimer Laser

Stulting et al. *J Cataract Refract Surg.* 2016;42:11-18*

Visual Acuity | Refractive Outcomes | Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Prospective, observational, nonrandomized, unmasked study to evaluate the safety and effectiveness of topography-guided custom ablation treatment (T-CAT) to correct myopia and myopic astigmatism

STUDY SITE(S)
Nine (9) clinical centers in the United States

PATIENTS
Two hundred forty-nine (249) eyes of 212 patients; mean age 34 years (range: 18 to 65 years); spherical equivalent: 0.00 to -9.00; cylinder: 0.00 to -6.0D); normal, previously unablated eyes

SURGICAL METHODOLOGY
Topography-guided LASIK treatment

SURGICAL TECHNOLOGY
WaveLight® Allegretto Wave® Eye-Q excimer laser (400Hz), WaveLight® Allegro Topolyzer™ (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Manifest refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), visual symptoms, adverse events, responses on Refractive Status and Vision Profile (RSVP) questionnaire, up to 12 months postoperatively

ANALYSIS AND CONCLUSIONS

Topography-guided LASIK safely and effectively achieved predictable refractive outcomes and reduced visual symptoms with stable results through 12 months.

The authors noted that this approach can offer patients not only freedom from glasses and contact lenses but also a likely improvement in the quality of vision as well as in vision-related quality of life in most cases.

One author (BS Fant) and Clinical Research Consultants, Inc. were supported by Alcon Laboratories, Inc.

STUDY RESULTS

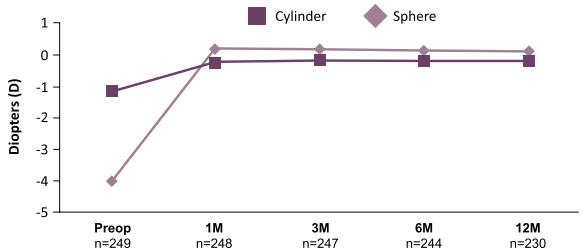
REFRACTIVE OUTCOMES
- Topography-guided LASIK resulted in a significant reduction in manifest refraction spherical equivalent (MRSE) and cylinder (both P<0.0001), reaching stability 3 months after treatment (**Figure 1**)
- Three months postoperatively, 227 (91.9%) of 247 eyes were within ±0.50 D of plano and at 1 year, 218 (94.8%) of 230 eyes were within ±0.50 D of plano.

VISUAL ACUITY
- Three months postoperatively, UDVA was 20/10 or better in 19 (7.7%) of 247 eyes and 20/20 or better in 229 (92.7%) of eyes (**Figure 2**)
- At 1 year, UDVA was 20/10 or better in 36 (15.7%) of 230 eyes and 20/20 or better in 213 (92.6%) of eyes (**Figure 2**)
- Overall, 63 (25.8%) of 244 eyes gained 1 or more lines of UDVA at 6 months compared with the CDVA preoperatively, and 71 (30.9%) of 230 eyes gained 1 or more lines at 12 months

PATIENT-REPORTED OUTCOMES
- The most commonly reported visual symptoms preoperatively were difficulty driving at night (mild to severe in 55.0% of eyes) and dryness (mild to severe in 51.8% of eyes)
- Most visual symptoms improved 3 months postoperatively, reaching statistical significance for light sensitivity, difficulty driving at night, reading difficulty, and glare; only double vision and foreign-body sensation were reported to be worse (these worsened in 0.8% and 0.4% of treated eyes, respectively)
- The incidence and severity of visual symptoms continued to decrease during the 12-month course of the study; 12 months after surgery, there was a statistically significant decrease in light sensitivity, difficulty driving at night, reading difficulty, glare, halos, and starbursts
- Responses to the RSVP questionnaire showed an improvement in all subscales evaluated at each postoperative visit and in the total composite score, including physical/social functioning, driving, visual symptoms, optical problems, and problems with corrective lenses

CORNEAL ABERRATIONS
- A mean 8.9% decrease in total root-mean square (RMS) magnitude was observed for 2nd- through 5th-order corneal aberrations, reflecting the overall effect of topography-guided LASIK on corneal irregularities
- Although the cylinder treatment was based on the refractive cylinder, a reduction in topographic cylinder contributed to the 24.4% decrease in corneal astigmatism RMS

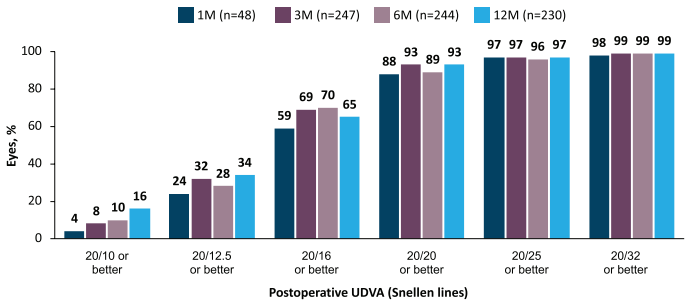
Figure 1. Change in manifest refraction and cylinder with time following topography-guided LASIK.



	Preop	1M	3M	6M	12M
MRSE (D)	-4.61	0.06	0.06	0.01	0.00
Std Dev (D)	2.43	0.36	0.33	0.35	0.27

MRSE, manifest refraction spherical equivalent.

Figure 2. Cumulative postoperative uncorrected distance visual acuity following topography-guided LASIK.



UDVA, uncorrected distance visual acuity.

Wavefront-Optimized Ablation Versus Topography-Guided Customized Ablation in Myopic LASIK: Comparative Study of Higher Order Aberrations

El Awady et al. *Ophthalmic Surg Lasers Imaging.* 2011;42:314-320

Visual Acuity
Refractive Outcomes
Contrast Sensitivity
Higher-Order Aberrations

OVERVIEW

STUDY DESIGN
Prospective study to compare the outcomes of wavefront-optimized ablation and topography-guided ablation in fellow eyes of patients undergoing LASIK for myopia

STUDY SITE(S)
Single surgical center, Egypt

PATIENTS
One hundred sixty-eight (168) eyes of 84 consecutive patients; mean age 26.9 ± 3.1 years (range: 21 to 42 years)

SURGICAL METHODOLOGY
Wavefront-optimized LASIK in one eye (group I) and topography-guided LASIK in the fellow eye (group II)

SURGICAL TECHNOLOGY
WaveLight® Allegretto Wave Excimer Laser (Alcon Laboratories, Inc); Moria M2 Microkeratome (Moria Ophthalmic Instruments); WaveLight® Topolyzer (Alcon Laboratories, Inc); WaveLight® Analyzer (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Refractive outcomes and higher-order aberrations (HOAs) 6 months postoperatively

ANALYSIS AND CONCLUSIONS

Our study found that both wavefront-optimized ablation and topography-guided customized ablation treatments provided good refractive results, but the topography-guided customized ablation induced fewer HOAs.

The authors speculated that a better understanding of how individual aberrations interact with each other may allow researchers to achieve a higher level of customization; further studies are needed to evaluate quality of vision, pupil size, and wavefront aberrations.

STUDY RESULTS

VISUAL AND REFRACTIVE OUTCOMES

- Six months postoperatively, the mean uncorrected visual acuity of group II (topography-guided ablation) was statistically better than that of group I (wavefront-optimized ablation) (P=0.02) **(Table 1)**
- Postoperative spherical equivalent of group I was -0.2 ± 0.07 D (range: -1.25 to +1.25 D), whereas that of group II was -0.016 ± 0.057 D (range: -1.5 to +0.75 D) (P=0.043) **(Table 1)**
- Seventy percent of group I and 83% of group II achieved a postoperative spherical equivalent refraction of ±0.5 diopters (P=0.004)

HIGHER-ORDER ABERRATIONS

- The postoperative total root-mean-square of HOAs of group II (topography-guided ablation) was smaller than that of group I (wavefront-optimized ablation), but the difference was not statistically significant (P=0.51) **(Figure 1)**
- There was a decrease in most of the individual terms of HOAs in group II, but it was only statistically significant in Z_3^{-1} (vertical coma; P=0.04)
- The reverse occurred in group I, where most of the individual terms of HOAs increased, but it was not statistically significant; significant improvement was only noted in Z_5^3 (combination of coma and higher cylindrical aberration; P=0.05) and Z_5^5 (higher cylindrical aberration, P=0.04)

CONTRAST SENSITIVITY

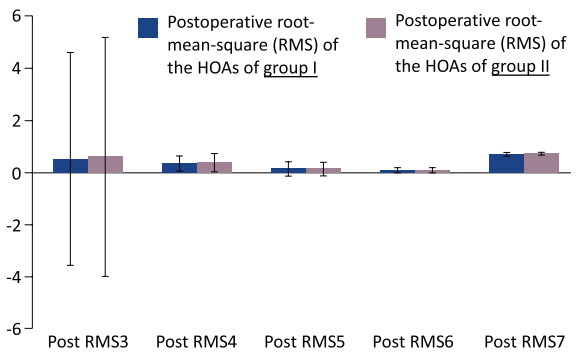
- There were no significant difference in visual acuity contrast between groups
- Mean high-contrast spatial frequency in group I (wavefront-optimized ablation) was 4.92 ± 1.52, compared with 4.74 ± 1.63 in group II (topography-guided ablation) (P=0.12); mean low-contrast spatial frequency in group I was 5.72 ± 1.84, compared with 4.92 ± 1.76 in group II (P=0.11)

Table 1. Postoperative refraction and visual acuity of group I (wavefront-optimized ablation) and group II (topography-guided ablation)

Variable	Group I	Group II	P-value
Postop SE, D Mean ± SD Range	-0.2 ± 0.07[b] (-1.25 to +1.25)	-0.016 ± 0.057[b] (-1.5 to +0.75)	0.043[a]
Postop SE, D Mean ± SD Range	-0.64 ± 0.63[b] (-2.55 to -1.0)	-0.5 ± 0.23[b] (-1.0 to -0.57)	0.15
Postop UCVA (logMAR) Mean ± SD	0.8 ± 0.2[b]	0.88 ± 0.2[b]	0.02[a]

Group I, wavefront optimized; Group II, topography-guided customized; Postop, postoperative; SE, spherical equivalent; SD, standard deviation; D, diopters; UCVA, uncorrected visual acuity; LogMAR, logarithm of minimum angle of resolution. [a]Statistically significant, P≤0.05, Student's t test (group I vs group II). [b]Statistically significant, P≤0.05, paired t test (increase from preoperative level).

Figure 1. Postoperative root-mean-square (RMS) of the HOAs of group I and group II. Difference was not significantly different (P=0.04 in RMS3, P=0.29 in RMS4, P=0.56 in RMS5, P=0.35 in RMS6, and P=0.51 in total RMS)



Topography-Guided LASIK Versus Small Incision Lenticule Extraction (SMILE) for Myopia and Myopic Astigmatism: A Randomized, Prospective, Contralateral Eye Study

Visual Acuity

Refractive Outcomes

Kanellopoulos. *J Refract Surg.* 2017;33:306-312

OVERVIEW

STUDY DESIGN

Prospective, randomized contralateral eye study to compare the safety and efficacy of topography-guided LASIK and contralateral eye SMILE for myopia and myopic astigmatism correction

STUDY SITE(S)

Private clinical ophthalmology practice, Greece

PATIENTS

Forty-four (44) eyes of 22 patients; mean age 29.5 years (range 21-45 years)

SURGICAL METHODOLOGY

Topography-guided LASIK or small incision lenticule extraction (SMILE); LASIK: flap 8.5 mm diameter, 110 µm thick, cylinder and axis adjusted to match topography measured; sphere adjusted to maintain spherical equivalent; SMILE: lenticule 6.5 mm, cap 130 µm

SURGICAL TECHNOLOGY

WaveLight® Refractive Suite, including FS200 Femtosecond Laser and EX500 Excimer Laser (Alcon Laboratories, Inc); WaveLight® Topolyzer™ VARIO

KEY ENDPOINT(S)

Uncorrected distance vision acuity (UDVA), corrected distance vision acuity (CDVA), refractive error, corneal keratometry, contrast sensitivity, and Objective Scatter Index

ANALYSIS AND CONCLUSIONS

Topography-guided LASIK was superior to SMILE in all visual performance parameters studied, both subjective and objective.

The main difference between the two techniques likely derives from eye tracking, cyclorotation compensation, and active centration control in the LASIK technology, which appear to affect refractive and visual aberration performance outcomes.

STUDY RESULTS

VISUAL ACUITY

- Three months postoperatively, 86.4% of the LASIK group and 68.2% of the SMILE group had UDVA of 20/20 (P<0.002), and 59.1% and 31.8%, respectively, had UDVA of 20/16 (P<0.002) (**Figure 1**)
- Gain–loss data (preoperative CDVA versus postoperative UDVA) indicated that 9.1% of the eyes in the LASIK group and 4.5% of the eyes in the SMILE group gained two lines (P<0.02).

REFRACTIVE PREDICATABILITY AND OTHER OUTCOMES

- The residual manifest spherical equivalent between 0.00 and +0.50 D was achieved in 95.5% of the eyes in the LASIK group compared to 77.3% in the SMILE group (P<0.002) (**Figure 2**)
- Rate of residual refraction cylinder ≤ 0.25 D was 81.8% for the LASIK group and 50% for the SMILE group (P<0.001)
- Contrast sensitivity (6 cycles/degree) was 7.2 ± 1.01 in the LASIK group (an improvement in comparison to the preoperative measurements) and 6.20 ± 1.52 in the SMILE group (not statistically different from preoperative values)
- Objective Scatter Index measurements at 3 months were 1.35 in the LASIK group (statistically better than preoperative mean value) and 1.42 in the SMILE group (not statistically different from preoperative values)

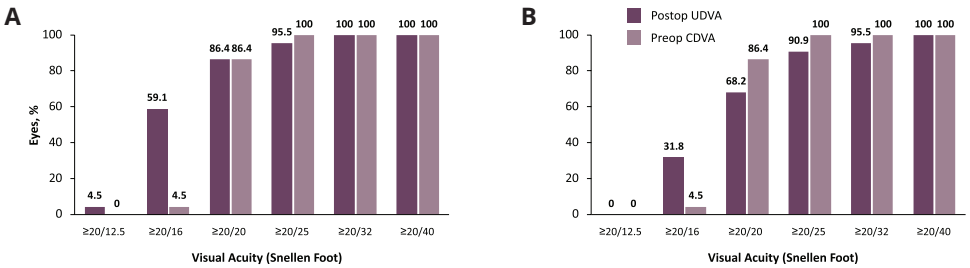


Figure 1. Postoperative UDVA and preoperative CDVA for LASIK (**A**) and SMILE (**B**) 3 months postoperatively.

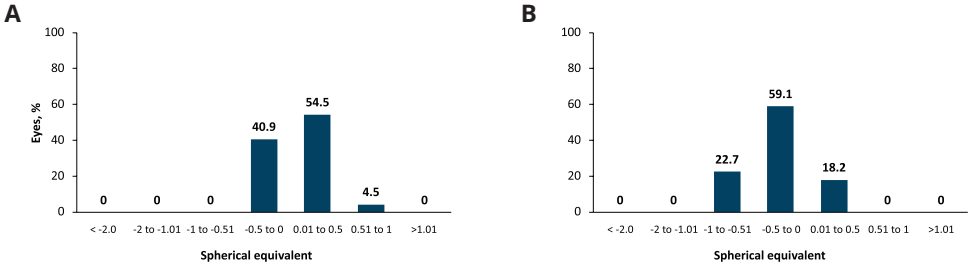


Figure 2. Spherical equivalent refraction correction in diopters for the (**A**) topography-guided LASIK and (**B**) SMILE groups.

Meta-analysis of the FDA Reports on Patient-Reported Outcomes Using the Three Latest Platforms for LASIK

Visual Acuity

Visual Phenomena

Patient-Reported Outcomes

Moshirfar et al. *J Refract Surg.* 2017;33:362-368

OVERVIEW

STUDY DESIGN

Retrospective meta-analysis of the submitted U.S. Food and Drug Administration (FDA) summary of safety and effectiveness data from the three latest approved LASIK platforms to assess the impact on patient-reported outcomes after LASIK treatment

STUDY SITE(S)

Not applicable (aggregated FDA data)

PATIENTS

Seven hundred eighteen (718) eyes of 530 patients; mean age 33.4 ± 8.7 years

SURGICAL METHODOLOGY

Topography-guided LASIK with Contoura® Vision or CATz; wavefront-guided LASIK with iDESIGN®

SURGICAL TECHNOLOGY

WaveLight® Allegretto Wave® Eye-Q excimer laser with WaveLight® ALLEGRO Topolyzer® and T-CAT treat-ment planning software (Contoura® Vision, Alcon Laboratories, Inc); STAR S4 IR® Excimer Laser with iDESIGN® Advanced WaveScan Studio System (iDESIGN®, Johnson & Johnson Vision); EC-5000 Excimer Laser with topography-assisted LASIK treatment (CATz, NIDEK)

KEY ENDPOINT(S)

Pooled data for the three LASIK systems at 3 and 12 months for cumulative postoperative uncorrected distance visual acuity (UDVA) and change in lines of corrected distance visual acuity (CDVA); patient-reported outcomes (visual symptoms, quality of life, and satisfaction rates)

ANALYSIS AND CONCLUSIONS

System-specific data are not presented, but pooled data from the three LASIK systems incorporating Contoura® Vision, iDesign®, or CATz showed superb efficacy and safety, achieving visual outcomes that exceeded FDA criteria for these measurements.

The LASIK systems produced a significant reduction in preoperative symptoms such as light sensitivity, driving difficulty at night, reading difficulty, glare, and halos; the magnitude of this reduction was larger than the increase in new visual symptoms after surgery.

STUDY RESULTS

VISUAL ACUITY

- At 12 months postoperatively, a UDVA of 20/20 or better was achieved in 86% of eyes, and 20/12.5 or better in 24% of eyes (**Figure 1**)
- Nearly all eyes achieved UDVA of 20/40 or better, far exceeding the FDA cut-off for efficacy (**Figure 1**)
- Eighty percent of eyes had UDVA at 12 months that was equal to or better than CDVA preoperatively
- No eye lost two or more lines of CDVA at the 12-month postoperative follow-up compared to preoperative CDVA, exceeding the FDA criteria for safety
- At 12 months postoperatively, 4% of eyes lost one line of CDVA compared to preoperative CDVA, and approximately 48% of eyes gained at least one line of CDVA
- Ninety-six percent of eyes were within ±1.00 D of their intended target 12 months postoperatively

VISUAL PHENOMENA AND PATIENT-REPORTED OUTCOMES

- At 12 months post-LASIK:
  - 11% of patients reported complete resolution from preoperative light sensitivity (P=0.11) and 9% of patients reported reduction from preoperative moderate to severe symptoms (P=0.004)
  - 29% of patients reported complete resolution of preoperative symptoms of difficulty driving at night (P<0.001), and 22% reported a reduction in moderate to severe preoperative symptoms (P<0.001) (**Figure 2**)
  - There was no statistically significant resolution in prior moderate to severe symptoms (pre-op vs post-op) for reading difficulty, double vision, fluctuation in vision, glare, dryness, pain, foreign body sensation
  - There was significant postoperative reduction in prior moderate to severe symptoms for light sensitivity (9%), reading difficulty (8%), glare (12%), and halos (6%)

Figure 1. Cumulative uncorrected distance visual acuity 12 months postoperatively (pooled data from the three LASIK systems).

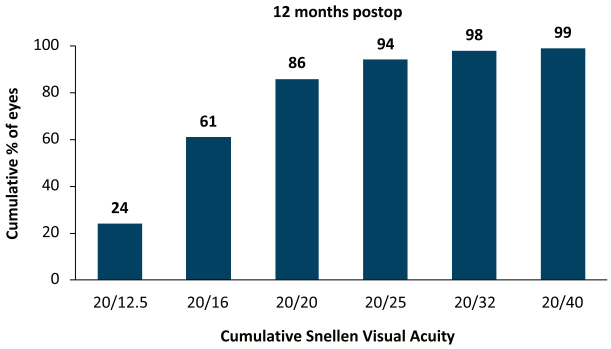
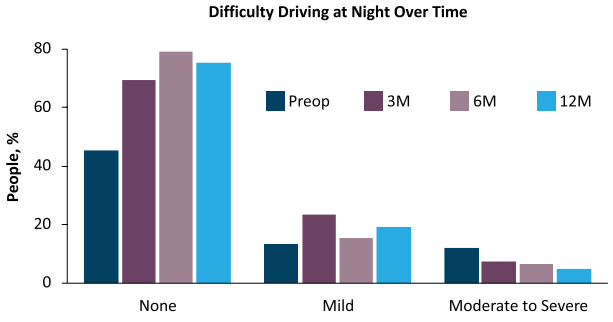


Figure 2. Changes in visual symptoms over time for difficult driving at night (pooled data from the three LASIK systems).



The Use of WaveLight® Contoura to Create a Uniform Cornea: The LYRA Protocol. Part 3: The Results of 50 Treated Eyes

Motwani et al. *Clin Ophthalmol.* 2017;11:915-921

Visual Acuity

Refractive Outcomes

Higher-Order Aberrations

OVERVIEW

STUDY DESIGN
Retrospective analysis to demonstrate how using the Contoura® Vision-measured astigmatism and axis eliminates corneal astigmatism and creates uniformly shaped corneas

STUDY SITE(S)
Single center in the United States

PATIENTS
Fifty (50) eyes of 26 patients; average age of 31.65 years (range: 19 to 62 years)

SURGICAL METHODOLOGY
Topography-guided LASIK treatment with Contoura® Vision using the LYRA (Layer Yolked Reduction of Astigmatism*) protocol

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser, WaveLight® Topolyzer™ VARIO (Alcon Laboratories, Inc.); Moria M2 Microkeratome (Moria Ophthalmic Instruments)

KEY ENDPOINT(S)
Higher-order aberrations (HOAs), visual acuity, refractive outcomes

ANALYSIS AND CONCLUSIONS

Using Contoura® Vision-measured astigmatism and axis removed HOAs and allowed for the creation of a more uniform cornea with accurate removal of astigmatism, and reduction of aberration polynomials.

Contoura® Vision successfully linked the refractive correction layer and aberration repair layer using the LYRA protocol to demonstrate how aberration removal can affect refractive correction.

**LYRA protocol requires the surgeon to use topography measured astigmatism and axis and an adjusted sphere power of the spherical equivalent difference in between the manifest and topography measured astigmatism*

STUDY RESULTS

REFRACTIVE OUTCOMES
- The average difference of astigmatic power from manifest to measured was 0.5462 D (range: 0–1.69 D), and the average difference of axis was 14.94 degrees (range: 0–89 degrees)
- Forty-seven of 50 eyes had a goal of plano and 3 eyes had a monovision goal
- Overall, only 2 eyes had residual astigmatism; thus, 48 out of 50 eyes (96%) had full astigmatic correction, and one (1) eye had regression with an astigmatic component

HIGHER-ORDER ABERRATIONS
- Astigmatism polynomials C3 and C5 values were measured preoperatively and at 3 months at the 5.0 and 6.5 mm zones, as epithelium grows from the limbus toward the center
- At 5.0 mm, the average C3 was reduced by 74.33%, and the average C5 by 51.84%; at 6.5 mm, the average C3 was reduced by 86.5% and the average C5 by 85.14%

VISUAL ACUITY
- Of the 47 eyes with plano as the goal, 3 (6.38%) were 20/10 or better, 38 (80.85%) were 20/15 or better, and 47 (100%) were 20/20 or better
- Of the other 3 monovision eyes, distance vision was 20/30, 20/40, 20/70 and reading was Jaeger score 2 (J2) or Jaeger score 1 (J1)

SAMPLE CASE
- **Figure 1** shows preoperative and postoperative topography for a sample case
- The preoperative manifest in this patient was −3.00 (**Figure 1A**), and Contoura® Vision-measured treatment was −2.50, −1.00×179; at postoperative week 1, the patient was plano with 20/15 vision (**Figure 1B**)
- In this case, the patient's aberrations were masking and offsetting the astigmatism

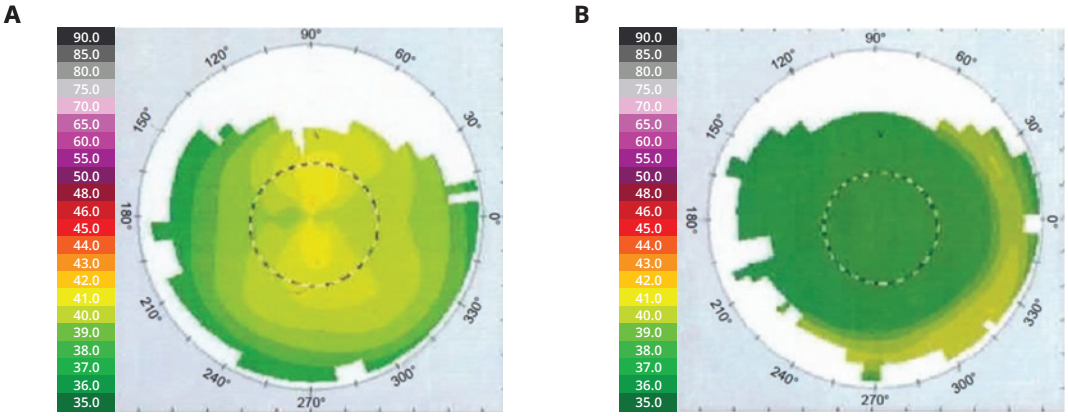


Figure 1. Topography-guided LASIK treatment with Contoura® Vision using the LYRA protocol: preoperative (**A**) and postoperative (**B**) topography for a sample case.

A Prospective Study to Compare Visual Outcomes Between Wavefront-optimized and Topography-guided Ablation Profiles in Contralateral Eyes with Myopia

Visual Acuity | Refractive Outcomes | Higher-Order Aberrations

Shetty et al. *J Refract Surg.* 2017;33:6-10

OVERVIEW

STUDY DESIGN
Prospective interventional study to analyze refractive outcomes of wavefront-optimized (WFO) ablation and topography-guided custom ablation (TCAT) profiles using an excimer laser platform in the treatment of myopia

STUDY SITE(S)
India

PATIENTS
Sixty (60) eyes of 30 patients with stable myopia for at least a year; mean age of 27.2 years (range: 18 to 35 years)

SURGICAL METHODOLOGY
Topography-guided ablation (TCAT) in one eye, wavefront-optimized ablation (WTO) in the other; flaps cut to expose a stromal bed of at least 9.0 mm in diameter and 135 µm in depth

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser, WaveLight® FS200 Femtosecond Laser, WaveLight® Topolyzer® (Alcon Laboratories, Inc.); Pentacam HR (Oculus Optikgeräte GmbH)

KEY ENDPOINT(S)
Uncorrected and corrected distance visual acuity (UDVA, CDVA), refractive outcomes, corneal aberrations 6 months postoperatively

ANALYSIS AND CONCLUSIONS

Refractive outcomes and visual acuity were similar in both the WFO and TCAT groups, while less change in corneal asphericity and lower RMS values of lower order and higher order aberrations were observed in eyes treated with TCAT.

These findings suggest that although both WFO and topography-guided regimens are equally accurate, safe, and effective in correcting myopia and myopic astigmatism, TCAT may have a lesser effect on corneal shape and aberrations.

STUDY RESULTS

CORNEAL ABERRATIONS

- The total root mean square (RMS) of the anterior surface of the cornea was higher (P=0.04) in the WFO group (2.04 ± 0.72) than in the TCAT group (1.73 ± 0.61) 6 months after surgery
- The total RMS of the entire cornea was also higher (P=0.04) in the WFO group (1.94 ± 0.78) than the TCAT group (1.60 ± 0.63)
- The RMS of lower order aberrations for the anterior surface (P=0.04) and entire cornea (P=0.03) was significantly greater in the WFO group
- Six months after the procedure, the Q value was +0.60 in the WFO group and +0.51 in the TCAT group, and induced positive spherical aberration was 0.57 ± 0.25 and 0.42 ± 0.25, respectively
- There was a more positive change in Q value and spherical aberrations in the WFO group, but this was not statistically significant

VISUAL ACUITY

- In the WFO group, 93% of eyes achieved a UDVA of 20/20 or better at 6 months, compared with 97% in the TCAT group; these percentages were not significantly different
- CDVA remained stable in 83.3% and 90% of the eyes in the WFO and TCAT groups, respectively (P=0.70) **(Figure 1)**

REFRACTIVE OUTCOMES

- The percentage of eyes with a spherical equivalent (SE) less than +0.50 D was 80% in the WFO group and 83% in the TCAT group (P=0.90)
- The coefficient of determination between the attempted and achieved mean refractive SE was also similar (P=0.89) between the WFO (R^2=0.96) and TCAT (R^2=0.97) groups **(Figure 2)**

Figure 1. Corrected distance visual acuity in the (A) TCAT and (B) WFO groups 6 months postoperatively.

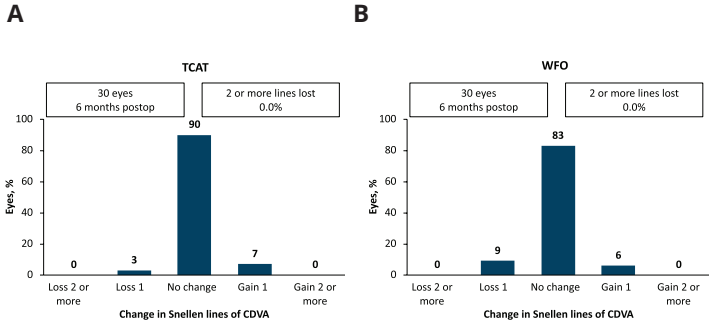
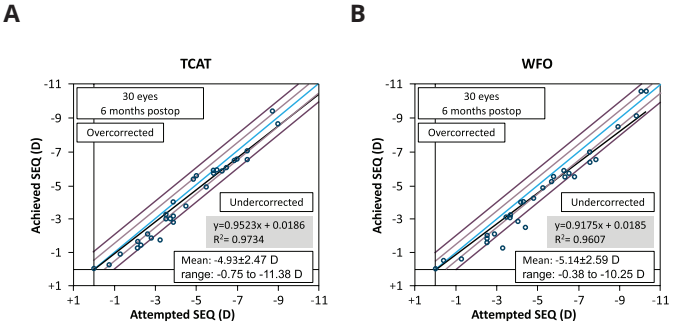


Figure 2. Attempted versus achieved spherical equivalent in the (A) TCAT and (B) WFO groups 6 months postoperatively.



The Use of WaveLight Contoura to Create a Uniform Cornea: 6-Month Results with Subjective Patient Surveys

Visual Acuity

Patient-Reported Outcomes

Motwani et al. *Clin Ophthalmol.* 2018;12:1559-1566†

OVERVIEW

STUDY DESIGN
Retrospective analysis to assess visual and patient-reported outcomes 6 months after bilateral LASIK treatment with Contoura® Vision incorporating the Layer Yolked Reduction of Astigmatism (LYRA) protocol

STUDY SITE(S)
Single center, United States

PATIENTS
Fifty (50) eyes of 25 patients; mean age 27.04 years (range 19-36 years)

SURGICAL METHODOLOGY
Topography-guided LASIK treatment with Contoura® Vision (LYRA protocol*)

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser and WaveLight® Topolyzer™ VARIO (Alcon Laboratories, Inc); WaveLight® FS200 Femtosecond Laser (Alcon Laboratories, Inc) or Moria M2™ Microkeratome (Moria Ophthalmic Instruments)

KEY ENDPOINT(S)
Patient-reported outcomes as measured by the Refractive Status and Vision Profile (RSVP) standardized survey, uncorrected visual acuity (UCVA), corrected distance visual acuity (CDVA), subjective patient results, and rates of regression

ANALYSIS AND CONCLUSIONS

After LASIK treatment with Contoura® Vision incorporating the LYRA protocol, 98% of eyes achieved 20/20 or better vision after primary correction, and all patients (100%) were either satisfied or very satisfied with their vision.

Results from this study support the theory that a more uniform cornea with LASIK (theoretically due to LYRA protocol) leads to both excellent objective vision outcomes and patient-reported outcomes; a larger study is needed to provide support for this conclusion.

†Manoj Motwani received an unrestricted IIT grant for this study from Alcon Laboratories, Inc.
**LYRA protocol requires the surgeon to use topography measured astigmatism and axis and an adjusted sphere power of the spherical equivalent difference in between the manifest and topography measured astigmatism.*

STUDY RESULTS

- Mean deviation of axis from manifest to topography measured was 11.46° (range 0-87°)

VISUAL ACUITY

- After primary correction using LASIK treatment with Contoura® Vision and the LYRA protocol, most (78%) of the eyes achieved UCVA of 20/15 and 98% of the eyes achieved an UCVA of ≥ 20/20 vision after 6 months (**Figure 1**)
- Nine eyes showed a postoperative change in refraction from plano which was corrected for with an enhancement during the first 7 months; after enhancement, 90% of uncorrected eyes achieved 20/15 vision and 100% achieved 20/20 vision (**Figure 1**)
- No patient showed any loss of lines of CDVA; most (45) of the eyes gained a line of vision by the end of the study

PATIENT-REPORTED OUTCOMES

- RSVP patient-related outcomes showed that all patients (100%) were either satisfied or very satisfied with their vision after LASIK treatment with Contoura® Vision using the LYRA protocol; most patients (21/25, 84%) were very satisfied (**Figure 2**)
- Postoperatively, on a numerical ordinal scale of 1–10 (where 10 is the best vision), 15 (60%) patients reported a vision score of 10, nine (36%) patients reported a score of 9, and one (4%) patient reported a score of 8
- When surveyed for comfort driving, glare, optical problems, physical and social functions, and dry eye symptoms postoperatively, patient scores were very low meaning they did not have issues with these symptoms

Figure 1. Uncorrected postoperative vision at 6 months pre-and post-enhancement in patients who underwent LASIK treatment with Contoura® Vision using the LYRA protocol.

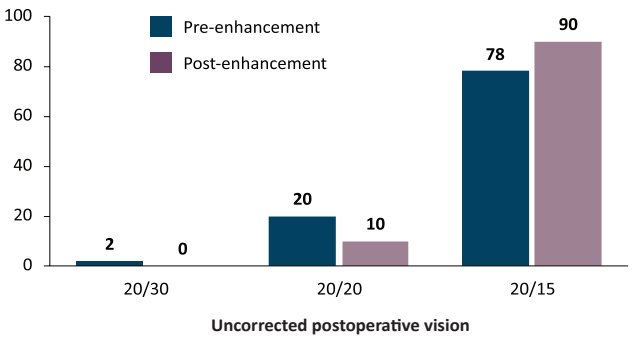
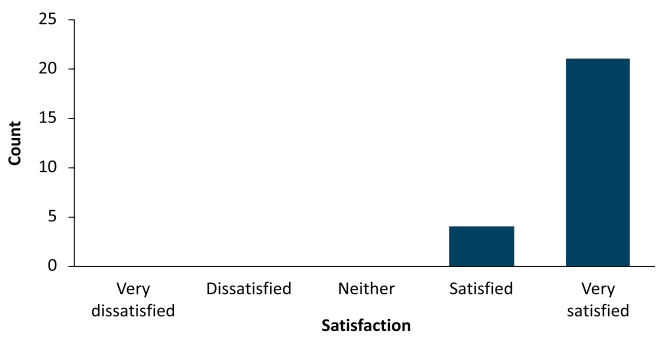


Figure 2. Satisfaction with vision in patients who underwent LASIK treatment with Contoura® Vision using the LYRA protocol.



Comparing Wavefront-Optimized, Wavefront-Guided and Topography-Guided Laser Vision Correction: Clinical Outcomes Using an Objective Decision Tree

Visual Acuity

Refractive Outcomes

Stonecipher et al. *Curr Opin Ophthalmol*. 2018;29:277-285

OVERVIEW

STUDY DESIGN

A literature review of types of LASIK ablation profiles is given. A previously established decision tree was used in a prospective study of patients receiving LASIK treatment in order to determine the optimal type of ablation treatment. Outcomes from this study were used to create an updated decision tree for surgeons to use in the future.

STUDY SITE(S)

Single center, United States

PATIENTS

One thousand forty-two (1042) eyes

SURGICAL METHODOLOGY

A previously established decision tree was used to determine type of LASIK ablation: Wavefront-optimized (WFO), wavefront-guided (CustomVue™), topographic-modified refraction (TMR), or topography-guided (Contoura® Vision) laser vision correction.

SURGICAL TECHNOLOGY

WaveLight® EX500 Excimer Laser and FS200 Femtosecond Laser (Alcon Laboratories, Inc.) or VISX CustomVue™ platform and Intralase femtosecond laser (Johnson & Johnson Vision)

KEY ENDPOINT(S)

Uncorrected visual acuity achieved 1 day postoperatively

ANALYSIS AND CONCLUSIONS

Wavefront-optimized, wavefront-guided (CustomVue™), topography-guided (Contoura® Vision) and topographic-modified LASIK treatments all produce excellent outcomes at the first postoperative day.

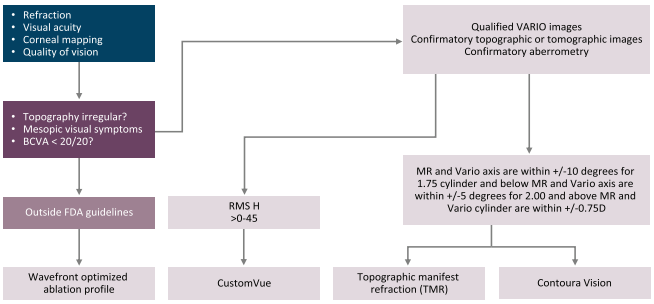
With an appropriate decision tree and nomogram adjustments, uncorrected visual acuities better than 20/20 can be achieved in a high percentage of patients.

STUDY RESULTS

DEVELOPMENT OF A DECISION TREE

- On the basis of the clinical data in the literature, a preliminary decision tree was designed to assist the surgeon in choosing the optimal ablation profile for a patient (WFO, CustomVue™, TMR, or Contoura® Vision) (**Figure 1**)
- The decision tree was developed for use with the WaveLight® EX500 Allegretto Excimer Laser in conjunction with the WaveLight® FS200 femtosecond laser
- Results from the branches of the decision tree were compared, and then these results were compared with an additional group of patients treated with a wavefront-guided ablation using the same decision tree and the VISX CustomVue™ platform with an Intralase femtosecond laser
- Evaluation of the decision tree was based on clinical results achieved at a single site with a single surgeon over a 12-month period
- The decision tree used for surgical planning yielded the following breakdown: WFO (n=430), CustomVue™ (n=27), TMR (n=169), and Contoura® Vision (n=416)

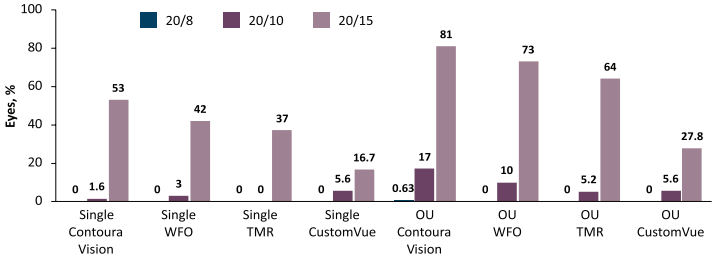
Figure 1. A decision tree for choosing the ablation profile for a LASIK patient.



VISUAL ACUITY AND REFRACTIVE OUTCOMES

- All groups performed similarly with regard to providing acuity of 20/20 or better at day one, but there were differences in the number of eyes achieving better than 20/20 vision (**Figure 2**)
  - Acuity of 20/15 or better was achieved in bilateral eyes in 81% of the Contoura® Vision group, 73% of the WFO group, 64% of the TMR group, and 28% of the CustomVue™ group
- The Contoura® Vision group showed a greater visual acuity for monocular results and binocular results against TMR (P=0.030, P=0.033), WFO (P=0.004, P<0.001) and CustomVue™ (P<0.001, P<0.001)
- Both TMR and WFO showed better visual acuity than the CustomVue™ group for monocular and binocular results (P=0.020, P=0.002; P=0.027, P=0.003)
- The groups were similar with regard to spherical equivalent refraction and astigmatism; however, the spherical equivalent refraction and the residual cylinder were slightly higher in the WFO group

Figure 2. Uncorrected visual acuity in single eyes and bilateral eyes at the post-operative 1-day visit reporting better outcomes than 20/20, by treatment group.



Consistent Comparison of Angle Kappa Adjustment Between Oculyzer and Topolyzer Vario Topography Guided LASIK for Myopia by EX500 Excimer Laser

Visual Acuity | Refractive Outcomes | Synclastic Adjustments

Sun et al. *Int J Ophthalmol.* 2018;11:662-667

OVERVIEW

STUDY DESIGN
Retrospective comparative study to evaluate and compare the uniformity of angle Kappa adjustment between Oculyzer™ and Topolyzer™ VARIO topography-guided LASIK for myopia

STUDY SITE(S)
China

PATIENTS
Two hundred ninety (290) consecutive eyes of 145 patients with myopia; mean age of 24.8 years in study group, 24.2 years in control group

SURGICAL METHODOLOGY
Topography-guided LASIK guided manually by Oculyzer™ topography (study group) or automatically by Topolyzer™ VARIO topography (control group)

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser, WaveLight® Topolyzer™ VARIO, WaveLight® Oculyzer™ (Alcon Laboratories, Inc); One Use-Plus Microkeratome (Moria Ophthalmic Instruments)

KEY ENDPOINT(S)
Horizontal and vertical synclastic adjustments; visual acuity (uncorrected and distance visual acuity [UDVA and CDVA]), refractive error (sphere, cylinder, spherical equivalent)

ANALYSIS AND CONCLUSIONS

This study found high consistency in angle Kappa adjustment guided manually by Oculyzer™ and automatically by Topolyzer™ VARIO during corneal refractive surgery with the WaveLight® EX500 excimer laser.

The authors concluded that manual adjustment guided by Oculyzer™ topography is recommended in cases where there is a mismatch between Topolyzer™ VARIO topography and the live image during surgery.

STUDY RESULTS

VISUAL ACUITY AND REFRACTIVE OUTCOMES

- There was no statistically significant difference between the Oculyzer™ and Topolyzer™ VARIO groups with respect to visual acuity and refractive outcomes preoperatively and at 1 day, 1 week, and 1 month postoperatively

SYNCLASTIC ADJUSTMENTS

- The relative positions of pupil centers with respect to corneal apex were registered by means of topographic Cartesian coordinates (dx_{ocu} and dy_{ocu} with Oculyzer™, dx_{topo} and dy_{topo} with Topolyzer™ VARIO)
- Topolyzer™ VARIO topography images were matched with live images with the Cartesian coordinates dx_{auto} and dy_{auto}, while Oculyzer™ was matched with coordinates dx_{manu} and dy_{manu}
- In the horizontal direction, 61 eyes (35.5%) were synclastic adjusted and 73 eyes (42.4%) were unadjusted in the study group, while 64 eyes (54.2%) were synclastic adjusted and 29 eyes (24.6%) were unadjusted in the control group **(Figure 1)**
- In the vertical direction, 95 eyes (55.2%) were synclastic adjusted and 50 eyes (29.1%) were unadjusted in the study group, while 78 eyes (66.1%) were synclastic adjusted and 20 eyes (16.9%) were unadjusted in the control group **(Figure 2)**
- The mean ratio of Cartesian coordinates in synclastic adjusted eyes in the study group (dx_{manu}/dx_{ocu} of 0.78±0.48, dy_{manu}/dy_{ocu} of 0.61±0.42) was similar with the control group (dx_{auto}/dx_{ocu} of 0.79±0.66, dy_{auto}/dy_{ocu} of 0.66±0.65) in both directions; there was no statistically significant difference between the two groups (P=0.951 and P=0.621, respectively)

Figure 1. Comparison of percentage of eyes in four groups between the study group (Oculyzer™) and the control group (Topolyzer™ VARIO) in the horizontal direction.

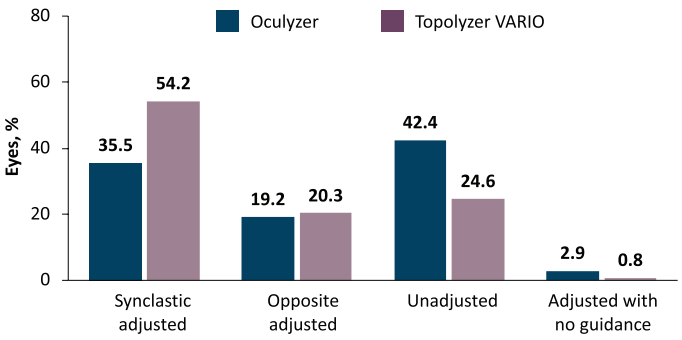
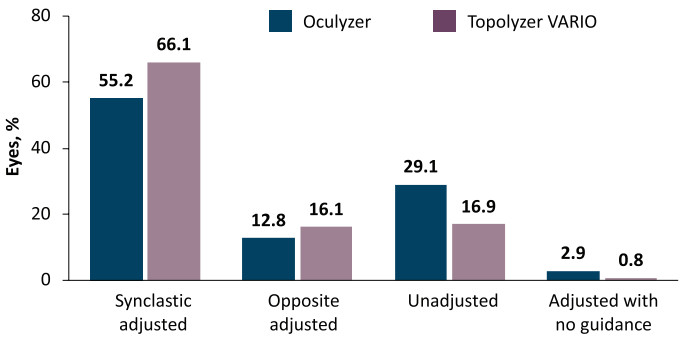


Figure 2. Comparison of percentage of eyes in four groups between the study group (Oculyzer™) and the control group (Topolyzer™ VARIO) in the vertical direction.



WaveLight® Contoura Topography-Guided Planning: Contribution of Anterior Corneal Higher-Order Aberrations and Posterior Corneal Astigmatism to Manifest Refractive Astigmatism

Wallerstein et al. *Clin Ophthalmol.* 2018;12:1423-1426

OVERVIEW

STUDY DESIGN
Presumed retrospective analysis to assess the contribution of anterior corneal higher-order aberrations (CHOAs) and posterior corneal astigmatism (PCA) to manifest refractive astigmatism (RA)

STUDY SITE(S)
Canada (Not specified)

PATIENTS
Comparison of RA to anterior corneal astigmatism (ACA) magnitude: 5,403 eyes; vectorial relationship between calculated CHOAs and ACA ellipses: 12 eyes

SURGICAL METHODOLOGY
Topography-guided planning with Contoura® Vision

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Comparison of RA to ACA magnitude; vectorial relationship between calculated CHOAs and ACA ellipses (no postsurgical endpoints)

ANALYSIS AND CONCLUSIONS

The vectorial relationship between calculated CHOAs and ACA ellipses does not support the theory that anterior CHOAs are the cause of the discrepancy between RA and ACA in eyes with significant ocular residual astigmatism.

Development of a more accurate nomogram for topography-guided ablations will require a full understanding of the contribution of anterior CHOAs to manifest RA, as well as the effects of PCA and remaining internal optics.

STUDY RESULTS

COMPARISON OF RA TO ACA MAGNITUDE

- A comparison of RA to ACA magnitude in 5,403 eyes demonstrated that 87% with-the-rule corneal cylinder eyes had less RA magnitude than ACA magnitude, and 89% against-the-rule corneal cylinder eyes had RA magnitude greater than ACA magnitude (**Figure 1**)
- Published data have shown that 87% of corneas have against-the-rule posterior corneal astigmatism, which, if additive to ACA, could explain decreased RA seen in most with-the-rule corneal cylinder eyes, and increased RA in most against-the-rule corneal cylinder eyes (**Figure 1**)
- The ACA axis location correlates to the amount of difference between RA and ACA (**Figure 1**), supporting the notion that the interaction between ACA and PCA impacts RA by modifying total corneal astigmatism

RELATIONSHIP BETWEEN CALCULATED CHOAS AND ACA ELLIPSES

- It has been theorized that anterior CHOAs are the cause of the discrepancy between RA and ACA in eyes with significant ocular residual astigmatism
- The authors of the current study developed an advanced algorithm that analyzed the Contoura® Vision CHOA ablation profile in 3D to accurately detail the CHOA ellipse (**Figure 2**)
- Looking at the vectorial relationship between calculated CHOAs and ACA ellipses in 12 eyes, the investigators found that 6 cases supported and 6 cases contradicted a previous theory that anterior CHOAs are the cause of the discrepancy between RA and ACA in eyes with significant ocular residual astigmatism
- RA encompasses all sources of astigmatism, from the anterior cornea to the brain, and Contoura® measured ACA does not consider manifest RA nor does it supply information on how anterior CHOAs influence RA
- Thus, development of a more accurate nomogram for topography-guided ablations will require a full understanding of the contribution of anterior CHOAs to manifest RA, as well as the effects of PCA and remaining internal optics

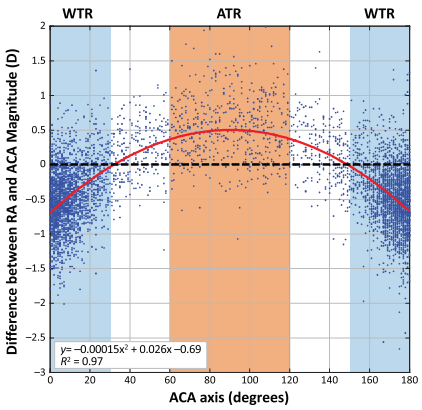


Figure 1. Difference between manifest refractive astigmatism (RA) and anterior corneal astigmatism (ACA) magnitude (i.e., RA magnitude – ACA magnitude) in relation to the ACA axis and quadratic fitting of this relationship (red curve). Data points (blue dots) above the black dashed line indicate eyes where the ACA is smaller than the RA magnitude, and below show eyes where the ACA is greater. Blue-shaded area: with-the-rule ACA eyes; red-shaded area: against-the-rule ACA eyes.

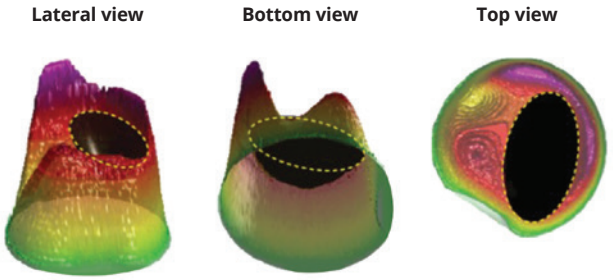


Figure 2. Objective algorithm-based identification of a 3D ellipsoid in a representative Contoura® Vision corneal higher-order aberration (CHOA) ablation profile visualized at different angles. The CHOAs' ellipse axis was calculated using the top view.

ACA, anterior corneal astigmatism; ATR, against-the-rule; RA, refractive astigmatism; WTR, with-the-rule.

Analysis of Planning Strategies in Primary Eyes Gaining a Line or More of Visual Acuity after Topography-Guided Laser In Situ Keratomileusis

Visual Acuity

Higher-Order Aberrations

De Stefano et al. *J Cataract Refract Surg.* 2019;45:321-327

OVERVIEW

STUDY DESIGN

Retrospective noncomparative case series to analyze planning strategies for eyes that gained 1 or more line of corrected distance visual acuity (CDVA) after topography-guided LASIK.

STUDY SITE(S)

Single clinic, United States

PATIENTS

Two hundred fifty-six (256) eyes of 158 patients; mean age 32.9 ± 9.2 years (range: 18-58 years)

SURGICAL METHODOLOGY

Topography-guided LASIK; LASIK flap diameter 9.5 mm, thickness 100 µm; tomography and wavefront aberrometry were used to assist in determining the cylinder magnitude and axis.

SURGICAL TECHNOLOGY

WaveLight® FS200 Femtosecond Laser (Alcon Laboratories, Inc) or the VisuMax® femtosecond laser (Carl Zeiss Meditec AG); WaveLight® Allegretto Wave® Eye-Q excimer laser (400 Hz, Alcon Laboratories, Inc); WaveLight® Allegretto Topolyzer (Alcon Laboratories, Inc); Pentacam HR tomographer (Oculus); Galilei G4 (Ziemer Ophthalmic Systems); Ladarwave 4000 aberrometer (Alcon Laboratories, Inc)

KEY ENDPOINT(S)

Uncorrected distance visual acuity (UDVA), manifest refraction, CDVA, and tomography and aberrometry scans evaluated at 3 months

ANALYSIS AND CONCLUSIONS

Topography-guided LASIK treatment produced a significant improvement in vision, with more than 25% of eyes having an improvement in CDVA of at least 1 full line.

Topography-guided LASIK treatment was associated with a statistically significant induction of whole-eye aberration, but this outcome was of minimal magnitude and in the authors' view, probably not highly contributory to final visual quality.

STUDY RESULTS

VISUAL ACUITY

- Three months after topography-guided LASIK treatment, UDVA was 20/20 or better in 95.7% of cases and 20/15 or better in 81.4% of cases (**Figure 1**)
- Compared with the preoperative CDVA, postoperative CDVA showed 66 eyes (25.6%) gained at least 1 full line (5 or more letters), whereas 6 eyes (2.3%) lost 1 line
- Of the patients that gained at least 1 line of CDVA, the topography measured and manifest cylinder axes differed by less than 15 degrees in 59% (39 eyes), between 15 degrees and 30 degrees in 18% (12 eyes), and by more than 30 degrees in 23% (15 eyes)
- When the topography measured and manifest cylinder axes differed by at least 5 degrees (41 eyes), the measured axis was treated in 79%, 75%, and 73% of eyes, respectively
- In eyes with higher measured cylinder, 75% were treated between the manifest and topography measured cylinder magnitude values, with 7% at full measured value; when the manifest value was greater, 60% were treated at the total measured value and 40% in between

OPTICAL PHENOMENA

- **Table 1** shows the overall measurements of the preoperative and postoperative higher-order aberrations (HOAs); although the magnitude was small, there was a statistically significant increase in coma and spherical aberration as well as in the total HOA root mean square (RMS)
- When patients were divided into those with improved CDVA vs those with no improvement, the former showed a greater reduction in the magnitude of astigmatic aberration (P=0.02) and a lesser increase in coma (P=0.04) and total HOA RMS (P=0.02)

Figure 1. Accuracy of topography-guided LASIK (CDVA at 3 months). The dark blue bar at the left indicates the percentage of eyes within ±0.50 D of the target refraction.

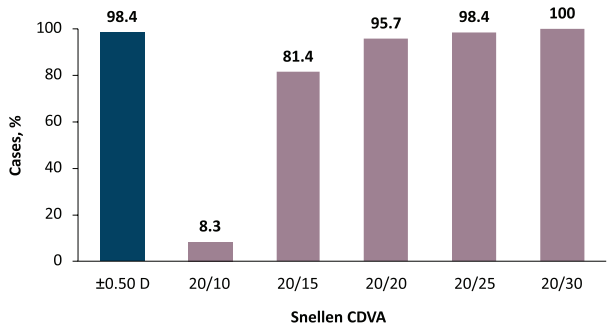


Figure 2. Preoperative and 3-month postoperative higher-order aberrations (HOAs) measured with the pupil diameter set to 5.5 mm.

HOA	Mean (µm) ± SD	P-value*
Mean defocus ± SD		
Preoperative	4.50 ± 2.00	<0.001
Postoperative	0.46 ± 0.37	
Difference	4.04	
Mean astigmatism ± SD		
Preoperative	0.61 ± 0.47	<0.001
Postoperative	0.30 ± 0.20	
Difference	0.31	
Mean coma ± SD		
Preoperative	0.15 ± 0.09	<0.001
Postoperative	0.19 ± 0.11	
Difference	-0.04	

HOA	Mean (µm) ± SD	P-value*
Mean SA ± SD		
Preoperative	0.10 ± 0.07	<0.001
Postoperative	0.12 ± 0.09	
Difference	-0.02	
Mean other ± SD		
Preoperative	0.16 ± 0.07	0.883
Postoperative	0.16 ± 0.06	
Difference	0.00	
Mean RMS ± SD		
Preoperative	0.26 ± 0.10	<0.001
Postoperative	0.29 ± 0.11	
Difference	-0.04	

Difference, mean difference, preoperative versus postoperative; HOA, higher-order aberration; RMS, root mean square; SA, spherical aberration.
**Preoperative versus postoperative.*

Longitudinal and Regional Non-uniform Remodeling of Corneal Epithelium After Topography-Guided FS-LASIK

Visual Acuity

Corneal Epithelium

Fan et al. *J Refract Surg.* 2019;35:88-95

OVERVIEW

STUDY DESIGN
Prospective study to observe epithelial remodeling induced by topography-guided LASIK using spectral-domain optical coherence tomography

STUDY SITE(S)
Single surgical center, China

PATIENTS
Forty-three (43) eyes of 22 patients; mean age: 27.51 ± 7.15 years (range: 19-42 years)

SURGICAL METHODOLOGY
Topography-guided LASIK treatment; 120 µm thick and 8.5 mm diameter flap; 6.5 mm optical zone; 1.25 mm transition zone; cylinder amount adjusted to match topography measured amount and axis, sphere adjusted based on Alcon nomogram.

SURGICAL TECHNOLOGY
WaveLight® FS200 Femtosecond Laser and EX500 Excimer Laser (Alcon Laboratories, Inc); WaveLight® Topolyzer™ VARIO (Alcon Laboratories, Inc.); RTVue XR anterior segment OCT (Optovue)

KEY ENDPOINT(S)
Epithelial thickness, refractive outcomes at 1, 3 and 6 months postoperatively

ANALYSIS AND CONCLUSIONS

Wide epithelial remodeling was observed after topography-guided LASIK; this uneven corneal epithelial redistribution did not affect refractive stability.

A comprehensive investigation of the corneal epithelial remodeling associated with topography-guided LASIK treatment is recommended for refining ablation algorithms and refractive procedures.

STUDY RESULTS

EPITHELIAL REMODELING

- The average epithelial thickness in different zones before and after topography-guided LASIK treatment is shown in **Figure 1**.
  - One month postoperatively, significant increases in epithelial thickness were observed in the central and paracentral zones (both P<0.05), whereas a non-significant decrease was observed in the midperipheral zone
  - From 1 to 3 months after surgery, epithelial thickness in the central zone increased significantly (P<0.05) but was unaltered in the paracentral and mid-peripheral zones
  - No statistically significant changes were observed in all zones between 3 and 6 months after surgery
- There was a statistically significant increase in epithelial thickness in all inner nine sections at one month (all P<0.001), with the greatest increase seen in the inferotemporal section; this remained at 6 months with no significant change between 1 and 6
- Change of epithelial thickness in the central and paracentral inferotemporal zones at 6 months showed statistically significant correlations with the corrected spherical equivalent, ablation depth, and ablation ratio (all P<0.05)

VISUAL ACUITY

- Six months postoperatively, mean uncorrected distance visual acuity (UDVA) was -0.071 ± 0.071 logMAR (range: -0.079 to 0.097 logMAR); no significant regression was observed between 1 and 6 months after surgery (P>0.05)
- Cumulative Snellen UDVA was 20/20 in 95% of eyes 6 months postoperatively, compared with 91% preoperatively (**Figure 2**)

Figure 1. Changes in corneal epithelial thickness over 6 months postoperatively.

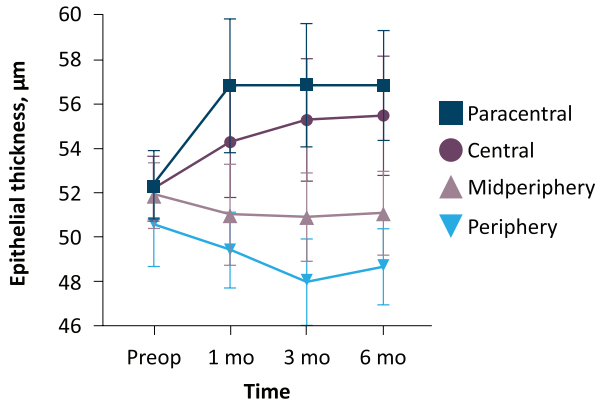
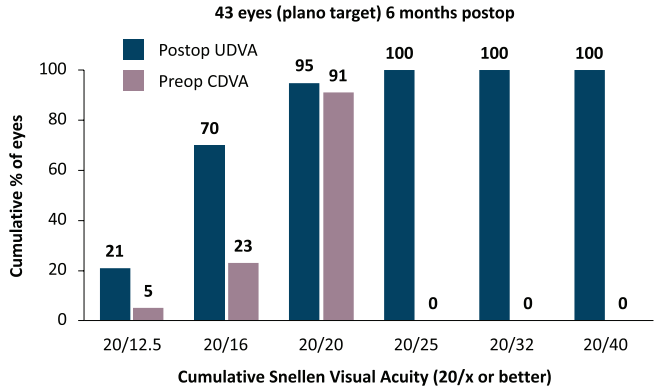


Figure 2. Uncorrected distance visual acuity 6 months postoperatively.



Topography-Guided Versus Wavefront-Optimized Laser In Situ Keratomileusis for Myopia: Surgical Outcomes

Kim et al. *J Cataract Refract Surg.* 2019;45:959-965

Visual Acuity

Higher-Order Aberrations

Refractive Outcomes

OVERVIEW

STUDY DESIGN
Prospective contralateral case study to compare the outcomes of topography-guided and wavefront-optimized surgery in patients undergoing LASIK for myopia

STUDY SITE(S)
Single clinic, South Korea

PATIENTS
Eighty-six (86) eyes of 43 patients

SURGICAL METHODOLOGY
Topography-guided LASIK (Contoura® Vision) or wavefront-optimized LASIK in contralateral eyes; manifest refraction adjusted using Alcon's nomogram; flap diameter 9.0 mm; thickness 105 mm

SURGICAL TECHNOLOGY
WaveLight® FS200 Femtosecond Laser and EX500 Excimer Laser (Alcon Laboratories, Inc); WaveLight® Topolyzer™ VARIO and WaveLight® Analyzer (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), higher-order aberrations (HOAs) 3 months postoperatively

ANALYSIS AND CONCLUSIONS

Both topography-guided LASIK and wavefront-optimized LASIK treatments achieved predicted refractive and visual outcomes, but topography-guided LASIK technique induced fewer HOAs and decreased trefoil, corneal total HOAs and coma.

Further studies should be performed to identify specific situations in which topography-guided LASIK would be the preferred surgical approach.

STUDY RESULTS

VISUAL ACUITY AND REFRACTIVE OUTCOMES

- With respect to visual acuity, both topography-guided and wavefront-optimized LASIK treatments were equally efficacious: 39 eyes (90.7%) in both groups had a UDVA of 0.0 logMAR (20/20) or better after 3 months (**Figure 1**)
- The mean MRSE at 3 months was –0.30 ± 0.72 D in the wavefront-optimized group and –0.24 ± 0.72 D in the topography-guided group (P=0.349)
- Thirty-five eyes (81.4%) in both groups had an MRSE within ±0.75 D of emmetropia at 3 months (**Figure 2**)
- Refractive astigmatism was <0.25 D in 27 eyes (62.8%) in the wavefront-optimized group and 27 eyes (62.8%) in the topography-guided group, and <0.50 D in 34 eyes (79.1%) and 37 eyes (86.1%) in these two groups, respectively
- Based on vector analysis, the change in astigmatism was similar between wavefront-optimized and topography-guided. Astigmatism was decreased postoperatively; however, there was slight overcorrection of astigmatism in both groups

HIGHER-ORDER ABERRATIONS

- There was significant induction of ocular (whole eye) total HOAs, coma and spherical aberration in both the topography-guided and wavefront-optimized groups at 3 months, however, ocular trefoil decreased significantly in the topography-guided group (P=0.038).
- For corneal HOAs, topography-guided ablation induced significantly lower total HOAs (P=0.013) and coma (P=0.003) than wavefront-optimized ablation

Figure 1. Visual outcomes 3 months postoperatively in the **A**) topography-guided group and **B**) wavefront-optimized group.

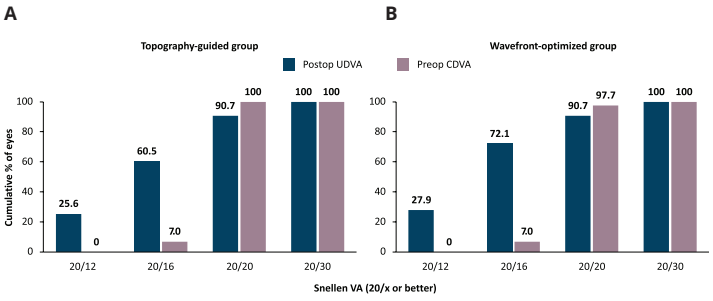
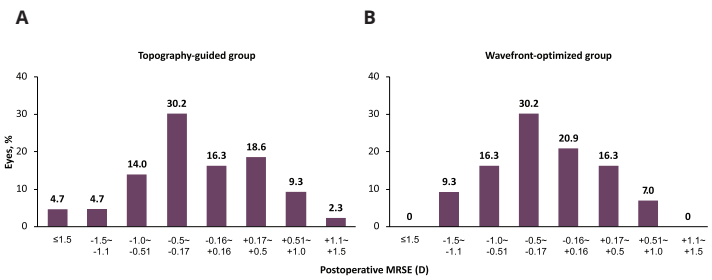


Figure 2. Accuracy of manifest refraction spherical equivalent (MRSE) 3 months postoperatively in the **A**) topography-guided group and **B**) wavefront-optimized group.



Comparison of Wavefront-Optimized Ablation and Topography-Guided Contoura Ablation with LYRA Protocol in LASIK

Visual Acuity | Higher-Order Aberrations | Refractive Outcomes

Ozulken et al. *J Refract Surg.* 2019;35:222-229

OVERVIEW

STUDY DESIGN
Comparative contralateral eye study to compare refractive outcomes and aberration data for topography-guided LASIK with Contoura® Vision or wavefront-optimized (WFO) LASIK for patients with myopia or myopic astigmatism

STUDY SITE(S)
Single center, Turkey

PATIENTS
Sixty-four (64) eyes of 32 patients; mean age 27.5 ± 4.9 years (range 19 to 41 years)

SURGICAL METHODOLOGY
Topography-guided LASIK with Contoura® Vision using the Layer Yolked Reduction of Astigmatism (LYRA)* protocol; wavefront-optimized LASIK treatment; flap diameter 9 mm, thickness 120 µm and optical diameter 6.5-7 mm.

SURGICAL TECHNOLOGY
WaveLight® FS200 Femtosecond Laser, WaveLight® EX500 Excimer Laser, WaveLight® ALLEGRO Topolyzer®, and WaveLight® Oculyzer™ II (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Visual acuity, refractive outcomes, total corneal higher order aberrations (HOAs) including vertical and oblique astigmatism, coma, trefoil, spherical aberration, and Q value 3 months postoperatively

ANALYSIS AND CONCLUSIONS

Statistically similar visual outcomes were achieved with LASIK treatment incorporating either topography-guided ablation with Contoura® Vision or WFO ablation.

However, the Contoura® Vision protocol was associated with a significantly lower induction in vertical and horizontal coma and smaller amount of tissue ablation compared to WFO ablation.

**LYRA protocol requires the surgeon to use topography measured astigmatism and axis and an adjusted sphere power of the spherical equivalent difference in between the manifest and topography measured astigmatism*

STUDY RESULTS

VISUAL ACUITY AND REFRACTIVE OUTCOMES

- In the WFO group, 92% of eyes achieved an uncorrected distance visual acuity (UDVA) of 20/20 or better at 3 months postoperatively, compared with 96% in the topography-guided Contoura® Vision group (**Figure 1**)
- No patient lost lines of visual acuity, and there were no significant differences between the two procedures or postoperative visual acuity values (UDVA and corrected distance visual acuity (CDVA)) and refractive errors (spherical and cylindrical)
- When the surgical predictability was defined as percentage of eyes corrected to ±0.50 D of the intended correction, 94% of eyes in the WFO group and 97% of eyes in the topography-guided Contoura® Vision group met this criterion
- Both procedures had similar predictability for manifest refraction spherical equivalent within ±0.50 D of emmetropia

HIGHER-ORDER ABERRATIONS

- Preoperative corneal HOAs and Q values (asphericity) were similar between the groups (P>0.05) (**Table 1**)
- At 3 months postoperatively, vertical and horizontal coma values in the WFO group were statistically significantly higher compared to the topography-guided Contoura® Vision group (P=0.013 and 0.020, respectively)
- Less stromal tissue was ablated in the topography-guided Contoura® Vision group (60.5 ± 13.5) compared to the WFO group (75.7 ± 13.5 µm) (P<0.001)

Figure 1. Postoperative uncorrected distance visual acuity 3 months postoperatively in 64 eyes.

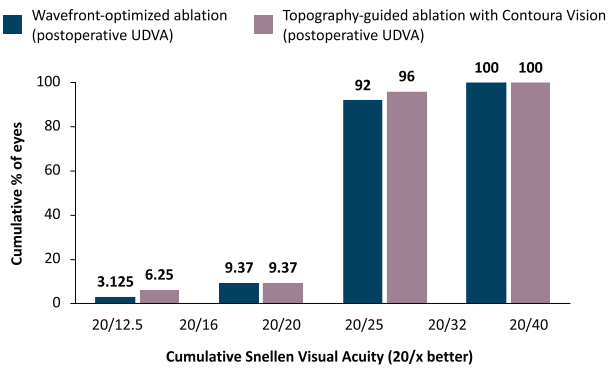


Table 1. Comparison of preoperative and postoperative (3 months) corneal aberration and asphericity data. Adapted from Ozulken et al. *J Refract Surg.* 2019;35:222-229.

Parameter	WFO[a]	TG (Contoura Vision)[a]	P-value[b] (intergroup)
Vertical astigmatism (Z^{-2}_2)			
Difference at 3 months postoperatively	0.337 ± 0.255	0.369 ± 0. 279	0.293
P-value[b] (intragroup)	0.002	0.001	-
Oblique astigmatism (Z^{-2}_2)			
Difference at 3 months postoperatively	0.118 ± 0.181	0.123 ± 0. 203	0.505
P-value[b] (intragroup)	0.013	0.016	-
Coma (Z^{1}_3)			
Difference at 3 months postoperatively	0.480 ± 0.401	0.090 ± 0. 279	0.016
P-value[b] (intragroup)	0.008	0.260	-
Coma (Z^{1}_3)			
Difference at 3 months postoperatively	0.393 ± 0.443	0.045 ± 0.279	0.018
P-value[b] (intragroup)	0.011	0.364	-

Parameter	WFO[a]	TG (Contoura Vision)[a]	P-value[b] (intergroup)
Trefoil (Z^{3}_3)			
Difference at 3 months postoperatively	0.025 ± 0.237	-0.051 ± 0.180	0.396
P-value[b] (intragroup)	0.556	0.136	-
Trefoil (Z^{3}_3)			
Difference at 3 months postoperatively	0.033 ± 0.289	0.006 ± 0.189	0.338
P-value[b] (intragroup)	0.288	0.601	-
Spherical aberration (D)			
Difference at 3 months postoperatively	0.070 ± 0.447	0.067 ± 0.366	0.815
P-value[b] (intragroup)	0.536	0.588	-
Q value			
Difference at 3 months postoperatively	-0.421 ± 0.419	0.448 ± 0.402	0.480
P-value[b] (intragroup)	0.088	0.061	-

WFO, wavefront-optimized; TG, topography-guided ablation with Contoura Vision; D, diopters; intergroup, comparison of WFO and TG profiles; intragroup, comparison of preoperative and postoperative data. [a]Values are expressed as mean ± standard deviation unless otherwise noted. [b]Paired-samples t test.

Topography-Guided Excimer Treatment Planning: Contribution of Anterior Corneal Coma to Ocular Residual Astigmatism

Wallerstein et al. *J Cataract Refract Surg.* 2019;45:878-880

OVERVIEW

STUDY DESIGN
Presumed retrospective analysis to describe anterior corneal coma and ocular residual astigmatism (ORA) in a large cohort of preoperative laser vision correction eyes, and to investigate correlations between axis and magnitude of anterior corneal coma and ORA

STUDY SITE(S)
Canada (Not specified)

PATIENTS
Preoperative data was reviewed in 37,454 eyes; a sub-group of 101 eyes with <0.10 D and refractive astigmatism of >0.25 D.*

SURGICAL METHODOLOGY
Anterior corneal astigmatism and vertical and horizontal anterior corneal coma (Zernike C7 and C8) data were collected from topography-guided treatment planning for Contoura® Vision

SURGICAL TECHNOLOGY
WaveLight® Topolyzer™ VARIO

KEY ENDPOINT(S)
Anterior corneal astigmatism, anterior corneal coma, ORA, refractive astigmatism; correlations between axis and magnitude of anterior corneal coma and ORA

ANALYSIS AND CONCLUSIONS

Anterior corneal coma is not a significant cause of the observed discrepancy between anterior corneal astigmatism and refractive astigmatism or ORA; the main contributors to the difference must stem from the posterior cornea and other factors.

Posterior corneal astigmatism likely contributes more to ORA than anterior corneal coma in primary eyes and should be taken into account in cases where treatment is based solely on topography-measured anterior corneal astigmatism.

**For this subgroup, since ORA virtually had no contribution from anterior corneal astigmatism, it should equal the refractive astigmatism and this group was identified as the ORA ≈ refractive astigmatism group*

STUDY RESULTS

REFRACTIVE, CORNEAL AND OCULAR VARIABLES

- The eyes in this study had a mean refractive astigmatism of 0.50 ± 0.26 (SD), anterior corneal astigmatism of 0.06 ± 0.02 D, ORA of 0.51 ± 0.25 D, and anterior corneal coma of 0.27 ± 0.13 mm
- **Table 1** shows the characteristics of 10 randomly selected ORA ≈ refractive astigmatism eyes: ORA and refractive astigmatism were found to be equal (P=0.9998)

AXIS AND MAGNITUDE CORRELATIONS

- No significant relationship and a quasi-null correlation coefficient were found between anterior corneal coma and ORA magnitude (R=0.025, P=0.8042) (**Figure 1A**) and between anterior corneal coma and ORA axis (R=0.019, P=0.8453) (**Figure 1C**)
- No clinically meaningful magnitude or axis correlations were found between anterior corneal coma and ORA when including all 37,454 eyes with quasi-null correlation coefficients (R=0.030 and R=0.017; **Figure 1B and 1D**, respectively), although the magnitude correlation was statistically significant because of the very large sample of eyes
- ORA was against-the-rule in 85% of ORA ~~ refractive astigmatism eyes and 86% in the entire cohort; anterior corneal coma was against-the-rule in only 27.6% of ORA ~~ refractive astigmatism eyes and 28.3% in the entire cohort
- Overall, no meaningful correlation was found between anterior corneal coma and ORA in the ORA ~~ refractive astigmatism eyes or in the entire cohort

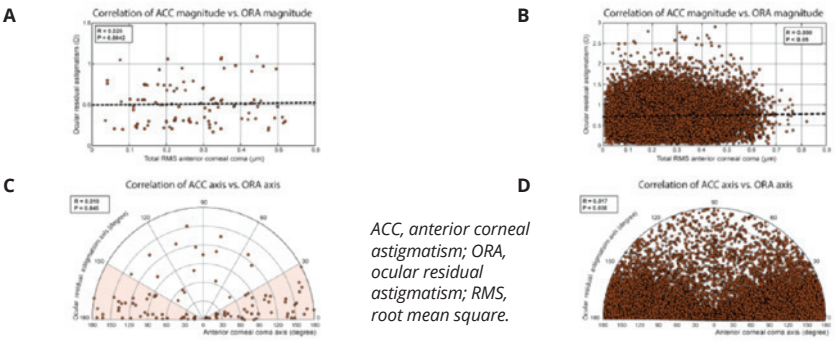
Table 1. Refractive, corneal, and ocular variables for a sample set of 10 ORA ≈ refractive astigmatism eyes.

		RA		ACA		ORA		ACC		Total ACC	
ID	Eye	Mag	Axis	Mag	Axis	Mag	Axis	C7	C8	RMS	Axis
4	OD	0.75	1	0.03	133	0.75	178	0.06	0.13	0.143	25
17	OS	0.50	164	0.02	133	0.49	15	−0.36	0.13	0.383	110
35	OS	0.25	155	0.06	143	0.20	21	−0.02	0.08	0.082	166
42	OD	1.00	1	0.03	004	0.97	179	−0.35	0.30	0.461	131
56	OD	0.50	108	0.10	140	0.46	78	0.21	0.22	0.304	136
61	OS	0.25	3	0.03	20	0.23	179	−0.06	0.20	0.209	163
74	OS	0.50	171	0.05	22	0.48	12	0.31	0.32	0.446	136
82	OS	0.50	180	0.05	86	0.55	180	−0.45	0.06	0.454	82
91	OD	1.00	12	0.10	130	1.06	14	0.23	0.26	0.347	41
100	OS	0.75	180	0.07	47	0.76	177	0.01	0.04	0.041	14

*ACA, anterior corneal astigmatism; ACC, anterior corneal coma; C7, vertical coma (Zernike); C8, horizontal coma (Zernike); Mag, magnitude; ORA, ocular residual astigmatism; RA, refractive astigmatism; RMS, root mean square. *Reported using the positive cylinder notation.*

Figure 1. Results in 101 eyes with anterior corneal astigmatism of 0.10 diopter (D) or less and refractive astigmatism of 0.25 D or more (**A** and **C**), and in the entire cohort of 37,454 eyes (**B** and **D**). **A**. Ocular residual astigmatism in relation to total RMS anterior corneal coma and linear fitting of this relationship (black dashed line). **B**. Ocular residual astigmatism in relation to total RMS anterior corneal coma and linear fitting of this relationship (black dashed line). **C**. Polar plot of the ORA axis (angle coordinates in the polar plot) in relation to total RMS anterior corneal coma axis (radius coordinates in the polar plot). **D**. Polar plot of the ORA axis in relation to total RMS anterior corneal coma axis. Figure adapted from Wallerstein et al. *J Cataract Refract Surg.* 2019;45:878-880.

Anterior corneal astigmatism ≤ 0.10 D (N=101) | **Entire cohort (N = 37,454)**



ACC, anterior corneal astigmatism; ORA, ocular residual astigmatism; RMS, root mean square.

Primary Topography-Guided LASIK: Treating Manifest Refractive Astigmatism Versus Topography-Measured Anterior Corneal Astigmatism

Wallerstein et al. *J Refract Surg.* 2019;35:15-23

OVERVIEW

STUDY DESIGN
Retrospective analysis of those receiving topography-guided LASIK with Contoura® Vision to investigate whether topography measured anterior corneal astigmatism (ACA) leads to better refractive outcomes than use of measured manifest refractive astigmatism (RA) axis in eyes with primary myopic astigmatism

STUDY SITE(S)
Canada (Not specified); electronic medical record database

PATIENTS
1,274 topography-guided treated eyes (905 manifest RA axis; 369 topography-measured ACA axis); manifest vs ACA axis difference of 5-45 degrees

SURGICAL METHODOLOGY
Contoura® Vision LASIK treatment based on the manifest RA axis or based on the topography-measured ACA axis; 8.5- or 9.5-mm corneal flaps; 6.5mm OZ

SURGICAL TECHNOLOGY
WaveLight® EX500 Excimer Laser with WaveLight® Topolyzer™ VARIO (Alcon Laboratories, Inc.); Intralase iFS® femtosecond laser (Abbott Medical Optics, Inc.) or Z15, Z16, or Z18 Hansatome microkeratome (Bausch & Lomb)

KEY ENDPOINT(S)
Visual acuity (uncorrected distance visual acuity [UDVA], corrected distance visual acuity [CDVA], refractive accuracy, predictability, and Alpins cylinder vector analysis 1 and 3 months postoperatively; safety

ANALYSIS AND CONCLUSIONS

This large cohort study demonstrated excellent results for LASIK with Contoura® Vision treated on the topography-measured ACA axis in eyes with preoperative refractive astigmatism of >0.75D.

However, treating on the ACA axis resulted in inferior refractive and visual outcomes compared to treating on the clinical manifest RA axis, and these lesser outcomes were more evident when manifest RA to ACA axis discrepancy was >20° in eyes treated on the ACA axis.

STUDY RESULTS

VISUAL ACUITY

- Of the 1,274 eyes, 86.1% had a RA versus ACA axis difference ranging between 5° and 20° (small angle group), and 13.9% had a discrepancy ranging between 21° and 45° (large angle group)
- In the small angle group, cumulative postoperative UDVA was comparable in eyes treated on the RA or ACA axes; both treatment modalities achieved 20/20 UDVA in 90% of eyes (**Figure 1**)
- In the large angle group, cumulative post-operative unilateral UDVA was 20/20, 20/25, 20/30, and 20/40 in 89%, 99%, 100%, and 100%, respectively, in RA axis treated eyes, compared to 74%, 91%, 96%, and 98%, respectively, in ACA axis treated eyes (P<0.05) (**Figure 1**)

REFRACTIVE AND OTHER OUTCOMES

- In the large angle group, a higher proportion of RA axis treated eyes than ACA axis treated eyes had a defocus equivalent of 0.25 (65.6% vs 52.7%), 0.50 (86.9% vs 80.0%), and 0.75 (97.5% vs 90.9%) D or less (P<0.05 for all); results between treatment modalities were comparable in the small angle group (**Figure 2**)
- In the large angle group, a greater number of ACA axis treated eyes had residual astigmatism of 0.75 D or greater compared to RA axis treated eyes (18.2% vs 7.4%; P=0.03)
- In both the small and large angle groups, the incidence of absolute angle of error greater than 15° was much higher in the ACA axis treated eyes compared to refractive astigmatism axis treated eyes (small angle group: 8.6% vs 4.2%, P=0.0039; large angle group: 25.4% vs 8.1%, P=0.0037)
- In the small angle group, 0.6% of RA axis treated eyes received a subsequent laser retreatment compared to 2.2% in ACA axis treated eyes; in the large angle group, 1.6% of RA axis eyes received an enhancement compared to 11.0% in ACA axis treated eyes (P<0.05)

Figure 1. Cumulative unilateral postoperative Snellen uncorrected distance visual acuity (UDVA) of refractive astigmatism (RA) axis and anterior corneal astigmatism (ACA) axis treated eyes, compared with preoperative corrected distance visual acuity (CDVA)

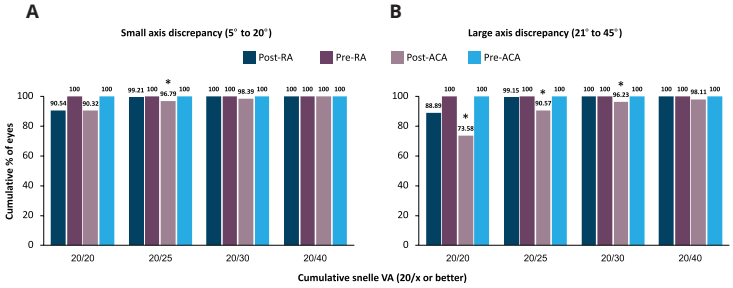
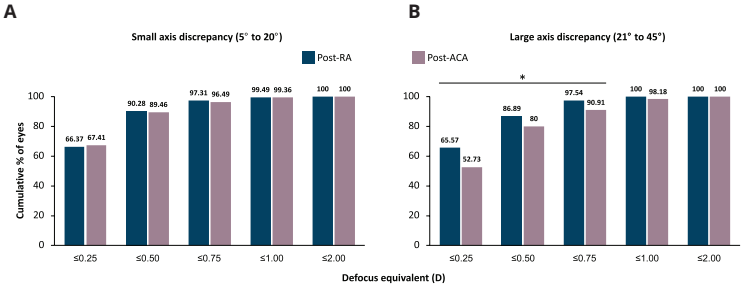


Figure 2. Cumulative defocus equivalent histograms of refractive astigmatism (RA) axis and anterior corneal astigmatism (ACA) axis treated eyes.



A Randomized Comparative Study of Topography-Guided Versus Wavefront-Optimized FS-LASIK for Correcting Myopia and Myopic Astigmatism

Visual Acuity | Higher-Order Aberrations | Refractive Outcomes

Zhang et al. *J Refract Surg.* 2019;35:575-582

OVERVIEW

STUDY DESIGN
Prospective, randomized contralateral study to compare clinical outcomes between topography-guided customized ablation treatment (TCAT) and wavefront-optimized (WFO) LASIK in fellow eyes of myopic patients

STUDY SITE(S)
Single clinic, China

PATIENTS
Four hundred thirty-two (432) eyes of 216 patients; mean age 28.0 ± 6.9 years (range: 18 to 47 years)

SURGICAL METHODOLOGY
Topography-guided (TCAT) LASIK treatment in one eye, WFO LASIK in fellow eye; refraction for TCAT followed the topography-modified refraction scheme (cyl magnitude and axis from topography with adjusted sphere) and WFO used the subjective manifest; flap thickness of 110 µm; flap diameter of 8.5 to 9 mm; optic zone of 6 to 6.5 mm with a 1.25-mm transition zone

SURGICAL TECHNOLOGY
WaveLight® FS200 femtosecond laser, WaveLight® EX500 excimer laser and WaveLight® Topolyzer Vario (Alcon Laboratories, Inc); Sirius aberrometer (CSO)

KEY ENDPOINT(S)
Refractive and visual outcomes and corneal aberrations

ANALYSIS AND CONCLUSIONS

Topography-guided (TCAT) LASIK treatment in normal corneas induced less corneal optical path difference, fewer higher order aberrations, and less coma than WFO LASIK.

However, the topography-modified refraction in TCAT was not as accurate as the manifest refraction in WFO, especially in astigmatism correction, suggesting the need for a more accurate design method to improve postoperative visual acuity and refractive outcomes.

STUDY RESULTS

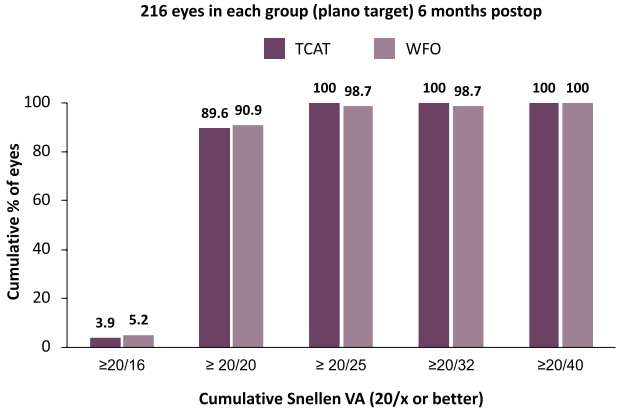
VISUAL ACUITY

- At 1 month postoperatively, uncorrected distance visual acuity (UDVA) was 20/20 or better in 89.4% of eyes in the TCAT group and 93.5% of eyes in the WFO group (P<0.05); UDVA was similar between the groups at 6 months (**Figure 1**)
- With respect to corrected distance visual acuity, 12.5% of the eyes in the TCAT group and 15.3% in the WFO group gained one line at 1 month, while 19.5% of the eyes in the TCAT group and 15.3% in the WFO group gained one line at 6 months

AXIS AND MAGNITUDE CORRELATIONS

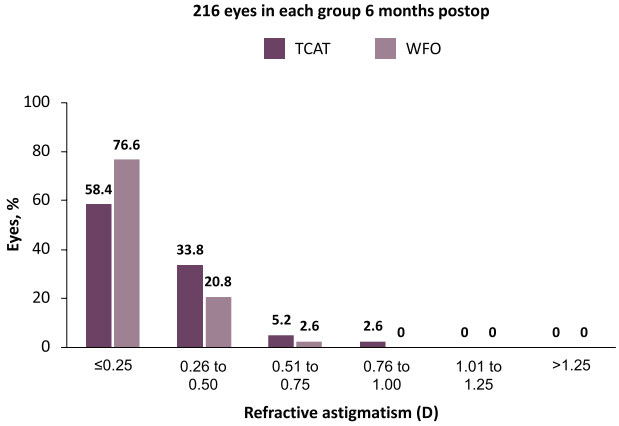
- Postoperative residual manifest refractive spherical equivalent (MRSE) was similar between the groups; at 6 months, residual MRSE within ±0.13 D was achieved in 59.7% of eyes in the TCAT group compared to 64.9% of eyes in the WFO group
- Postoperative residual refractive astigmatism in the TCAT group was greater than in the WFO group (P<0.05); at 6 months, 58.4% of eyes in the TCAT group and 76.6% of eyes in the WFO group had refractive residual astigmatism of 0.25 D or less (**Figure 2**)
- The optical path difference and root mean square of higher order aberrations and coma were significantly lower in eyes in the TCAT group at 1 and 6 months postoperatively (P<0.05)

Figure 1. Uncorrected distance visual acuity 6 months after surgery.



TCAT, topography-guided customized ablation treat¬ment; WFO, wavefront-optimized treatment

Figure 2. Refractive astigmatism accuracy 6 months after surgery.



TCAT, topography-guided customized ablation treat¬ment; WFO, wavefront-optimized treatment

Clinical Outcomes after Topography-Guided LASIK: Comparing Results Based on a New Topography Analysis Algorithm to Those Based on the Manifest Refraction

Visual Acuity

Refractive Outcomes

Lobanoff et al. *J Cataract Refract Surg.* 2020 Mar 11. Epub ahead of print.

OVERVIEW

STUDY DESIGN
Double-arm, non-masked, non-randomized retrospective chart review to compare outcomes after topography-guided LASIK planned with either manifest refraction or a new topography analysis system

STUDY SITE(S)
Four (4) clinics in the United States

PATIENTS
Matched group of 317 eyes in the manifest group and 323 eyes in the analytic (Phorcides) group

SURGICAL METHODOLOGY
Topography-guided LASIK with Contoura® Vision using either manifest refraction or an ablation profile determined by the Phorcides Analytic Engine

SURGICAL TECHNOLOGY
WaveLight® Topolyzer™ VARIO system (Alcon Laboratories, Inc)

KEY ENDPOINT(S)
Residual refractive error (sphere and cylinder) and visual acuity (uncorrected distance visual acuity [UDVA], corrected distance visual acuity [CDVA]) at least 2 months after LASIK

ANALYSIS AND CONCLUSIONS

This study demonstrated that using the Phorcides Analytic Engine for topography-guided surgery planning increased the likelihood of 20/16 UDVA and CDVA compared with using the manifest refraction.

Of the 640 eyes in this study, only 24% would have met the criteria for the FDA Contoura® Vision study; the population in this study is likely more representative of that seen in typical clinical experience.

STUDY RESULTS

REFRACTIVE OUTCOMES

- There were statistically significant differences in spherical equivalent fraction by surgeon (P=0.01) and by group (P<0.01), but no interaction effect; mean differences were less than 0.07 D, which were considered clinically insignificant
- The percentage of eyes within 0.25 D of plano was not statistically significantly different between groups (84.9% in the manifest group vs. 81.4% in the analytic group)
- There was no statistically significant difference in residual refractive cylinder between groups; 96% of eyes in both groups had a refractive cylinder less than 0.50 D after surgery (**Figure 1**)

VISUAL ACUITY

- Over 94% of treated eyes had 20/20 or better UDVA after surgery in both groups, but significantly more eyes had 20/16 or better (-0.1 logMAR) in the analytic group (62.5%) than in the manifest group (41.3%) (**Figure 2**)
- These results are better than observed in the FDA study for Contoura Vision, which excluded eyes with a large difference between manifest and topographic astigmatism; in that study; 59% of eyes had 20/16 or better UDVA and 88% had 20/20 or better UDVA at 1 month
- The percentage of eyes with 20/16 or better CDVA was also higher in the analytic group than in the manifest group (77.1% vs 51.4%); all eyes but one had a CDVA of 20/20 or better after surgery
- The number of patients with a UDVA better than their preoperative CDVA was significantly higher in the analytic group than in the manifest group (36.5% vs 23.0%)
- No eye in either group lost more than 1 line of CDVA; significantly more eyes in the analytic group (42.7%) than in the manifest group (30.3%) gained 1 or more lines of CDVA

Figure 1. Postoperative refractive cylinder by group.

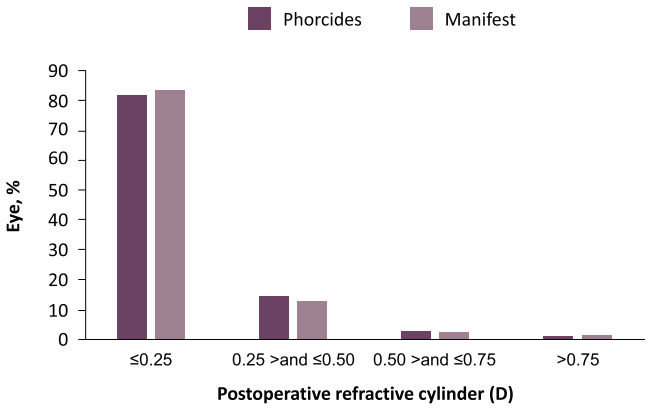
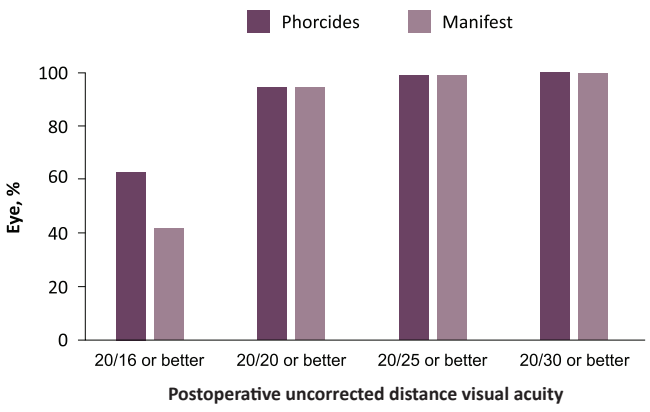


Figure 2. Postoperative uncorrected distance visual acuity by group.



Topography-Guided Refractive Astigmatism Outcomes: Predictions Comparing Three Different Programming Methods

Stulting et al. Clinical Ophthalmology. 2020;14:1091-1100

Visual Acuity

Refractive Outcomes

OVERVIEW

STUDY DESIGN

Retrospective data review to identify the laser programming strategy that will achieve optimal refractive outcomes of LASIK with Contoura® Vision for eyes with a disparity between cylinder measured by manifest refraction and cylinder measured by topography

STUDY SITE(S)

Five (5) clinical sites (6 surgeons), United States

PATIENTS

Fifty-two (52) eyes with myopia or myopic astigmatism stratified on basis of vector difference between Manifest and Topo cylinder (High, > 0.75 D; and Low, ≤ 0.75 D); mean age was 32.73 years (range: 19 to 50 years)

SURGICAL METHODOLOGY

Topography-guided LASIK with Contoura® Vision; refractive inputs for treatment planning: manifest cylinder (based on the clinical refraction), Topo cylinder (based on Placido topography obtained with the Vario topographer), and Phorcides cylinder (calculated using the Phorcides Analytic Engine, Phorcides LLC)

SURGICAL TECHNOLOGY

WaveLight® EX500 Excimer Laser (Alcon Laboratories, Inc), WaveLight® Topolyzer™ VARIO (Alcon Laboratories, Inc)

KEY ENDPOINT(S)

Cylindrical correction that would, theoretically, have completely eliminated postoperative refractive cylinder; uncorrected and corrected distance visual acuity (UDVA, CDVA)

ANALYSIS AND CONCLUSIONS

This study found that using the topographically measured cylinder or the cylinder selected by Phorcides would produce more desirable refractive outcomes than entry of the preoperative refractive cylinder as the basis for correction of myopia and myopic astigmatism with Contoura® Vision.

The investigators noted that a larger, prospective, multicenter clinical trial that includes UDVA as a primary outcome variable should lead to further refinement of the appropriate strategy for determining treatment refraction for use with Contoura® Vision.

STUDY RESULTS

REFRACTIVE OUTCOMES

- The poorest calculated theoretical outcomes were obtained with manifest refraction (centroid: −0.43, 0.11; mean calculated error vector: 0.56 ± 0.42 D; P=ns) (**Table 1**)
  - The error vectors tend to be with the rule (**Figure 1A**)
- Better outcomes were obtained with topographically measured refraction (centroid: 0.37, 0.02; mean calculated error vector: 0.47 ± 0.33 D; P=ns) (**Table 1**)
  - The error vectors tend to be against the rule (**Figure 1B**)
- The best outcomes were obtained with Phorcides (centroid: − 0.15, 0.06; mean calculated error vector: 0.39 ± 0.28 D; P=ns) (**Table 1**)
  - The error vectors tend to be with the rule, but the deviation from the origin was minimal (**Figure 1C**)
- The mean error vector magnitude in the Phorcides Low group was significantly lower than for the Manifest and Topo Low groups (0.26 D vs 0.48 D and 0.33 D; P<0.01) (**Table 1**)
- The mean error magnitude in the Phorcides High group was nearly 0.25 D lower than for the Manifest High group (0.48 D vs 0.70 D; P<0.01), but was the same as for the Topo High group (**Table 1**)

VISUAL ACUITY

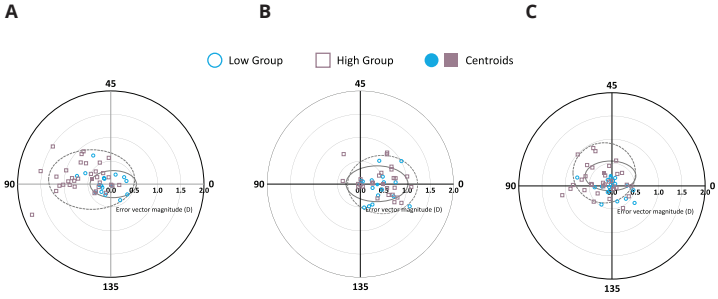
- Overall, visual outcomes were excellent, with a tendency for increased UDVA and no complications; however, a small and measurable residual refractive error remained in many subjects

Table 1. Centroids and error magnitude for expected or actual cylinder error by method.

Method	Group	X Coordinate	Y Coordinate	Magnitude (D)	Mean Error (D)
Manifest	High Low All	−0.48 [0.47]ª −0.17 [0.25] −0.43 [0.47]	0.15 [0.28] −0.07 [0.15] 0.11 [0.28]	0.51 0.18 0.44	0.70 [0.46] 0.33 [0.23] 0.56 [0.42]
Topo	High Low All	0.49 [0.37] 0.36 [0.33] 0.37 [0.36]	0.03 [0.31] −0.08 [0.20] 0.02 [0.28]	0.49 0.37 0.37	0.47 [0.35] 0.48 [0.31] 0.47 [0.33]
Phorcides	High Low All	−0.17 [0.34] −0.01 [0.28] −0.15 [0.36]	0.10 [0.33] −0.08 [0.17] 0.06 [0.28]	0.19 0.08 0.16	0.48 [0.28] 0.26 [0.20] 0.39 [0.28]

ªValue [SD].

Figure 1. Error vectors: difference between calculated Manifest (**A**), Topo (**B**), and Phorcides (**C**) and Best outcomes. Ellipses are the centroid ± SD for the low (———) and high (- - -) groups.



References

De Stefano VS, Meister C, Ehlke GL, Krueger RR. **Analysis of Planning Strategies in Primary Eyes Gaining a Line or More of Visual Acuity after Topography-Guided Laser In Situ Keratomileusis.** *J Cataract Refract Surg.* 2019;45:321-327.

El Awady HE, Ghanem AA, Saleh SM. **Wavefront-Optimized Ablation Versus Topography-Guided Customized Ablation in Myopic LASIK: Comparative Study of Higher Order Aberrations**. *Ophthalmic Surg Lasers Imaging.* 2011;42:314-320.

Fan L, Xiong L, Zhang B, Wang Z. **Longitudinal and Regional Non-uniform Remodeling of Corneal Epithelium After Topography-Guided FS-LASIK.** *J Refract Surg.* 2019;35:88-95.

Kanellopoulos AJ. **Topography-Guided LASIK Versus Small Incision Lenticule Extraction (SMILE) for Myopia and Myopic Astigmatism: A Randomized, Prospective, Contralateral Eye Study.** *J Refract Surg.* 2017;33:306-312.

Kim J, Choi SH, Lim DH, Yang CM, Yoon GJ, Chung TY. **Topography-Guided Versus Wavefront-Optimized Laser In Situ Keratomileusis for Myopia: Surgical Outcomes.** *J Cataract Refract Surg.* 2019;45:959-965.

Lobanoff M, Stonecipher K, Tooma T, Wexler S, Potvin R. **Clinical Outcomes after Topography-Guided LASIK: Comparing Results Based on a New Topography Analysis Algorithm to Those Based on the Manifest Refraction.** *J Cataract Refract Surg.* 2020 Mar 11. Epub ahead of print.

Moshirfar M, Shah TJ, Skanchy DF, Linn SH, Durrie DS. **Meta-analysis of the FDA Reports on Patient-Reported Outcomes Using the Three Latest Platforms for LASIK.** *J Refract Surg.* 2017;33:362-368.

Motwani M, Pei R. **The Use of WaveLight Contoura to Create a Uniform Cornea: 6-Month Results with Subjective Patient Surveys.** *Clin Ophthalmol.* 2018;12:1559-1566.

Motwani M. **The Use of WaveLight® Contoura to Create a Uniform Cornea: The LYRA Protocol. Part 3: The Results of 50 Treated Eyes.** *Clin Ophthalmol.* 2017;11:915-921.

Ozulken K, Yuksel E, Tekin K, Kiziltoprak H, Aydogan S. **Comparison of Wavefront-Optimized Ablation and Topography-Guided Contoura Ablation with LYRA Protocol in LASIK.** *J Refract Surg.* 2019;35:222-229.

Shetty R, Shroff R, Deshpande K, Gowda R, Lahane S, Jayadev C. **A Prospective Study to Compare Visual Outcomes Between Wavefront-optimized and Topography-guided Ablation Profiles in Contralateral Eyes with Myopia.** *J Refract Surg.* 2017;33:6-10.

Stonecipher K, Parrish J, Stonecipher M. **Comparing Wavefront-Optimized, Wavefront-Guided and Topography-Guided Laser Vision Correction: Clinical Outcomes Using an Objective Decision Tree.** *Curr Opin Ophthalmol.* 2018;29:277-285.

Stulting RD, Durrie DS, Potvin RJ, Linn SH, Krueger RR, Lobanoff MC, Moshirfar M, Motwani MV, Lindquist TP, Stonecipher KG. **Topography-Guided Refractive Astigmatism Outcomes: Predictions Comparing Three Different Programming Methods.** *Clin Ophthalmol.* 2020;14:1091-1100

Stulting RD, Fant BS, the T-CAT Study Group. **Results of Topography-Guided Laser In Situ Keratomileusis Custom Ablation Treatment with a Refractive Excimer Laser.** *J Cataract Refract Surg.* 2016;42:11-18.

Sun MS, Zhang L, Guo N, Song YZ, Zhang FJ. **Consistent Comparison of Angle Kappa Adjustment Between Oculyzer and Topolyzer Vario Topography Guided LASIK for Myopia by EX500 Excimer Laser.** *Int J Ophthalmol.* 2018;11:662-667.

Wallerstein A, Gauvin M, Cohen M. **WaveLight® Contoura Topography-Guided Planning: Contribution of Anterior Corneal Higher-Order Aberrations and Posterior Corneal Astigmatism to Manifest Refractive Astigmatism.** *Clin Ophthalmol.* 2018;12:1423-1426.

Wallerstein A, Gauvin M, McCammon K, Cohen M. **Topography-Guided Excimer Treatment Planning: Contribution of Anterior Corneal Coma to Ocular Residual Astigmatism.** *J Cataract Refract Surg.* 2019;45:878-880.

Wallerstein A, Gauvin M, Qi SR, Bashour M, Cohen M. **Primary Topography-Guided LASIK: Treating Manifest Refractive Astigmatism Versus Topography-Measured Anterior Corneal Astigmatism.** *J Refract Surg.* 2019;35:15-23.

Zhang Y, Chen Y. **A Randomized Comparative Study of Topography-Guided Versus Wavefront-Optimized FS-LASIK for Correcting Myopia and Myopic Astigmatism.** *J Refract Surg.* 2019;35:575-582.

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 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 < 6.0 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. 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.

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