


Retrospective Study Comparing Topography-Guided and Wavefront-Optimized LASIK Procedures in a Single Center

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Purpose: To compare visual outcomes of eyes that had laser refractive surgery with the Contoura Phorcides treatment plan and eyes that had laser refractive surgery with the wavefront-optimized treatment plan using the same laser.

Methods: Retrospective chart review of clinical outcomes of eyes that had either Contoura with Phorcides (CP) or wavefront-optimized (WFO) corneal refractive procedures using the Wavelight EX500 (Alcon Vision, LLC). Data were collected and compared for uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refraction, change in postoperative UDVA compared to preoperative CDVA, and change in postoperative CDVA compared to preoperative CDVA.

Results: Total eyes included were 348, with 227 in the CP Group and 121 in the WFO Group. Post-operatively, there was a significantly higher percentage of eyes in the CP Group that were 20/16 or better compared to the WFO Group (57%, 129 eyes, and 17%, 21 eyes, respectively; $p < 0.001$). The percentage of eyes that gained 1 or more Snellen lines of UDVA compared to preoperative CDVA was higher in the CP Group (47%; 107 eyes) compared to the WFO Group (12%; 14 eyes), which was statistically significant ($p < 0.001$). Differences in refraction were statistically significant.

Conclusion: Topography-guided and wavefront-optimized treatment profiles both provided excellent refractive results. A higher percentage of eyes that were treated using Contoura with Phorcides achieved 20/16 or better unaided distance vision compared to eyes receiving a wavefront-optimized treatment plan.

Plain Language Summary: Laser in situ keratomileusis (LASIK) is a common procedure performed to reshape the cornea (transparent part of the eye) and provide clear, spectacle-free vision. There are many different technologies available for surgeons to choose a treatment plan. One of the most popular is called wavefront-optimized LASIK (WFO), which takes into account the curvature of the cornea. Recently, topography-guided LASIK treatment plans that incorporate a proprietary planning software (Contoura Phorcides) have been available that can factor in the individualized surface elevation characteristics of the cornea. The purpose of this study was to compare visual outcomes in patients that had LASIK with the Contoura Phorcides treatment plan to patients that had LASIK with the WFO treatment plan. The results of this study suggest that both treatment profiles both provided excellent refractive results. In addition, a higher percentage of eyes that were treated using Contoura with Phorcides achieved 20/16 or better unaided distance vision compared to eyes receiving a WFO treatment plan.

Keywords: topography-guided LASIK, wavefront-optimized LASIK, Phorcides, Contoura

Introduction

Laser in situ keratomileusis (LASIK) is a common procedure performed to correct myopia, hyperopia, and astigmatism. Correction is accomplished by reshaping the cornea. In early LASIK, the reshaping took into account only the refractive sphere and cylinder.¹ LASIK procedures have evolved greatly since then and currently the most popular treatment plan is wavefront-optimized LASIK (WFO), which also takes into account corneal curvature and allows for more accurate

treatment in the periphery.² Recently, topography-guided LASIK treatment plans have been developed that factor in the individualized surface elevation characteristics of the cornea.³

Early treatments using topography-guided LASIK outside of the US focused on cases of irregular astigmatism.⁴ However, approval of the procedure within the US was focused on eyes that did not exhibit irregular astigmatism and whose manifest cylinder and topographic cylinder were closely matched. In 2016, a large multicenter US Food and Drug Administration (FDA) clinical trial of topography-guided LASIK using the Contoura Vision[®] procedure (Alcon Vision, LLC) published excellent visual outcomes in eyes with myopia or myopic astigmatism, where 93% and 65% of eyes were 20/20 or better and 20/16 or better, respectively, at 12 months postoperatively.³ However, these results were difficult to replicate in eyes where there were large differences between the manifest cylinder and topographic astigmatism.^{5–7} Reports of good clinical outcomes using the manifest cylinder are primarily from Wallerstein and colleagues.^{8–10}

The Phorides Analytic Engine (Phorides LLC) is a proprietary surgical planning software that can integrate with the Contoura Vision[®] procedure. The Phorides Analytic Engine combines both optics and geometric imaging software (GIS) to characterize anterior corneal irregularities to aid in treatment planning. It also considers anterior and posterior corneal astigmatism as well as lenticular astigmatism for treatment planning. The Phorides Analytic Engine has been reported to produce excellent clinical outcomes that are similar to those achieved in the FDA multicenter clinical trial of topography-guided LASIK using the Contoura Vision[®] procedure even in eyes with discrepancy in manifest versus topographic cylinder.^{11–13}

While both WFO LASIK and Phorides-based topography-guided LASIK have shown good clinical outcomes, there are no studies to date that directly compare these two procedures. The purpose of this study was to compare visual acuity outcomes of patients that had laser refractive surgery with the Contoura Phorides treatment plan and those patients that had laser refractive surgery with the WFO treatment plan using the EX500 laser.

Methods

This was a two-arm retrospective chart review of clinical outcomes of patients who had either Contoura with Phorides (CP) or WFO corneal refractive procedures using the Wavelight EX500 excimer laser (Alcon Vision, LLC). This study was reviewed and approved by an institutional review board (WCGIRB, approval number 1318069). A waiver of informed consent was granted for the use of chart data. All extracted chart data were deidentified. This study was conducted in compliance with Good Clinical Practice (GCP), International Harmonization (ICH) guidelines, and the tenets of the Declaration of Helsinki.

Inclusion criteria were prior on-label treatment for myopia with or without astigmatism using Contoura Phorides treatment planning (CP Group) or wavefront-optimized treatment planning (WFO Group) with Wavelight EX500, treatment targeting emmetropia, and available 3-month postoperative UDVA, CDVA, and manifest refraction. Exclusion criteria were pre-existing conditions that may affect the refractive outcomes (eg severe dry eye, corneal ectasia, keratoconus, corneal dystrophies, corneal degenerations), any complications during the treatment procedure or following the procedure, and eyes with enhancements after initial treatment.

Data records from consecutive cases between February 2020 and July 2021 were reviewed to identify subjects that met the eligibility criteria listed above. De-identified data were collected preoperatively, and 1 month and 3 months postoperatively. Data included sex, age, manifest refraction, laser treatment, and visual acuity. Visual acuities were measured to the nearest Snellen line and converted to equivalent log of the minimum angle of resolution (logMAR) notation for statistical analysis.

Results were analyzed for the 3-month postoperative UDVA, and specifically the percentage of eyes 20/16 or better, postoperative refraction, residual astigmatism, change in Snellen lines from preoperative CDVA to postoperative UDVA, change in Snellen lines from preoperative CDVA to postoperative CDVA, and to determine if there was a correlation between preoperative refractive cylinder and the postoperative residual refractive cylinder.

Using the sample size calculation assumptions from a similar study,¹¹ and using a beta of 0.8 and an alpha of 0.05, we estimated that each group would require 90 eyes to confirm a difference of 20% in the percentage of eyes 20/16 or better postoperative UDVA (primary endpoint). The sample size was increased to at least 120 eyes per group to allow for possible exploratory endpoint analysis.

All LASIK surgeries were performed by one experienced surgeon (TT) using the Phorides recommended treatment for the CP group and the surgeon's specific nomogram for the WFO group (Surgivision). The postoperative regimen was their preferred standard of care. Flaps were created using the Z-LASIK (Ziemer) or the VisuMax (Zeiss) femtosecond

lasers. The Wavelight EX500 was used for stromal ablation in both the CP and WFO groups. For the CP Group, the Phorides software integrated information from corneal topography to create the treatment plan. In the WFO Group, a wavefront-optimized algorithm was used to create the treatment plan. Visual acuity was measured by showing subjects 20/40 to 20/16 simultaneously and asking them to read the smallest line they could see.

The software program R (version 4.1.2; The R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis. For non-parametric data, the Wilcoxon rank sum test was used to compare differences between variables. The Chi-square statistic was used to compare differences between categorical data. A p-value less than or equal to 0.05 was considered significant.

Results

The retrospective chart review identified 227 eyes in the CP Group and 121 eyes in the WFO Group that fit the eligibility criteria. Differences for sex and age were not statistically significant between groups. Preoperative sphere, cylinder, manifest refraction spherical equivalent (MRSE), treatment cylinder, and CDVA were significantly different, though the differences do not appear to be clinically relevant. The preoperative and patient demographics are summarized in Table 1.

The standard graphs for the CP Group and WFO Group are shown in Figures 1 and 2, respectively. There was a higher percentage of eyes with UDVA 20/16 or better in the CP Group (57%; 129 eyes; Figure 1A) compared to the WFO Group (17%; 21 eyes; Figure 2A), which was statistically significant ($p < 0.001$). The percentages of eyes 20/20 or better were similar between groups for UDVA and were not significantly different ($p > 0.05$). The percentage of eyes with CDVA 20/16 or better or 20/20 or better was also not significantly different between groups ($p > 0.05$; Figure 3).

The percentage of eyes that gained 1 or more Snellen lines of UDVA compared to preoperative CDVA was higher in the CP Group (47%; 107 eyes; Figure 1B) compared to the WFO Group (12%; 14 eyes; Figure 2B) and was statistically significant ($p < 0.001$). The percentage of eyes that gained 1 or more Snellen lines of CDVA compared to preoperative CDVA was similar and not statistically significant between groups ($p > 0.05$; Figures 1C and 2C). There were no significant differences between the distributions of postoperative refractive astigmatism between the CP Group and the WFO Group (Figures 1G and 2G).

Refractive and visual outcomes are summarized in Table 2. Mean postoperative sphere and mean MRSE differed by about 0.1 D between groups, which was statistically significant ($p = 0.003$). Mean postoperative cylinder and CDVA were similar between groups and were not statistically significant. Mean postoperative UDVA was also slightly different between groups (0.05 logMAR). This difference was statistically significant ($p < 0.001$).

A Spearman rank correlation test was used to assess if any correlation existed between preoperative cylinder and postoperative cylinder for each group. For both groups, the correlation coefficient was close to zero ($r = 0.15$ CP Group

Table 1 Preoperative and Demographic Data

Baseline Factor	CP Group Mean \pm SD (Range)	WFO Group Mean \pm SD (Range)	P-value
Eyes	227	121	-
Sex			
Female (n)	111 (49%)	74 (61%)	>0.05
Male (n)	116 (51%)	47 (39%)	
Age (Years)	33.0 \pm 6.9 (20 to 54)	32.1 \pm 7.8 (19–54)	>0.05
Sphere (D)	-3.48 \pm 2.56 (-9.0 to 0.5)	-3.89 \pm 2.24 (-9.5 to 0.0)	0.04
Cylinder (D)	-1.02 \pm 0.75 (-3.25 to 0.0)	-0.91 \pm 0.82 (-3.75 to 0.0)	0.04
MRSE (D)	-3.96 \pm 2.58 (-9.88 to -0.50)	-4.35 \pm 2.33 (-10.38 to -0.63)	0.05
CDVA (logMAR)	-0.01 \pm 0.03 (-0.1 to 0.2)	-0.02 \pm 0.04 (-0.1 to 0.2)	0.03
Treatment Cylinder (D)	-1.00 \pm 0.71 (-3.37 to -0.06)	-0.76 \pm 0.72 (-3.0 to 0.0)	<0.001

Abbreviations: CDVA, correct distance visual acuity; D, diopters; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

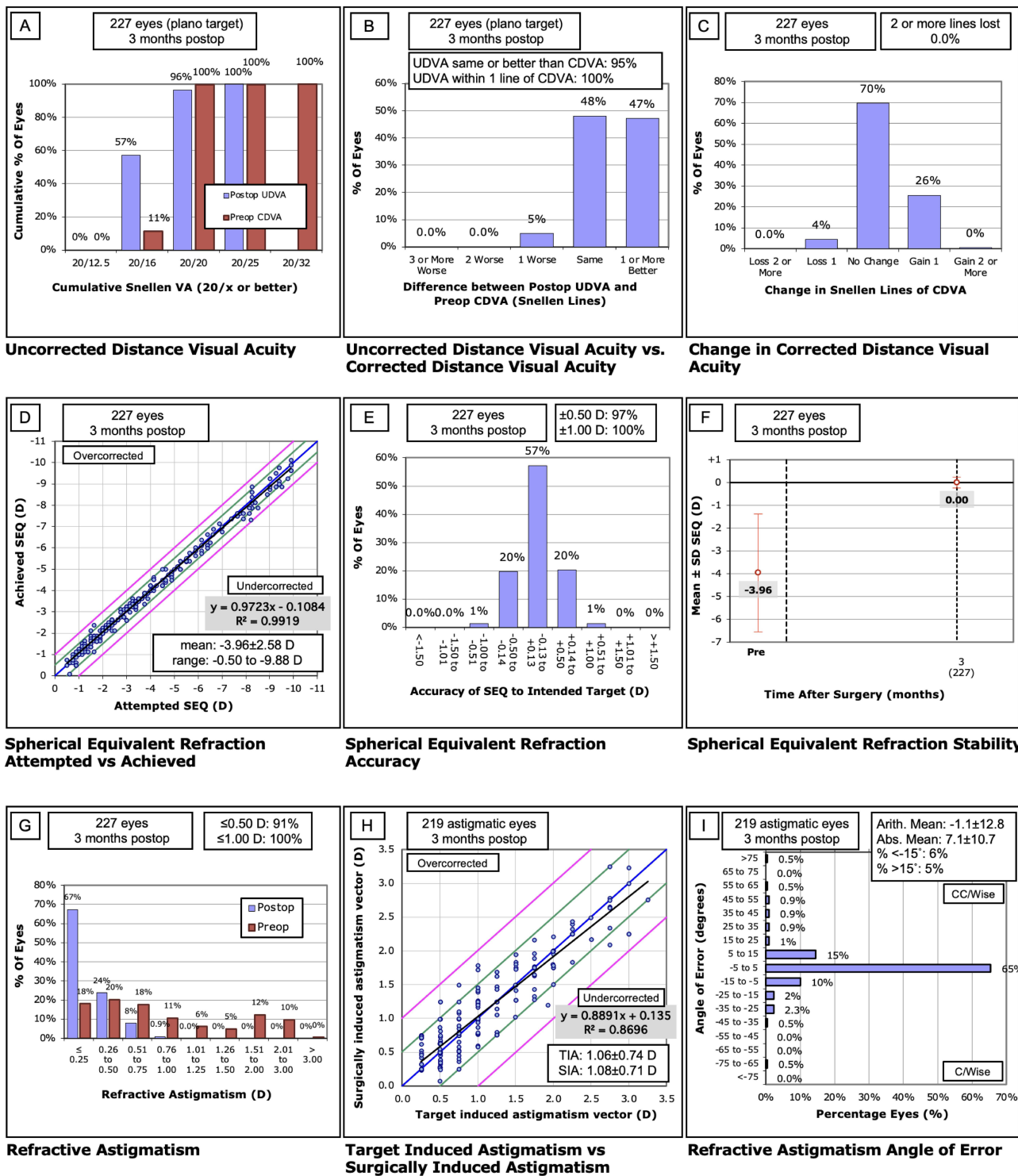


Figure I Standard nine graphs for reporting refractive outcomes (CP Group). (A) UDVA, (B) UDVA vs CDVA, (C) Change in CDVA, (D) Spherical Equivalent Refraction Attempted vs Achieved, (E) SEQ Accuracy, (F) SEQ Stability, (G) Refractive Astigmatism, (H) TIA vs SIA, (I) Refractive Astigmatism Angle of Error.

Abbreviations: CDVA, corrected distance visual acuity; D, diopters; SEQ, spherical equivalent refraction; SIA, surgically induced astigmatism; TIA, target-induced astigmatism; UDVA, uncorrected distance visual acuity.

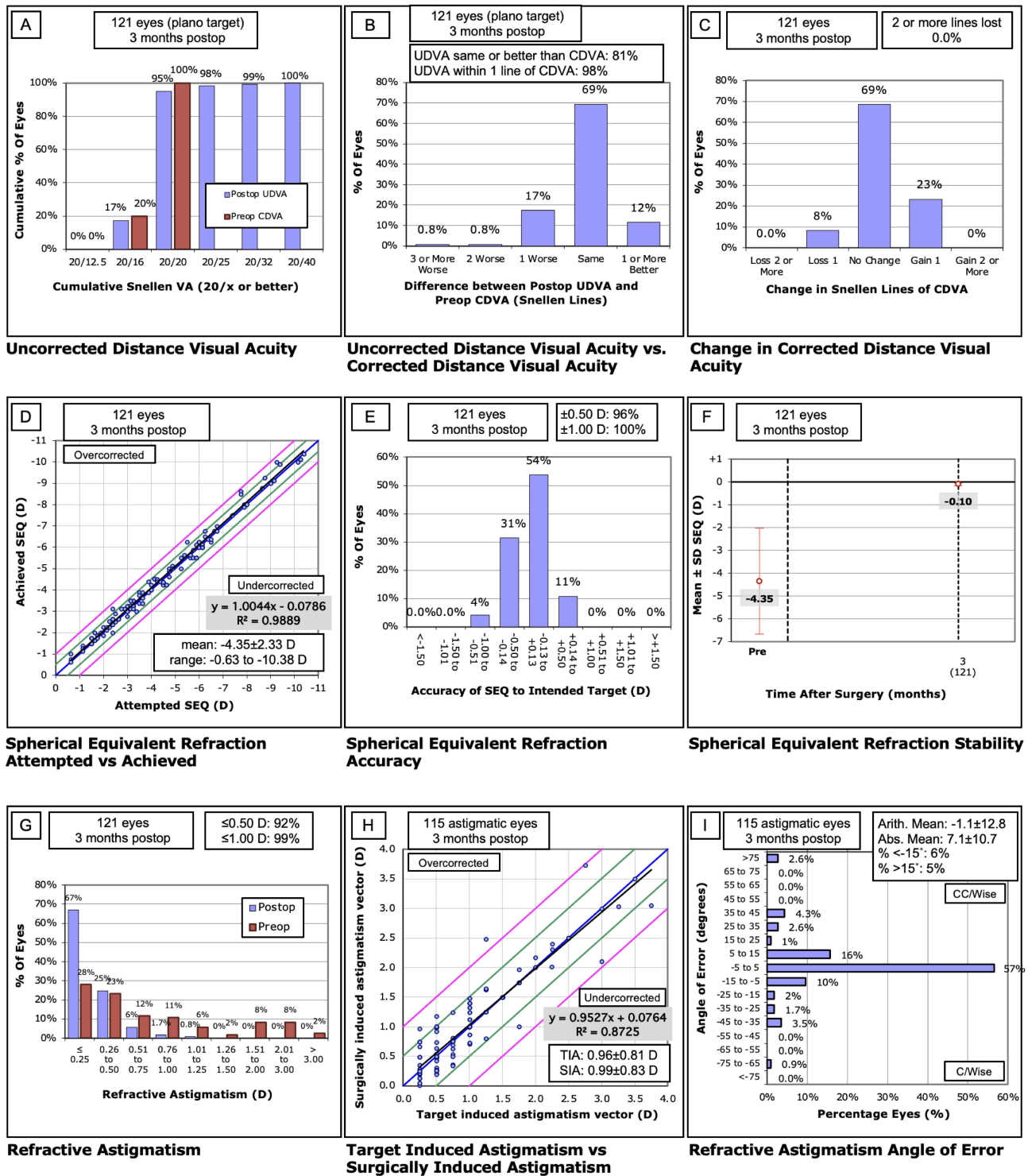


Figure 2 Standard nine graphs for reporting refractive outcomes (WFO Group). (A) UDVA, (B) UDVA vs CDVA, (C) Change in CDVA, (D) Spherical Equivalent Refraction Attempted vs Achieved, (E) SEQ Accuracy, (F) SEQ Stability, (G) Refractive Astigmatism, (H) TIA vs SIA, (I) Refractive Astigmatism Angle of Error.

Abbreviations: CDVA, corrected distance visual acuity; D, diopters; SEQ, spherical equivalent refraction; SIA, surgically induced astigmatism; TIA, target-induced astigmatism; UDVA, uncorrected distance visual acuity.

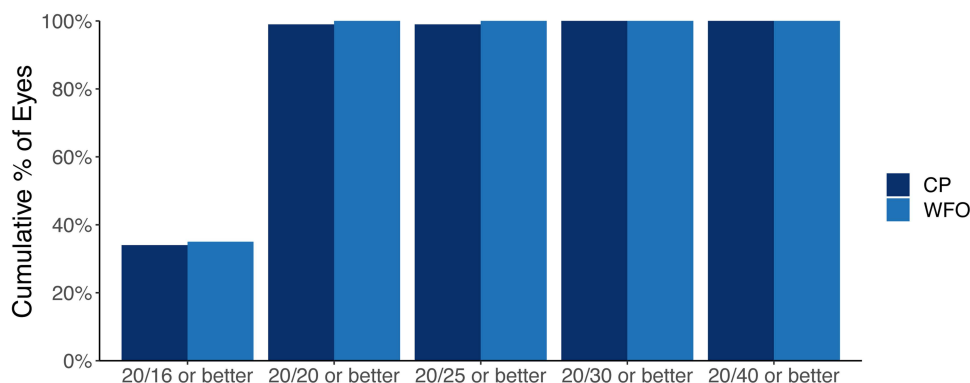


Figure 3 Cumulative postoperative corrected distance visual acuity between groups.

and $r = -0.04$ WFO Group). This indicated that there was no strong correlation between preoperative cylinder and postoperative cylinder for either group.

Discussion

This retrospective study, to the best of our knowledge, is the first to compare the clinical outcomes between laser refractive surgery with the Contoura Phorcides treatment plan and laser refractive surgery with the WFO treatment plan using the EX500 laser. We compared the 3-month postoperative UDVA between groups and observed that there was a higher percentage of eyes 20/16 or better in the CP Group (57%) compared to the WFO Group (17%). The 57% of CP eyes in this study was slightly lower than the multicenter FDA clinical trial of topography-guided LASIK (69%)³ but similar to other studies using the Phorcides software (approximately 60–62%).^{11,12} Other studies comparing WFO LASIK to topography-guided LASIK (but not using Phorcides) have reported mixed results with some authors observing that topography-guided LASIK resulted in a higher percentage of eyes 20/16 or better compared to WFO LASIK,¹⁴ while other studies have reported minimal differences,^{15–17} or that WFO resulted in a higher percentage of eyes 20/16 or better.¹⁸ Despite these mixed results, our study provides evidence that the Contoura with the Phorcides treatment can provide better visual outcomes compared to WFO LASIK.

We also observed that there was a higher percentage of eyes that had postoperative UDVA the same or better than preoperative CDVA in the CP Group (95%) compared to the WFO Group (81%). Other studies have reported similar results using Phorcides, observing that postoperative UDVA was the same or better than preoperative CDVA in 85–92% of eyes that received Contoura with Phorcides treatment planning.^{3,11} Studies of topography-guided LASIK (not using the Phorcides software) have described the percentage of eyes that had postoperative UDVA was the same or better than preoperative CDVA was 82–100%.^{3,14–16} We are not able to directly compare our results of Contoura with Phorcides to Contoura without Phorcides. However, previous studies have examined this.^{11–13}

A limitation of this study was the relatively short follow-up period. The 3 months postoperative visit was selected for data analysis, compared to the 12-month follow-up in the FDA clinical trial of Contoura.³ We are therefore not able to

Table 2 Postoperative Clinical Outcomes (n = 227 CP Group; n = 121 WFO Group)

Outcome	CP Group Mean ± SD (Range)	WFO Group Mean ± SD (Range)	P-value
Sphere (D)	0.13 ± 0.25 (−0.5 to 1.25)	0.03 ± 0.28 (−0.75 to 1.0)	0.003
Cylinder (D)	−0.26 ± 0.25 (−1.0 to 0.0)	−0.27 ± 0.27 (−1.25 to 0.0)	>0.05
MRSE (D)	0.0 ± 0.24 (−0.75 to 0.88)	−0.1 ± 0.24 (−0.88 to −0.38)	0.002
UDVA (logMAR)	−0.05 ± 0.06 (−0.1 to 0.1)	−0.01 ± 0.06 (−0.1 to 0.3)	<0.001
CDVA (logMAR)	−0.03 ± 0.05 (−0.1 to 0.2)	−0.04 ± 0.05 (−0.1 to 0.0)	>0.05

Abbreviations: CDVA, correct distance visual acuity; D, diopters; MRSE, manifest refraction spherical equivalent; SD, standard deviation; UDVA, uncorrected distance visual acuity.

draw any long-term conclusions for refractive and visual outcomes between the CP and WFO groups. However, a 3-month follow-up period is typical for topography-guided and WFO LASIK studies. Durrie et al¹⁹ have reported that UDVA with Contoura continued to improve between 3 months and 12 months postoperatively. The retrospective design of the study is also a limitation. With a retrospective design, we could not apply more stringent eligibility criteria, nor could we compare standardized variables that are not part of the standard of care at this site, such as patient reported outcomes about satisfaction and visual disturbances. However, with the retrospective design, we were able to compare a large number of eyes in each group for key variables, such as postoperative UDVA and postoperative UDVA improvement compared to preoperative CDVA. Also, with the retrospective design, we are not able to confirm that all subjects were pushed to read 20/16, even though subjects were shown 20/40 to 20/16 simultaneously and asked to read the smallest line they could see.

In conclusion, both the topography-guided and wavefront-optimized treatment profiles provided excellent refractive results. In this study, a significantly higher percentage of eyes that were treated using Contoura with Phorclides achieved 20/16 or better unaided distance vision compared to eyes receiving a wavefront-optimized treatment plan. In addition, a higher percentage of eyes that were treated using Contoura with Phorclides, compared to eyes treated with wavefront-optimized LASIK, had an improvement in unaided distance visual acuity as compared to corrected distance visual acuity prior to LASIK treatment.

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Disclosure

Brad Hall reports that he has received consulting fees from Ace Vision Group outside of the submitted work. Sheri Rowen is a consultant for Alcon, and the following companies outside the submitted work: Ace Vision Group, Azura, Abbvie, Bausch & Lomb, Centricity, iVIZIA, Glia, Kala, Johnson & Johnson, Orasis, RxSight, Science Based Health, Sight Sciences, Stuart Pharma, Tarsus, Viatrix, Visus, Zeiss. The authors report no other conflict of interest for this work.

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