Effect of Anterior Corneal Higher-Order Aberration Ablation Depth on Primary Topography-Guided LASIK Outcomes

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ABSTRACT

PURPOSE: To investigate the contribution of anterior corneal higher-order aberration ablation depth (HOA-AD) to topography-guided outcomes.

METHODS: This was a retrospective comparative analysis of 9,722 consecutive eyes undergoing laser in situ keratomileusis (LASIK) treated on the clinically measured refractive cylinder with Contoura software (Alcon Laboratories, Inc., Fort Worth, TX). Outcomes of the 3,246 eyes with the shallowest HOA-AD (first tercile: 5.4 ± 0.9 µm) were compared to the 3,362 eyes with the deepest HOA-AD (last tercile: 11.0 ± 1.7 µm).

RESULTS: The HOA-AD followed a left-skewed normal distribution (R^2 = 0.98) with a mean ± standard deviation of 8.02 ± 3.00 µm, with 1.8% of eyes greater than 15 µm. The efficacy index of shallow versus deep HOA-AD eyes was identical (0.98 ± 0.07 vs 0.98 ± 0.09; *P* = .99), with a similar percentage having spherical equivalent within ±0.50 diopters (D) (95.2% vs 95.0%; *P* = .71) and within ±0.75 D (98.9% vs 98.7%; *P* = .46) of intended target. The safety index (1.00 ± 0.03 vs 1.00 ± 0.04; *P* = .19) and Alpins correction index (1.00 ± 0.39 vs 1.01 ± 0.43; *P* = .53) were also identical. The mean postoperative refractive astigmatism difference between the shallow (0.15 D) and deep (0.20 D) groups was 0.05 D. The 3-month laser re-treatment rate was greater in the deep group (0.83% vs 0.37%; *P* = .02), but less than 1% for both groups.

CONCLUSIONS: The contribution of topography-guided HOA-AD to clinical outcomes in most virgin eyes is negligible, with excellent efficacy, accuracy, and safety in both the deep and shallow ablation groups. Eyes with deep HOA-AD greater than 15 µm trend to lesser outcomes, but should not be excluded from topography-guided surgery.

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Topography-guided laser vision correction regularizes the corneal surface, directly treating anterior corneal higher-order aberrations (HOAs).[1-3] The Alcon platform for topography-guided treatments includes the WaveLight Topolyzer VARIO topographer to image the cornea and the Contoura software (Alcon Laboratories, Inc., Fort Worth, TX), which generates an ablation map that combines both lower and higher-order aberration ablation profiles into one treatment, with ablation depth data. By inputting the sphere and cylinder treatment to zero in the Contoura planning software, one can separate out and only see the anterior corneal HOA ablation profile, which has clinical utility to describe the location and depth of anterior corneal HOAs to be treated. As part of the work flow, surgeons compare this HOA map to see if it concurs with the topography anterior elevation map as a verification step before proceeding with ablation. Many surgeons also consider deep HOA ablation depth (HOA-AD) as an exclusion criterion for the Contoura software, with concerns that these eyes will result in outlier outcomes.[4,5] The HOA-AD is directly correlated to the amount of anterior corneal HOAs.[6,7] Unlike the original U.S. Food and Drug Administration (FDA) approval study,[6] which had strict inclusion criteria for symmetrical corneas and therefore low HOA-AD,

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many surgeons use Contoura software in virgin eyes with some degree of corneal topographic asymmetrical bowties, skewed radial axes, or other features consistent with naturally occurring irregular astigmatism and elevated anterior corneal HOAs. These eyes have deeper HOA-AD.

There are no accepted or defined guidelines as to the degree of HOA-AD that can be accurately and safely treated with Contoura software in virgin eyes. This study set out to describe the distribution of HOA-AD in a large cohort of preoperative myopic eyes and to determine if and at what level HOA-AD influences visual and refractive outcomes.

PATIENTS AND METHODS

Patient Selection

A retrospective electronic medical record database review of 9,722 consecutive eyes that underwent a primary Contoura topography-guided procedure using the WaveLight EX500 excimer laser between July 2017 and August 2018 was conducted. Standard inclusion criteria for laser in situ keratomileusis (LASIK) were required, including no evidence of keratoconus or subclinical keratoconus on corneal topography, adequate corneal tissue, no previous ocular surgery or disease, including visually significant cataract or macular changes, no systemic diseases that affect corneal healing, and age older than 18 years. The difference between the clinically measured subjective refractive astigmatism and the Contoura-measured anterior corneal astigmatism magnitude and axis were not used as inclusion or exclusion criteria. Eyes with myopia and myopic astigmatism, naturally occurring irregular astigmatism, and asymmetrical topographies on keratometric maps were included, as were eyes with preoperative corrected distance visual acuity (CDVA) of less than 20/20. There were no exclusions based on the amount of anterior corneal HOAs or HOA-AD. Eyes with intraoperative flap complication(s) were removed from analysis.

This study was approved by the institutional ethics review board, and all patients provided a written consent for surgery and use of anonymized data for research. All procedures performed fulfilled the principles of the Declaration of Helsinki.

LASIK Surgical Technique

Surgeons followed the same previously described standardized technique,[7-9] using the same clinical settings, equipment, and identical surgical nomogram. The IntraLase femtosecond laser iFS (Abbott Medical Optics, Inc., Santa Clara, CA) or Hansatome Microkeratome (Z15 or Z16 heads; Bausch & Lomb, Rochester, NY) in combination with an 8.5- or 9.5-mm suction ring were used to create corneal flaps. The WaveLight EX500 excimer laser with Contoura software was used for the excimer ablations. A standardized postoperative regimen[9] of antibiotics and steroids was followed.

HOA Ablation Profile Image Creation

Contoura image acquisition was performed as described previously.[7,8] The ablation map generated by the Contoura software includes both lower order aberrations and HOAs. By manually inputting the sphere and cylinder treatment to zero in the Contoura treatment planning software, one can isolate and view the HOA ablation profile (**Figure AA**, available in the online version of this article). The maximum ablation depth, often corresponding to a peripheral ablation crescent or island on this map, was recorded and termed HOA-AD (**Figure AB**).

Contoura Surgical Planning

Prior to treatment, the HOA ablation pattern was verified to be consistent with anterior elevation topography, and examined to ensure that there were no artifacts affecting the ablation pattern. Eyes with scans that did not match appropriately were eliminated from the study. A 6.5-mm optical zone was used in all eyes. Clinically measured manifest refraction sphere and cylinder averages from preoperative examination and the day of surgery were entered into the Contoura software as treatment parameters. When these manifest refractions did not agree, a third refraction was performed, with outlier refractions discarded from the average. A custom nomogram developed using a large electronic medical record outcomes database was used. This nomogram did not factor in the HOA ablation profile, the HOA-AD, or any Zernike information and was not modified by the amount of discrepancy between refractive and Contoura-measured astigmatism. The target spherical refraction was plano with a modifier for age.

Study Outcome Variables

The HOA-AD was used as the single independent variable. Outcomes of the first tercile of eyes with the shallowest HOA-AD, termed the shallow HOA-AD group, were compared to those of the last tercile of eyes with the deepest HOA-AD, termed the deep HOA-AD group. The same surgeons performed the treatment in both the shallow and deep HOA-AD groups.

Data and Statistical Analysis

Ophthalmic examinations were performed preoperatively and between 1 and 3 months postoperatively.

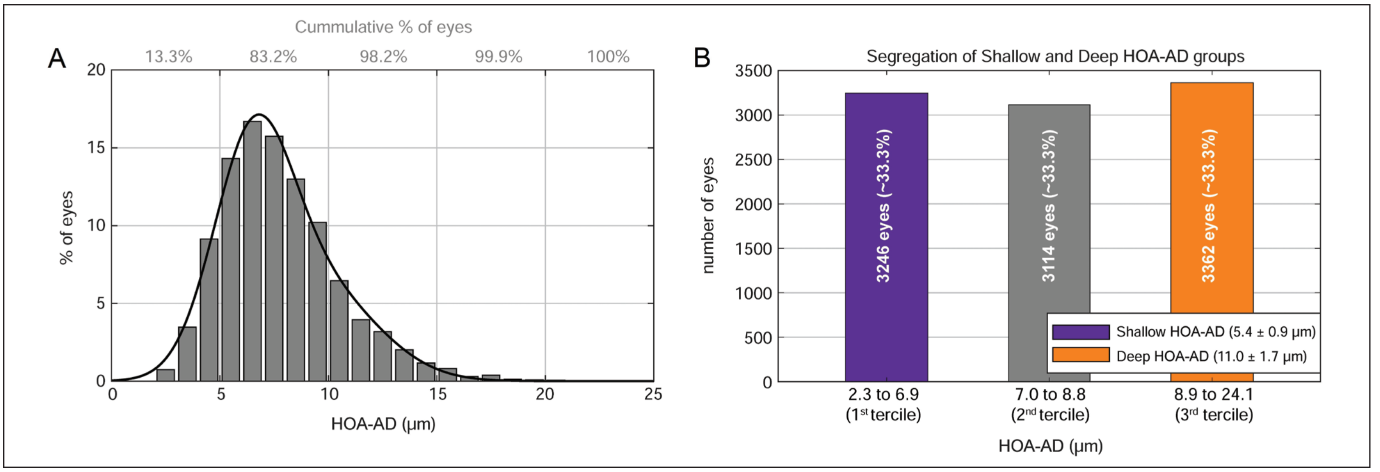

Figure 1. (A) Distribution of the anterior corneal higher-order aberration ablation depth (HOA-AD). The thick black curve represents the Gaussian fittings of the distribution, having good coefficients of determination (R^2 = 0.98). The cumulative percentage of eyes is shown on the top of the graph for each 5-μm increment. (B) Segregation of the shallow versus deep HOA-AD groups (purple and orange bars, respectively). The average HOA-AD is shown in the legend, the HOA-AD range is shown on the abscissa, and the number of eyes on the bars.

A short follow-up was chosen to minimize the effect of secondary corneal biomechanical and epithelial changes and to minimize cerebral adaptation to astigmatism. The intention was to get an accurate gauge of the immediate and actual impact of treatment with less effect from secondary compensation. Accuracy, efficacy, and safety were assessed. Standard graphs, defined by the *Journal of Refractive Surgery*,[10] were produced. Astigmatism correction was assessed using the Alpins vector analysis method.[10-12] Standard vector graphs, calculated at the corneal plane, were produced with the AstigMATIC software.[13] Postoperative data were reported before any subsequent excimer enhancement surgery.

Statistical analyses were conducted in MATLAB R2019a software (MathWorks, Natick, MA). Unpaired samples *t* tests and non-parametric Mann–Whitney–Wilcoxon tests were used where applicable. The Cohen's *d* statistic was used to investigate the effect size between two means. The Pearson correlation coefficient was used to assess the relationship between selected variables. Statistical significance was set at a *P* value of less than .05 and all data were reported as means ± standard deviations.

RESULTS

A total of 9,722 Contoura-treated eyes were included in this study. The median time interval between surgery and the last follow-up was 1.4 months. The HOA-AD followed a left-skewed normal distribution (R^2 = 0.98) with a mean ± standard deviation, median, and mode of 8.02 ± 3.00, 8.00, and 7.00 μm, respectively (**Figure 1A**). In this large cohort of 9,722 eyes, a total of 13.3%, 83.2%, 98.2%, 99.9%, and 100% of eyes had a HOA-AD shallower than or equal to 5, 10, 15, 20, and 25 μm, respectively (**Figure 1A**). Of the 9,722 eyes, 3,246 (33.3%; 1st tercile) had a HOA-AD of 6.9 μm or less (shallow HOA-AD group; **Figure 1B**: purple bar in the histogram), whereas 3,362 eyes (34.5%; last tercile) had a HOA-AD of 8.9 μm or greater (deep HOA-AD group; **Figure 1B**: orange bar in the histogram). The mean HOA-AD was 5.4 ± 0.9 and 11.0 ± 1.7 μm in the shallow and deep HOA-AD groups, respectively (P < .0001; **Table 1**). Outcomes of the intermediate HOA-AD (second tercile; **Figure 1B**: gray bar of the histogram) were not statistically or clinically different from the first and last terciles and are therefore not reported in the current study.

Preoperative Characteristics

Preoperatively, the deep HOA-AD group had 0.19 diopters (D) greater refractive cylinder and 0.30 D greater Contoura-measured anterior corneal cylinder than the shallow group (P < .0001; **Table 1**). A greater number of deep HOA-AD eyes had cylinder greater than 2.00 D preoperatively (8.3% vs 3.3%; P < .0001). The distribution of with-the-rule, against-the-rule, and oblique refractive astigmatism eyes was similar in both groups (**Table 1**). Deep HOA-AD eyes had significantly greater total root mean square (RMS) HOA (0.46 ± 0.11 vs 0.21 ± 0.06; P < .0001; **Table 1**) and total RMS coma (0.35 ± 0.13 vs 0.16 ± 0.08; P < .0001) than shallow HOA-AD eyes. Deep HOA-AD eyes had greater ocular residual astigmatism (P < .0001; **Table 1**), but the 0.11 D difference was not clinically meaningful. The difference of the discrepancy between refractive and Contoura-measured anterior corneal astigmatism was 0.09 D between groups (P < .0001; not clinically

TABLE 1
Comparison of Preoperative Characteristics (Mean ± SD)

Parameter	Shallow	Deep	*P* (ES)[a]
No. of eyes	3,246	3,362	
Age (y)	28.8 ± 5.97	29.9 ± 6.52	< .0001 (0.18)
Visual acuity			
UDVA (logMAR)	1.45 ± 0.57	1.35 ± 0.59	< .0001 (0.17)
CDVA (logMAR)	-0.04 ± 0.05	-0.04 ± 0.05	< .0001 (0.15)
Subjective manifest refraction			
SEQ (D)	-3.96 ± 1.87	-3.83 ± 1.96	.0011 (0.07)
Sphere (D)	-3.61 ± 1.86	-3.37 ± 1.94	.0031 (0.13)
Refractive astigmatism (D)[b]	0.65 ± 0.55	0.84 ± 0.72	< .0001 (0.29)
With-the-rule eyes (%)	69.1	72.6	.0081 (N/A)
Against-the-rule eyes (%)	19.7	16.6	.0050 (N/A)
Oblique eyes (%)	11.2	10.9	.6943 (N/A)
Contoura-measured topographic parameters at 6.5 mm			
Anterior corneal astigmatism (D)	1.10 ± 0.60	1.40 ± 0.80	< .0001 (0.42)
HOA ablation depth (µm)	5.41 ± 0.92	11.0 ± 1.7	< .0001 (4.08)
Total RMS HOA (µm)	0.21 ± 0.06	0.46 ± 0.11	< .0001 (2.09)
Total RMS coma (µm)	0.16 ± 0.08	0.35 ± 0.13	< .0001 (1.97)
Orbscan			
CCT (µm)	563.7 ± 36.50	561.0 ± 36.7	.0026 (0.07)
Kmin (D)	43.10 ± 1.81	43.40 ± 1.55	< .0001 (0.18)
Kmax (D)	44.00 ± 1.70	44.60 ± 1.75	< .0001 (0.23)
Discrepancy between refractive and anterior corneal astigmatism			
Magnitude discrepancy |(D)|	0.51 ± 0.38	0.60 ± 0.46	< .0001 (0.20)
Axis discrepancy (°)	16.2 ± 18.80	15.3 ± 18.9	.0011 (0.05)
Ocular residual astigmatism (D)	0.69 ± 0.38	0.80 ± 0.46	< .0001 (0.26)

SD = standard deviation; ES = effect size; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; SEQ = spherical equivalent; D = diopters; HOA = higher-order aberrations; RMS = root mean square; CCT = central corneal thickness; Kmin = minimum keratometry; Kmax = maximum keratometry
[a]*Calculated as Cohen's* d.
[b]*Calculated at the corneal plane.*
Contoura is manufactured by Alcon Laboratories, Inc., Fort Worth, TX, and Orbscan is manufactured by Bausch & Lomb, Rochester, NY.

meaningful; **Table 1**). The axis discrepancy between the two groups was also similar (**Table 1**). Other preoperative characteristics had statistical significance between groups because of the large number of eyes but were not clinically meaningful (**Table 1**). Although this study included eyes that had both femtosecond laser–assisted and microkeratome LASIK, the relative distribution of microkeratome and femtosecond laser flaps was the same in both groups.

Vision Efficacy

A marginally greater number of shallow HOA-AD eyes achieved a cumulative postoperative unilateral uncorrected distance visual acuity (UDVA) of 20/20 (91.8% vs 88.2%) and 20/25 (98.6% vs 97.1%) compared to deep HOA-AD eyes (**Figure 2**; *P* < .005), but there were also fewer deep HOA-AD eyes with a preoperative unilateral CDVA of 20/20 and 20/25 (**Figure 2**). The efficacy index of shallow HOA-AD eyes was therefore identical to that of deep HOA-AD eyes (**Figure 2**; 0.98 ± 0.07 vs 0.98 ± 0.09; *P* = .9897). A marginally greater number of shallow HOA-AD eyes had the same or better UDVA lines than CDVA (**Figure 2**; 92.0% vs 89.1%; *P* < .001). A similar number of eyes achieved a cumulative postoperative bilateral UDVA of 20/20 (98.6% vs 97.3%; *P* = .0002) and 20/25 (99.7% vs 99.5%; *P* = .2593).

Spherical Equivalent and Defocus Equivalent Accuracy

The attempted versus achieved spherical equivalent (SEQ) scatterplot revealed a high predictability in

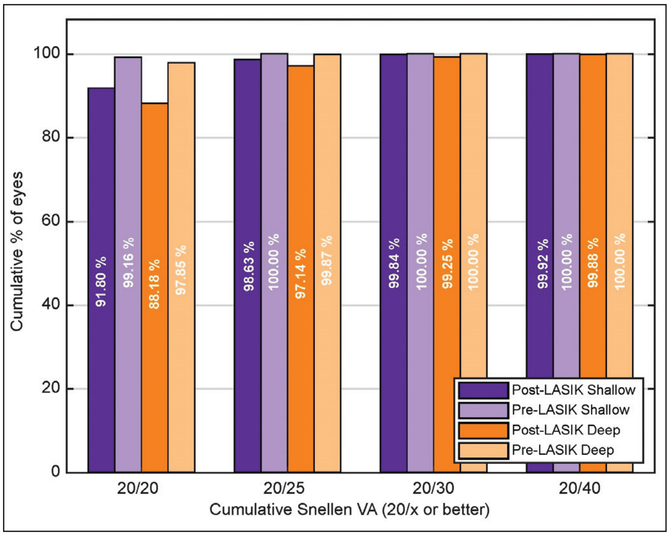

Figure 2. Difference in postoperative uncorrected distance visual acuity (VA) lines of shallow and deep higher-order aberration ablation depth eyes, compared to preoperative corrected distance visual acuity. LASIK = laser in situ keratomileusis

both the shallow and deep HOA-AD groups with R^2 values of 0.98 (**Figure B**, available in the online version of this article). A similar percentage of shallow and deep HOA-AD eyes had a SEQ within 0.25, 0.50, 0.75, and 1.00 D of intended target, (78.2% vs 77.9%, 95.2% vs 95.0%, 98.9% vs 98.7%, and 99.7 vs 99.7%; not clinically meaningful; **Figure 3A**). Cumulative defocus equivalent histograms revealed that the shallow HOA-AD group had marginally more eyes achieving a defocus equivalent of 0.25, 0.50, 0.75, and 1.00 D or less (69.7% vs 66.2%, 91.1% vs 88.4%, 97.4% vs 96.8%, and 99.2% vs 99.3%, $P = .0015$; **Figure 3B**).

Refractive Astigmatism Accuracy

In the shallow HOA-AD group, more eyes were within ±0.25, ±0.50, and ±0.75 D of intended plano cylinder (83.0% vs 76.7%, 96.9% vs 93.7%, 99.4% vs 98.5%; $P = .0004$; **Figure 3C**) compared to deep HOA-AD eyes, whereas 99.8% of eyes were within ±1.00 D of intended plano cylinder in both groups. A greater number of deep HOA-AD eyes had residual astigmatism of 0.75 D or greater, compared to shallow HOA-AD eyes (6.3% vs 3.1%; $P < .0001$). Due to the large sample size (9,722 eyes), there was a statistically significant correlation between the preoperative HOA-AD and the amount of postoperative sphere, refractive astigmatism, and SEQ ($P < .0001$), although the correlations were very weak ($R = 0.008$, 0.070, and 0.025, respectively).

Cylinder Vector Analysis

The target induced astigmatism to surgically induced astigmatism treatment predictability was not

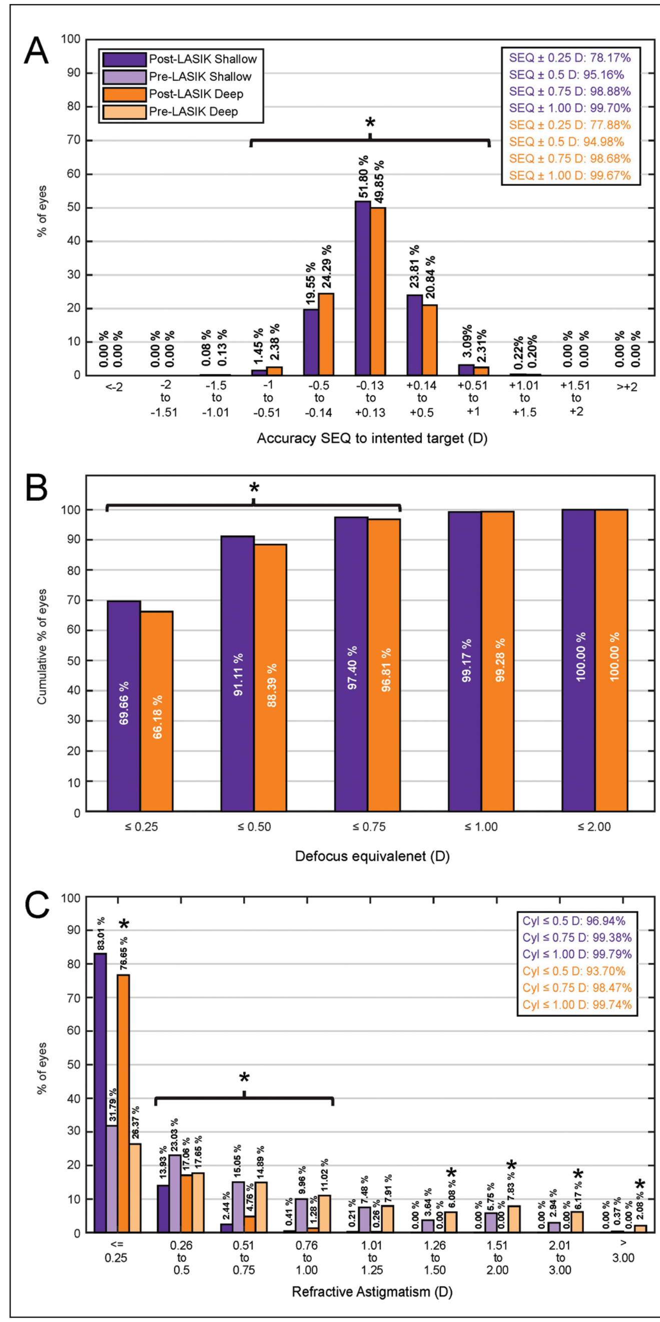

Figure 3. (A) Postoperative spherical equivalent (SEQ) histogram of shallow and deep higher-order aberration ablation depth (HOA-AD) eyes. (B) Cumulative postoperative defocus equivalent (DEQ) histogram of shallow and deep HOA-AD eyes. DEQ is defined as the summation of the absolute value of the SEQ and half the absolute value of the astigmatism. (C) Refractive astigmatism before and after surgery of shallow and deep HOA-AD eyes. Black asterisks indicate statistically significant differences. D = diopters, cyl = cylinder, LASIK = laser in situ keratomileusis

different between the deep and shallow HOA-AD groups, with an R^2 value of 0.90 versus 0.91 (**Figure B**). Shallow and deep HOA-AD eyes had identical Alpins correction index values (1.00 ± 0.39 vs 1.01 ± 0.43; P

TABLE 2

Comparison of Postoperative Astigmatism Vectors

Parameter	Shallow	Deep	*P* (ES)
No. of eyes	3,246	3,362	
TIA vector (D) (mean ± SD)	0.65 ± 0.55	0.84 ± 0.72	< .0001 (0.29)
SIA vector (D) (mean ± SD)	0.68 ± 0.55	0.87 ± 0.71	< .0001 (0.30)
DV vector (D) (mean ± SD)	0.15 ± 0.22	0.20 ± 0.25	.0004 (0.19)
Correction index (mean ± SD)	1.00 ± 0.39	1.01 ± 0.43	.5259 (0.02)
Index of success[a] (mean ± SD)	0.22 ± 0.35	0.24 ± 0.35	.0031 (0.05)
ME (D)[a] (mean ± SD)	0.01 ± 0.19	0.01 ± 0.23	.9655 (0.00)
AE (°)[a] (mean ± SD)	0.23 ± 11.4	0.65 ± 10.9	.1451 (0.03)
% ME within ±0.50 D (%)	97.76	96.01	.0036 (N/A)
% ME within ±1.00 D (%)	100	100	1.0000 (N/A)
% with | AE | within 15° (%)	90.12	90.70	.5683 (N/A)
% with AE greater than 15° (%)	5.15	5.78	.9948 (N/A)
% with AE less than -15° (%)	4.73	3.52	.0200 (N/A)

ES = effect size; TIA = target induced astigmatism; D = diopters; SD = standard deviation; SIA = surgically induced astigmatism; DV = difference vector; ME = magnitude of error; AE = angle of error; N/A = not applicable
[a]*Calculated in eyes with TIA ≥ 0.50 D. Percentage values are reported in eyes with TIA ≥ 0.50 D.*

= .5259; **Table 2**), with a similar index of success (0.22 ± 0.35 vs 0.24 ± 0.35; **Table 2**). The Alpins difference vector was similar between the two groups (0.15 ± 0.22 vs 0.20 ± 0.25; *P* = .0004; **Table 2**). Marginally fewer deep HOA-AD eyes had an Alpins magnitude of error within ±0.50 D (96.0% vs 97.7%, *P* = .0036; **Table 2**), compared to shallow HOA-AD eyes. The percentage of eyes with an absolute Alpins angle of error within 15° was similar in the shallow and deep HOA-AD groups (90.1% vs 90.7%, *P* = .5683; **Table 2**). Additional Alpins vectors and parameters are reported in **Table 2** and graphed as single-angle polar plots in **Figure C** (available in the online version of this article).

SAFETY

The safety index was identical between shallow and deep HOA-AD eyes (1.00 ± 0.03 vs 1.00 ± 0.04; *P* = .1893; **Figure 4**). In shallow HOA-AD eyes, 99.4% had no change or gained lines of CDVA, compared to 98.2% in deep HOA-AD eyes (*P* = .0002), which translates into 1% more deep HOA-AD eyes losing one line of CDVA, but 0.6% more gaining one line of CDVA (**Figure 4**).

RE-TREATMENTS

The laser re-treatment rate within 3 months was of 0.37% (11 eyes) in shallow HOA-AD eyes and 0.83% (28 eyes) in deep HOA-AD eyes (*P* = .0211).

DISCUSSION

Contoura software uses anterior corneal higher-order Zernike coefficients (C6 to C27) from the high-

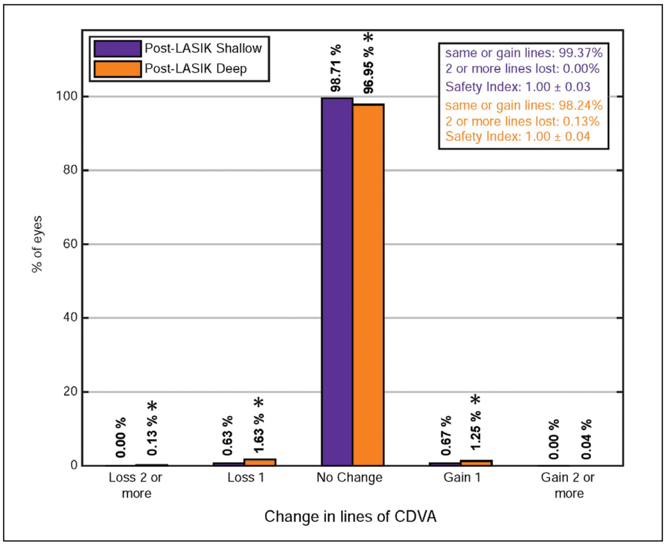

Figure 4. Change in postoperative Snellen lines of corrected distance visual acuity (CDVA) compared with preoperative CDVA in the shallow and deep higher-order aberration ablation depth (HOA-AD) groups. LASIK = laser in situ keratomileusis

resolution Placido VARIO scan to generate an ablation profile where the amount of anterior corneal HOAs are directly correlated to the HOA-AD.[6,7] The current study is the first to characterize the distribution of HOA-AD in a preoperative myopic study population of nearly 10,000 eyes. Using a 6.5-mm ablation zone size, HOA-AD showed a normal left-skewed distribution, centered at a mode of 7 μm with an average of 8 μm. Only 1.8% of eyes had a HOA-AD greater than

15 μm, whereas 0.1% had a depth greater than 20 μm, showing how infrequent high HOA-AD is in virgin eyes. The standard refractive outcomes of the first and last terciles (HOA-AD mean depth of 5.4 vs 11.0 μm) were compared after undergoing Contoura LASIK on subjective refractive astigmatism. The total RMS HOAs were 2.2-fold higher in the deep versus shallow HOA-AD group (0.46 vs 0.21 μm).

Contoura LASIK in the shallow HOA-AD group, less aberrated eyes resulted in 92% achieving 20/20 at 1 month. The refractive astigmatism accuracy was also excellent, with 97% of eyes having postoperative residual astigmatism of 0.50 D or less. The deep HOA-AD group, with greater preoperative HOAs, showed identical efficacy and safety indexes to those of the shallow HOA-AD group, with a mean postoperative refractive astigmatism difference between groups of only 0.05 D. Although the results are comparable, a greater number of deep versus shallow HOA-AD eyes (6.3% vs 3.1%) had postoperative residual astigmatism of 0.75 D or greater, which we defined as an outlier outcome. Considering that the Alpins correction indices were equal between groups, meaning the relative treatment accuracy was the same, the main contributing cause to the outcome difference was not the treatment itself. The preoperative incidence of cylinder of greater than 2.00 D was higher in the deep HOA-AD group (8.3% vs 3.3%). This likely explains the 3% higher rate of outlier eyes with residual cylinder of 0.75 D or greater postoperatively, because eyes with moderate to high cylinder have greater refractive cylinder after surgery with both topography-guided or conventional treatments.[8,14] Further ad hoc analysis revealed that the incidence of preoperative very deep HOA-AD (above 15 μm) was 1.7% in postoperative plano cylinder eyes, compared to 4.1% in postoperative outlier cylinder eyes. By calculating the ratio between those two incidence values (4.1% ÷ 1.7%), having a very deep HOA-AD results in a 2.4 times relative risk of an outlier outcome than a plano outcome. In comparison, the incidence of high cylinder greater than 2.00 D preoperatively was 4.1% in postoperative plano cylinder eyes versus 16.2% in postoperative outlier cylinder eyes. Therefore, having higher preoperative cylinder gives a 4 times relative risk (16.2% ÷ 4.1%) for an outlier outcome, almost double that for very deep HOA-AD. This provides further evidence that a higher preoperative cylinder is a more important risk factor than deep HOA-AD to inferior postoperative refractive astigmatism outcomes.

The FDA study,[6] which preselected minimally aberrated corneas, had a higher rate of postoperative cylinder of 0.75 D or greater (10% vs 6.3% in the current study deep group), and a greater loss of one line or more of CDVA (3.6% vs 1.8%) in both deep and shallow HOA-AD groups in the current study.[6] The superior outcomes of this study are likely attributed to the newer generation excimer laser (WaveLight EX500 vs Allegretto Wave Eye-Q 400, Alcon Laboratories, Inc.), faster repetition rate, cyclotorsional tracking, better image acquisition protocols, and the custom electronic medical record large database nomogram used. The current 1-month study outcomes would be expected to further improve at 3 and 12 months in both groups, due to epithelial remodeling, cortical adaptation, and amelioration of the ocular surface, as shown with progressive improvement in UDVA in recent reports.[6,15]

Because there was a suggestive trend of marginally lower accuracy and efficacy and greater cumulative defocus equivalent with progressively deeper HOA-AD, we performed an ad hoc analysis on extreme eyes with deep HOA-AD of 15 μm or greater, accounting for 1.8% of eyes (N = 175). Above this depth level, 81.6% of eyes achieve 20/20, and 90.3% of eyes are within ±0.50 D of intended plano cylinder, with efficacy and safety being 0.95 and 0.99. Although this shows a 10% reduction in 20/20 UDVA postoperatively, and a 3% efficacy index reduction compared to the shallow HOA-AD group (0.98), these outcomes are comparable to the subset of eyes with cylinder of greater than 2.00 D in the FDA study, where 80% of eyes achieved 20/20 UDVA, and 90% of eyes were within ±0.50 D of intended plano cylinder.[6] In other words, performing surgery on eyes with deep HOA-AD of 15 μm or greater gives good outcomes comparable to moderate to high cylinder eyes.[6,8]

A very weak correlation between the preoperative HOA-AD and the amount of postoperative sphere (R = 0.008; P = .4861), postoperative refractive astigmatism (R = 0.07; P < .0001), and postoperative SEQ (R = 0.025; P = .0267) was found in the 9,722 Contoura eyes. Because HOA-AD did not have a meaningful impact on outcomes in most eyes, this study provides evidence that the degree of preoperative anterior corneal HOA, which directly correlates to HOA-AD, does not influence the preoperative refractive astigmatism to be treated. It also suggests that the asymmetric nature of the anterior corneal HOA ablation, in most virgin eyes, does not induce a clinically meaningful refractive effect, unlike with highly aberrated irregular flap corneas or keratoconic eyes with high coma. These findings agree with previous studies showing that the amount of preoperative anterior corneal HOAs does not correlate with refractive astigmatism or ocular residual astigmatism.[16]

Without any published outcomes data up to now, many surgeons exclude deep HOA-AD eyes from Contoura, and rather treat with conventional wavefront-optimized or Custom-Q software. However, without topography-guided ablation, current symmetrical lower order ablation profiles can worsen preexisting corneal coma postoperatively,[5,17-19] leading to reduced quality of vision and complaints. Such complications would be further exacerbated in preoperative corneas with deep HOA-AD that have high coma. Studies have reported a significant increase in coma after non–topography-guided LASIK, and a lesser increase and even no increase after topography-guided LASIK.[5,17-19] "Fixing" symptomatic coma postoperatively is a more difficult problem than just re-treating residual or induced new cylinder. It is these more irregular preoperative eyes that can preferentially benefit from a topography-guided ablation. As such, the current authors recommend using topography-guided software in virgin eyes, particularly those with higher coma and deep HOA-AD, as a better option. Because HOA-AD of greater than 15 µm gives good outcomes comparable to moderate to high cylinder eyes, there would be no accuracy, efficacy, or safety reasons to exclude these eyes. To add context, a recently published Contoura study on eyes with cylinder of 2.00 D or greater showed 18% of eyes with postoperative cylinder of 0.75 D or greater[8] and significantly less accuracy than seen here in the deep and very deep groups. Therefore, deep HOA-AD would not be a reason to exclude eyes from surgery. Further studies with a direct comparison of topography-guided versus conventional software, principally in eyes with high preoperative coma with deep HOA-AD, together with contrast sensitivity and smaller optotype testing, could further add to the current findings.

The current study used the subjective refractive astigmatism (as opposed to corneal topographic astigmatism) as input for Contoura software in all eyes, demonstrating good outcomes, even in deep HOA-AD eyes. Eyes with naturally occurring irregular astigmatism or with large differences between refractive and corneal astigmatism were included in both groups. Several studies have also shown good outcomes using refractive astigmatism.[5-8,14,15,19-22] This study adds close to 10,000 eyes to the current literature using this methodology, validating that treating the refractive astigmatism is a strategy that works exceptionally well.

Almost all preoperative LASIK eyes have shallow to moderate HOA-AD, with greater than 15 µm depth found in less than 2% of eyes (using a 6.5-mm zone). The contribution of topography-guided HOA-AD to clinical outcomes in most virgin eyes is negligible, with excellent efficacy, accuracy, and safety in both deep and shallow groups. Eyes with deep HOA-AD of greater than 15 µm trend to lesser outcomes, but the latter are comparable to or better than those obtained in eyes with moderate to high cylinder. Eyes with greater HOA-AD should not be excluded from topography-guided surgery.

AUTHOR CONTRIBUTIONS

Study concept and design (AW, MG, MC); data collection (AW, MG, MC); analysis and interpretation of data (AW, MG, MC); writing the manuscript (AW, MG, MC); critical revision of the manuscript (AW, MG, MC); statistical expertise (AW, MG, MC)

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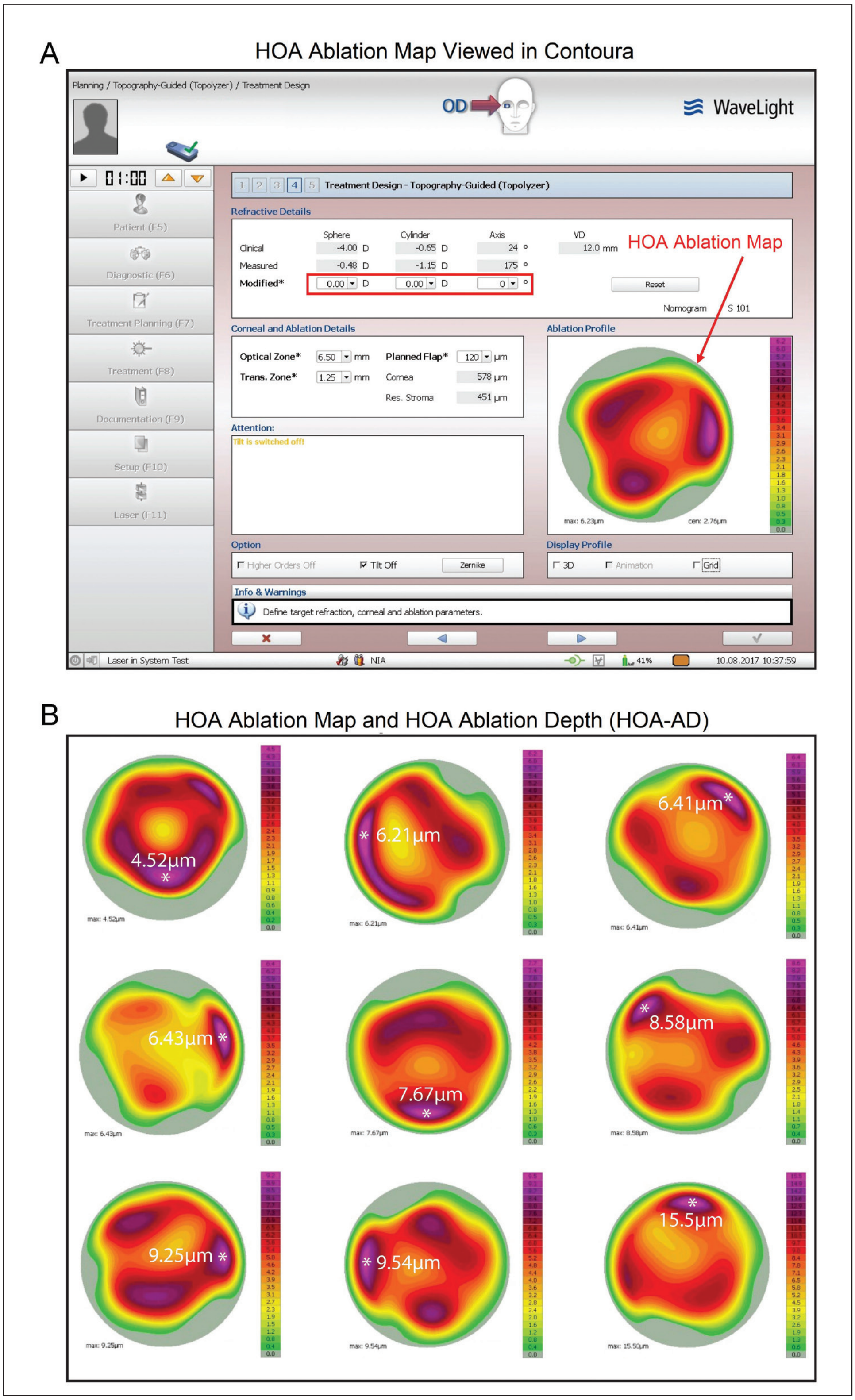

Figure A. (A) Creation of the anterior corneal higher-order aberration ablation profile (HOA-AD), obtained by setting sphere, cylinder, and axis to zero in the "Modified" treatment fields (red rectangle) in the Contoura software (Alcon Laboratories, Inc., Fort Worth, TX). (B) Representative HOA ablation profile. The maximum HOA ablation depth (white stars and corresponding white text values), termed HOA-AD, was recorded for every case. D = diopters

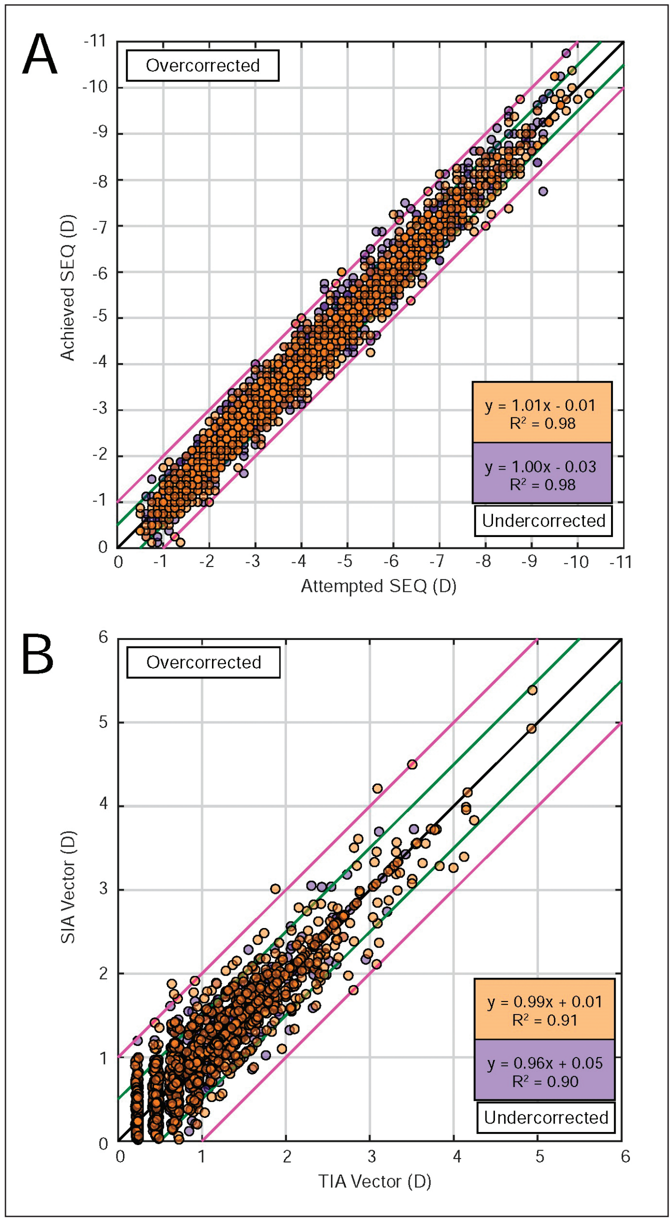

Figure B. (A) Attempted spherical equivalent (SEQ) before surgery vs achieved SEQ after surgery in the shallow and deep higher-order aberration ablation depth (HOA-AD) groups (orange and purple data-points, respectively). Black lines indicate attempted = achieved, green lines indicate ±0.50 diopters (D), and pink lines indicate ±1.00 D. (B) Preoperative target induced astigmatism (TIA) vector versus post-operative surgically induced astigmatism (SIA) vector in shallow and deep HOA-AD eyes (orange and purple data-points, respectively). Black lines indicate TIA = SIA, green lines indicate ±0.50 D, pink lines indicate ±1.00 D.

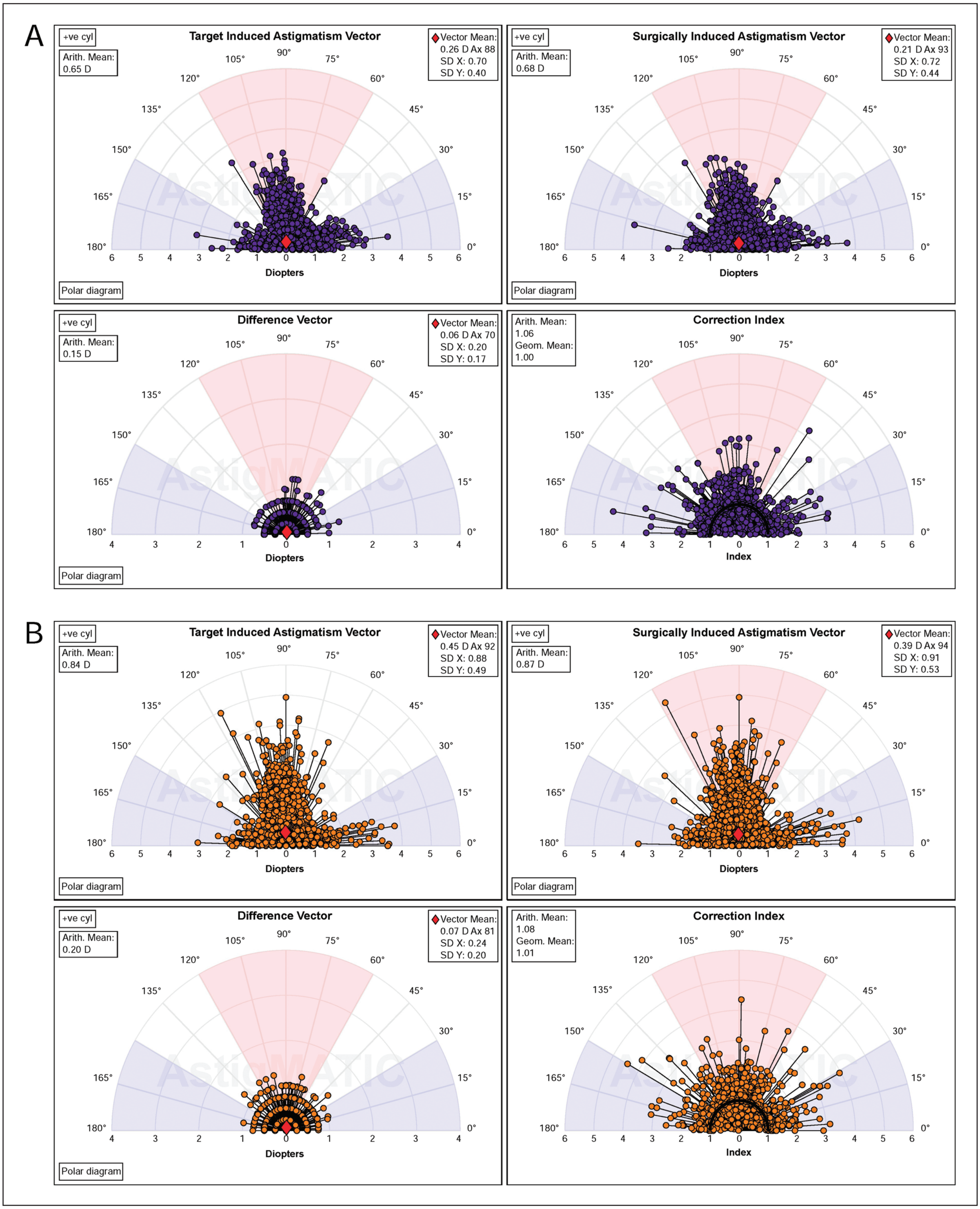

Figure C. Single-angle polar plots generated using the AstigMATIC software[13] to illustrate the target induced astigmatism (TIA) vector, surgically induced astigmatism (SIA) vector, difference vector (DV), and correction index (CI) in the (A) shallow and (B) deep higher-order aberration ablation depth groups. All vectors were calculated at the corneal plane. The vector means are plotted as a red diamond. D = diopters; SD = standard deviation