

Clinical Versus Measured Astigmatism Correction with Topography-Guided Laser in Situ Keratomileusis in Primary Myopia and Myopic Astigmatism

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Abstract:

Background and aim: The aim of this work was to compare the refractive outcomes between topography-guided LASIK with measured astigmatism on the Wave-Light Contoura software and clinically measured astigmatism in eyes with primary myopia and myopic astigmatism. **Subjects and methods:** This study is designed as a Retrospective Cohort Study. The study met the criteria of the Research Ethics committee (REC) with approval No. of Ms 4-4-2020 in Research setting Ebsar eye center between 2019 and 2020. Sixty eyes were selected from patients already had Topoguided-LASIK treatments for myopia and myopic astigmatism. The study included males and females, aged 18 to 45 years old and they were divided into two groups, one group was corrected with Topoguided-LASIK using clinical astigmatism and the other group was corrected using measured astigmatism provided by the software. **Data Synthesis:** The Chi-square test, Mann–Whitney U test and Generalized Linear Mixed

Model were utilized for the analysis in the current study. **Results:** There was statistically non-significant difference between the studied groups regarding mean K measurement preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group. There was statistically non-significant difference between the studied groups regarding pachymetry preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group. **Conclusion:** topography-guided LASIK

with the Contoura system was associated with less induction of HOAs with similar refractive and visual outcomes in clinical refraction.

Keywords: Topography-guided LASIK, Corneal topography, astigmatism, Myopia.

Introduction

Astigmatism is a commonly encountered refractive error, accounting for about 13 percent of the refractive errors of the human eye (1). Our knowledge of astigmatism appears to have begun in the early 1800s when Thomas Young reported on his own astigmatism but it was not until 1825 that the first cylindrical lens was used by George Airy for the purpose of correcting his own astigmatic refractive error (2).

One reason for this research interest is the fact that the presence of astigmatism appears to have potential to influence normal visual development, the presence of high degrees of astigmatism is associated with the development of amblyopia (3). Some associations have also been noted between astigmatism and development of myopia, advances in technology and instrumentation mean that our ability to measure, define and analyze the eye's optical and shape properties (including astigmatism) have improved markedly in recent years, despite extensive research, the exact cause of astigmatism is still unknown (4). Different factors have been

suggested in the development of astigmatism including age, gender, ethnicity, genetic predisposition, eyelid pressure and unequal tension of extraocular muscles on the cornea (5).

The nature of the effects of higher corneal aberrations on lower-order corneal astigmatism has until now been poorly understood, if the corneal astigmatism differed from manifest astigmatism, it was usually diagnosed as lenticular astigmatism by exclusion (6). Topography-guided ablation, market name Contoura on the WaveLight excimer lasers (WaveLight, Erlangen, Germany), has added yet another element of uncertainty, often manifest refraction (cyclopleged or not) and the auto refraction don't correspond with the astigmatism that Contoura Processing results in (7).

The advent of topographic-guided ablation to treat primary corrections has the power to change how refractive surgeons view laser vision correction. Throughout ophthalmic training, surgeons used to use their best

manifest refraction to perform vision correction with excimer laser. With FDA approval of WaveLight Contoura topographic-guided ablation, refractive surgeons now have a choice whether to use the manifest refraction or the Contoura measured astigmatic correction (the astigmatism and axis that Contoura calculates and displays on the Contoura surgical planning page) for topographic-guided laser correction (7).

Contoura is a relatively a new concept (although it has been used for repair worldwide, primary correction is a new development), and performs two separate layers of corrections: the first is the higher order aberrations (HOA) removal layer to remove the natural biological aberrations found in the cornea, the second is the refractive correction layer, which treats sphere and astigmatism. There is a link between HOA removal and astigmatism correction and the Contoura processing software is able to accurately analyze this linkage (7).

Materials and methods

This study is designed as a retrospective cohort study. The study met the criteria of the Research Ethics Committee (REC) with

approval number of MS 4-4-2020 in Research setting Ebsar eye center in the time between 2019 and 2020.

Inclusion Criteria: Patients aged from 18 y to 45 y, patients with myopia and myopic astigmatism only.

Exclusion Criteria: Patients under 18 y or above 45 y, previous ocular trauma or previous eye surgery, pre-existing diseases of the vitreous, macula, or optic nerve that can affect visual outcome, patients with uveitis and anterior segment pathology, patients with corneal pathology, Severe dry eye, pregnancy or breast-feeding females, uncontrolled vascular or autoimmune disease and patients unwilling to give informed consent.

Data collection: History: patient information (age, sex, occupation and residence), any chronic disease (e.g. diabetes). Refraction: Preoperative (Sphere, cylinder and axis), Cycloplegic (sphere, cylinder and axis) and measured astigmatism power and axis, visual acuity: The unaided, best corrected visual acuity, slit lamp examination for corneal state. IOP measurement, it will be performed one day before surgery and at 1 week postoperatively, fundus examination using indirect ophthalmoscope and slit lamp biomicroscopy for exclusion of vitreous hemorrhage, retinal detachment, optic

neuropathy or maculopathy and corneal topography (Pentacam) for fitness of patients for surgery.

Follow-up and Assessments: Regular postoperative follow-up was being conducted 1 month, 3 months, 6 months and 12 months with special attention to: Visual acuity, Best-corrected distance visual acuity and spherical equivalent and slit-lamp biomicroscopy (corneal state).

Sixty eyes (n = 60 subjects) were selected from patients already had Topoguided-LASIK treatments for myopia and myopic astigmatism. The study included males and females, aged 18 to 45 years old and they were divided into two groups, one group was corrected with Topoguided-LASIK using clinical astigmatism and the other group was corrected using measured astigmatism provided by the software.

Corneal topography was provided by ALLERGO-OCULYZER-WAVELIGHT

Fig.1 (8) which provides high definition corneal imaging and optical scanning system by presenting a Scheimpflug rotating camera, with a 360 degrees rotating light beam scanning the cornea with a high density of points from the corneal center (**Karim MN 2020**).

Pre-calculation considerations (**Contoura[®] Vision Training card**) which recommends wave front-optimized™ Ablation to your patient if any of the following conditions apply: A difference of >1.25 D between the refraction cylinder and the measured cylinder, a difference of $> 5^\circ$ between the refraction axis and measured axis if there fraction cylinder ≥ 2.00 D or a difference of $>10^\circ$ between the refraction axis and measured axis if there fraction cylinder < 2.00 D.

Professor AbdelMonem Hamed has developed some artificial intelligence (Excel sheet) calculator, which was named Contoura calculator (Beta version). The Contoura calculator facilitates calculating the modified refraction according to Alcon protocol (Contoura[®] Vision Training card) and prevents human errors through-out the manual calculation as well **(9)**.

Contoura calculator (Beta Version)

How to use the Contoura calculator?

Download the software, and then enable the MACRO to be able to use the Contoura calculator and enter the patient name. **Fig.2 (9)**.

In the first row enter the **manifest** sphere, cylinder, and axis. In the second row enter

the **measured** cylinder and axis. (You can get the measured cylinder magnitude and axis from the Allegretto machine T-CAT interface. **Fig.3 (9)**).

Over this point (second row): If the data entry of the measured cylinder and axis is compatible with Alcon pre-calculation considerations, so the results are fine and the warning sign will not appear, so you can use the data in the third row which is the modified sphere, cylinder and axis to enter them in the modified refraction boxes of the Allegretto excimer laser machine, and continue T-CAT treatment. Also, the Contoura calculator gives you the spherical equivalent (SE) of both the manifest and modified refraction, which are highlighted in green color, so if they are equal to each other, that means the calculation is correct. If the data is not compatible with the Alcon pre-calculation considerations, the Contoura calculator will give you a warning sign which is highlighted in red color to alert you to consider optimize laser ablation instead of T-CAT laser ablation in that case. The last row calculates the high order aberration of the cornea (C12) in diopters and adds the calculated value to the modified sphere to give the total value of the modified sphere including the value needed to correct the

corneal high order aberration (you can get this final value of modified sphere in the fourth row)

At the last: If you are going to perform T-CAT excimer laser ablation, so you need to use the modified refraction values in the 3rd row. If you are going to perform Contoura excimer laser ablation, you need to use the values in the 4th row.

Consider doing optimize ablation instead of T-CAT or Contoura excimer laser treatment if you have a warning sign highlighted in red color.

Statistical Analysis: The results were being analyzed using SPSS 25. Normally distributed continuous data will be expressed as mean \pm standard deviation and non-normally distributed continuous data will be expressed as median (range).

Results

There was statistically non-significant difference between the studied groups regarding spherical refraction preoperatively and 1 month postoperatively. There is statistically significant difference between the studied groups regarding spherical refraction 3, 6 and 12 months postoperatively. There was statistically

significant change over time in each group. **(Table 1)**

There was statistically non-significant difference between the studied groups regarding cylindrical refraction preoperatively and at each month postoperatively. There is statistically significant change over time in each group. **(Table 2)**

There was statistically non-significant difference between the studied groups regarding spherical equivalent preoperatively and at 1,6 and 12 months postoperatively. There is statistically significant difference between the studied groups regarding spherical equivalent at 3 months postoperatively .There is statistically significant change over time in each group. **(Table 3)**

There is statistically non-significant difference between the studied groups regarding K1 measurement preoperatively and 1, 3, 6and 12 months postoperatively. There is statistically significant change over time in each group. **(Table 4)**

There was statistically non-significant difference between the studied groups

regarding mean K measurement preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group. **(Table 5)**

There was statistically non-significant difference between the studied groups regarding pachymetry preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group. **(Table 6)**

There was statistically non-significant difference between the studied groups regarding UCVA preoperatively and at 1, 3, 6 or 12 months postoperatively. There is statistically significant change over time in each group. **(Table 7)**

There was statistically non-significant difference between the studied groups regarding percentage of patients who developed new axis for astigmatism. Thirteen patients (43.2%) of patients within clinical refraction group had astigmatism in new axis rather than preoperative axis versus twelve patients in measured Rx group. **(Table 8)**

Table (1) Comparison between manifest and measured refraction groups regarding manifested spherical refraction measurement over time:

Parameter	Groups		Test	
	Clinical refraction group	Measured Refraction group	Z	p
	N=30 (%) Median (range)	N=30 (%) Median (range)		
Preoperatively	-6.125 (-10, -1.5)	-4.75 (-9.5, -2.75)	-1.421	0.155
1 month postoperatively	0.25 (-1.5, 0.75)	0.25 (-1, 0.5)	-0.725	0.452
3 months postoperatively	-0.5 (-1.5, 0.75)	-0.5 (-1, 0.5)	-2.616	0.009*
6 months postoperatively	-0.5 (-1.5, 0.75)	-0.25 (-1.5, 0.75)	-2.096	0.036*
12 months postoperatively	-0.5 (-1.5, 0.75)	-0.25 (-1.5, 0.75)	-2.088	0.037*
P (Fr)	<0.001**	<0.001**		

Fr Friedman test Z Mann Whitney test *p<0.05 is statistically significant **p<0.001 is statistically highly significant

Table (2) Comparison between manifest and measured refraction groups regarding manifested cylindrical refraction measurement over time:

Parameter	Groups		Test	
	Clinical refraction group	Measured Refraction group	Z	p
	N=30 (%) Median (range)	N=30 (%) Median (range)		
Preoperatively	0.5 (0, 2.75)	1.125(0, 1)	-1.465	0.143
1 month postoperatively	0 (0, 1)	0 (0, 1)	-0.5	0.617
3 months postoperatively	0 (0, 1)	0 (0, 1)	-0.5	0.617
6 months postoperatively	0 (0, 1)	0 (0, 0.75)	-0.738	0.46
12 months postoperatively	0 (0,1)	0 (0, 0.75)	-0.738	0.46
P (Fr)	<0.001**	<0.001**		

Fr Friedman test Z Mann Whitney test *p<0.05 is statistically significant **p<0.001 is statistically highly significant

Table (3) Comparison between manifest and measured groups regarding Spherical equivalent measurement over time:

SE	Groups		Test	
	Clinical refraction group	Measured Refraction group	Z	p
	N=30 (%) Median (range)	N=30 (%) Median (range)		
Preoperatively	-5.5 (-8.75, -1.38)	-4.25 (-9, -2.13)	-1.73	0.084
1 month postoperatively	0.25 (-1.5, 0.88)	0.25 (-0.75, 0.75)	-0.881	0.378
3 months postoperatively	-0.5 (-1.5, 0.75)	-0.25 (-0.75,0.63)	-2.344	0.019*
6 months postoperatively	-0.31 (-1.5, 0.75)	-0.25 (-0.75, 0.88)	-1.850	0.64
12 months postoperatively	-0.31 (-1.5, 0.75)	-0.25 (-0.75, 0.88)	-1.850	0.64
P (Fr)	<0.001**	<0.001**		

Fr Friedman test Z Mann Whitney test *p<0.05 is statistically significant **p<0.001 is statistically highly significant

Table (4) Comparison between manifest and measured refraction groups regarding K1 measurement over time:

Parameter	Groups		Test	
	Clinical refraction group	Measured Refraction group	t	p
	N=30 (%) Mean ± SD	N=30 (%) Mean ± SD		
Preoperatively	43.915 ± 1.663	43.313 ± 1.279	1.57	0.122
1 month postoperatively	40.527 ± 1.364	40.395 ± 1.418	0.367	0.715
3 months postoperatively	40.527 ± 1.364	40.395 ± 1.418	0.367	0.715
6 months postoperatively	40.193 ± 1.705	40.24 ± 1.576	-0.112	0.911
12 months postoperatively	40.193 ± 1.705	40.24 ± 1.576	-0.112	0.911
P (Fr)	<0.001**	<0.001**		

Fr Friedman test Z Mann Whitney test *p<0.05 is statistically significant **p≤0.001 is statistically highly significant

Table (5) Comparison between manifest and measured refraction groups regarding mean K measurement over time:

Mean K	Groups		Test	
	Clinical refraction group	Measured Refraction group	t	p
	N=30 (%) Mean ± SD	N=30 (%) Mean ± SD		
Preoperatively	44.904 ± 1.861	44.608 ± 1.81	0.625	0.535
1 month postoperatively	40.999 ± 1.386	40.789 ± 1.833	0.501	0.618
3 months postoperatively	40.999 ± 1.386	40.789 ± 1.833	0.501	0.618
6 months postoperatively	40.779 ± 1.636	40.736 ± 1.738	0.098	0.922
12 months postoperatively	40.779 ± 1.636	40.736 ± 1.738	0.098	0.922
P (F)	<0.001**	<0.001**		

F Repeated measure ANOVA test t Independent sample t test *p<0.05 is statistically significant **p≤0.001 is statistically highly significant

Table (6) Comparison between manifest and measured refraction groups regarding Pachymetric measurement over time:

Pachymetry	Groups		Test	
	Clinical refraction group	Measured Refraction group	t	p
	N=30 (%) Mean ± SD	N=30 (%) Mean ± SD		
Preoperatively	557.17 ± 38.975	543.83 ± 33.71	1.417	0.162
1 month postoperatively	499.1±41.827	486.67±37.142	1.217	0.228
3 months postoperatively	499.1 ± 41.827	486.67 ± 37.142	1.217	0.228
6 months postoperatively	497±43.653	484.1±38.722	1.211	0.231
12 months postoperatively	497 ± 43.653	484.1 ± 38.722	1.211	0.231
P (F)	<0.001**	<0.001**		

F Repeated measure ANOVA test t Independent sample t test *p<0.05 is statistically significant **p≤0.001 is statistically highly significant

Table (7) Comparison between manifest and measured refraction groups regarding manifested UCVA measurement over time:

UCVA	Groups		Test	
	Clinical refraction group	Measured Refraction group	Z	p
	N=30 (%)	N=30 (%)		
	Median (range)	Median (range)		
Preoperatively	1.5 (0.5, 2)	1 (0.4, 2)	-1.266	0.205
1 month postoperatively	0 (-0.2, 0.7)	0 (-0.2, 0.5)	-0.387	0.699
3 months postoperatively	0 (-0.2, 0.7)	0 (-0.2, 0.5)	-0.387	0.699
6 months postoperatively	0 (-0.2, 0.7)	0 (-0.2, 0.5)	-0.356	0.722
12 months postoperatively	0 (-0.2, 0.7)	0 (-0.2, 0.5)	-0.356	0.722
P (Fr)	<0.001**	<0.001**		

Fr Friedman test Z Mann Whitney test *p<0.05 is statistically significant **p<0.001 is statistically highly significant

Table (8) Comparison between manifest and measured refraction groups regarding axis and power of astigmatism postoperative as compared to preoperative value:

	Groups		Test	
	Clinical refraction group	Measured Refraction group	χ^2	p
	N=30 (%)	N=30 (%)		
	Median (range)	Median (range)		
New axis	13 (43.2)	12 (40)	0.069	0.793
Corrected	17 (56.8)	18 (60)		
Not corrected	13 (43.2)	12 (40)	0.069	0.793
Corrected	17 (56.8)	18 (60)		

χ^2 Chi square test t Independent sample t test



Figure 1: ALLERGO-OCULYZER-WAVELIGHT (8)

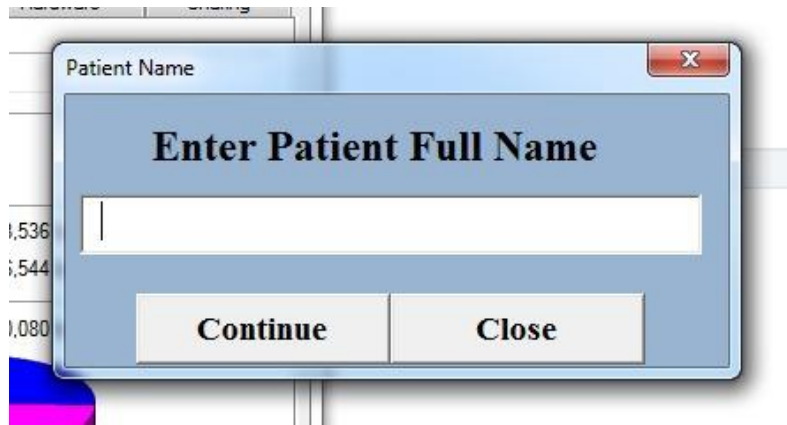


Figure 2: The contoura calculator (9)

	Sphere	Cylinder	Axis	SE	Patient Name
Clinical refraction	0.00	0.00	0.00	0.00	Muhammed
Measured [Cylinder & Axis]		0.00	0.00		
Modified refraction	0.00	0.00	0.00	0.00	Warning Message
Contoura refraction	0.00	0.00	0.00		
HOA	C12 (Micron)	C12 (Diopter)			T-Cat & Contours can be done
	0.00	0.00			

Figure 3: The contoura calculator (9)

Discussion

Established ablation profiles in conventional laser in situ keratomileusis (LASIK) frequently induce higher-order aberrations (HOAs). These aberrations cause visual disturbances, including light sensitivity, glare, halos, starbursts, and reduced contrast sensitivity. Therefore, custom correction of refractive errors has been gaining popularity. In the past decade, technological advancements have been made to avoid the

adverse effects of conventional LASIK on visual quality; these include wavefront-guided, wavefront-optimized and topography-guided surgery (10).

However, to date few contralateral-eye studies have compared the surgical outcomes of wavefront-optimized treatment and topography-guided treatment performed using the WaveLight EX500 excimer laser and Contoura Vision software (both Alcon

Laboratories, Inc.), the most recent LASIK technology to be approved by the United States Food and Drug Administration (10).

In this study we found that there is statistically non-significant difference between the studied groups regarding spherical refraction preoperatively and 1 month postoperatively. There is statistically significant difference between the studied groups regarding spherical refraction 3, 6 and 12 months postoperatively.

A comparison was done the preoperative characteristics and intraoperative parameters between the wavefront-optimized group and topography-guided group (10). There were no statistically significant between-group differences in any preoperative or intraoperative characteristic, including Sphere (D), corneal astigmatism and refractive astigmatism (10).

It was shown that after 3 months, the total HOAs, coma, and spherical aberration were significantly higher than preoperatively in both groups (10).

It was also shown that preoperative ocular (whole-eye) HOAs and corneal HOAs with a 6.0 mm pupil diameter did not differ significantly between the 2 groups (Table 3). However, after 3 months, the total HOAs,

coma, and spherical aberration were significantly higher than preoperatively in both groups (10).

In this study we cleared that there is statistically non-significant difference between the studied groups regarding cylindrical refraction preoperatively and at each month postoperatively. There is statistically significant change over time in each group

It was reported that there were no statistically significant between-group differences in any preoperative or intraoperative characteristic, including Cylinder (D) (10).

In this study we reported that there is statistically non-significant difference between the studied groups regarding spherical equivalent preoperatively and at 1,6 and 12 months postoperatively. There is statistically significant difference between the studied groups regarding spherical equivalent at 3 months postoperatively. There is statistically significant change over time in each group.

It was elicited that only 7.93% and 8.20% had a change greater than 0.5 D in groups A and B, respectively (P= 0.8). However, the spherical equivalent had insignificant

change from -0.23 ± 0.41 D at 3rd month to -0.26 ± 0.33 D at 12th month in group A and from -0.26 ± 0.40 D at 3rd month to -0.25 ± 0.33 D at 12th month in group B (9).

In a study done previously, and regarding the refractive and visual acuity outcomes in all eyes there was a mean change in mean refractive spherical equivalent (MRSE) of 0.03 ± 0.39 D between 1 week and 1 month postoperatively. The MRSE changed by 0.02 D from 1 month to 3 months and by 0.04 D from 3 months to 6 months. Refractive stability was reached by 3 months (11).

It was reported that there were no statistically significant between-group differences in any preoperative or intraoperative characteristic, including mean refractive spherical equivalent (MRSE) (10).

It was shown that there were no statistically significant between-group differences in preoperative SEQ (12).

It was proved that 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) ($P=0.043$)(13).

In this study we illustrated that there is statistically non-significant difference between the studied groups regarding K1 measurement preoperatively and 1, 3, 6 and 12 months postoperatively. There is statistically non-significant difference between the studied groups regarding K2 measurement preoperatively and 1, 3, 6 or 12 months postoperatively.

Kim et al. (10) showed that there were no statistically significant between-group differences in any preoperative or intraoperative characteristic, including Flat keratometry and Steep keratometry (10).

In this study we demonstrated that there is statistically non-significant difference between the studied groups regarding mean K measurement preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group.

It was accepted that all other preoperative characteristics, including age, visual acuity, manifest refraction, ACA, magnitude of discrepancy between refractive astigmatism and ACA, ocular residual astigmatism (ORA), corneal HOA maximum ablation depth, keratometry, and corneal thickness, were also comparable between eyes treated on the refractive astigmatism and ACA axes.

There is no significant difference between groups as regard preoperative keratometry (12).

In this study we showed that there is statistically non-significant difference between the studied groups regarding pachymetry preoperatively and at 1, 3, 6 and 12 months postoperatively. There is statistically significant change over time in each group.

It was proved that there was no statistically significant difference between-group in any preoperative or intraoperative characteristic, including Pachymetry (10).

In this study we reported that there is statistically non-significant difference between the studied groups regarding UCVA preoperatively and at 1, 3, 6 or 12 months postoperatively. There is statistically significant change over time in each group.

Kim et al. (10) showed that the number of patients who achieved a postoperative UCVA of 0.2 logMAR and 0.1 logMAR did not differ significantly between studied groups in his study (25.6% and 60.5%, respectively).

Another study showed that there was no significant difference between groups in his study as regard UCVA (12).

In the 12 months' postoperative visit, 97% and 71% of the eyes demonstrated a UCVA of 20/20 and 20/16 or better, respectively, in group A. Whereas in group B, 98% and 70% of the eyes presented with a UCVA of 20/20 and 20/16 or better, respectively (9).

In this study we showed that there is statistically non-significant difference between the studied groups regarding percentage of patients who developed new axis for astigmatism. Thirteen patients (43.2%) of patients within clinical refraction group had astigmatism in new axis rather than preoperative axis versus twelve patients in measured Rx group

It was stated that the number of patients who achieved a postoperative refractive astigmatism of less than 0.50 D was not significantly different between the 2 groups (79.1% versus 86.1%). We postulate that the similar visual and refraction outcomes are mainly the result of both groups having same correction target based on the manifest sphere and cylinder and a similar surgically induced total HOAs (10).

Limitations of the study: However, the present study had several limitations, including a small sample and short follow-up. In addition, contrast sensitivity was not measured, and symptoms affecting quality

of vision (eg, glare, haze, and halo) were not compared. Future studies are warranted to further evaluate vision quality.

Conclusion:

Topography-guided LASIK using the WaveLight excimer laser with the Contoura system was associated with less induction of HOAs, although the topography-guided with clinical refraction provided similar refractive and visual outcomes.

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