

Ray-tracing–Guided or Q-Value–Adjusted FS-LASIK for Correction of Myopia and Myopic Astigmatism: A Comparative Contralateral Eye Study

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ABSTRACT

PURPOSE: To compare the safety and efficacy of individualized ray-tracing-guided femtosecond laser-assisted in situ keratomileusis (FS-LASIK) for correction of myopia and myopic astigmatism.

METHODS: This prospective, randomized, double-blind, contralateral eye study included 68 eyes of 34 patients with myopia or myopic astigmatism requiring FS-LASIK treatment. For each patient, one eye was randomly assigned to receive the ray-tracing-guided treatment, whereas the contralateral eye underwent Q-value-adjusted ablation. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), sphere, cylinder, effective optical zone (EOZ), and 6-mm corneal aberrations were measured and analyzed before operation and after a 3-month postoperative follow-up.

RESULTS: At 3 months postoperatively, the UDVA of 20/16 or better was measured in 94% of eyes in the ray-tracing

group and 85% of eyes in the Custom-Q group ($P = .064$). Forty-seven percent in the ray-tracing group and 32% in the Custom-Q group gained one or more Snellen lines of CDVA ($P = .043$). The MRSE, refractive astigmatism, surgically induced astigmatism, and difference vector were better in the Custom-Q group ($P < .05$). The postoperative corneal HOAs and optical path difference were significantly better in the ray-tracing group ($P = .008$). The EOZs of the ray-tracing and Custom-Q groups were 5.77 and 5.43 mm ($P < .001$), and the average ablation depths of the ray-tracing and Custom-Q groups were 100.97 and 85.24 μm ($P < .001$), respectively.

CONCLUSIONS: Despite the overcorrection and excessive ablation of corneal tissue, ray-tracing-guided FS-LASIK in clinical practice was found to be safe and effective for myopic correction both with and without astigmatism, particularly in achieving UDVA and inducing fewer corneal HOAs and less OPD.

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As myopia prevalence rises, the pursuit of safer and more satisfying refractive surgery has spurred the development of various treatment techniques and excimer laser ablation profiles.¹ To date, most of the ablation profiles used in corneal laser vision correction surgery, whether conventional or customized, were developed from the Gullstrand reduced eye model.² The calculations were based on average refractive values of the eye. However, the eyeball is a complex multi-lens optical system.³ Although

those laser ablation profiles were proven extremely effective in correcting sphere, cylinder, and even higher order aberrations (HOAs), they did not resolve all ocular optical errors and resulted in relatively unsatisfactory postoperative vision and visual quality.

In 2008, Mrochen et al³ proposed a laser ablation profile based on ray-tracing theory, which took into account all optically significant structures of the eye. The new optical ray-tracing algorithm uses data from a beam of light passing through the various refract-

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ing media of the eye to focus precisely on the fovea, contributing data to a highly individualized custom ablation profile.⁴ Previous studies have evaluated the safety and efficacy of the ray-tracing algorithm (WaveLight Plus; Alcon Laboratories, Inc), using multiple instruments to supply biometry, tomography, and wavefront patient data to the algorithm.^{4,5} Recently, a single diagnostic device called InnovEyes Sightmap (Alcon Laboratories, Inc) integrated three ocular measuring instruments into one. These measurements are applied to the InnovEyes platform (Alcon Laboratories, Inc) to generate an automated ray-tracing algorithm that could treat sphere, cylinder, and HOAs simultaneously. Additionally, the algorithm also provided an enhanced precompensation calculation that considers laser efficiency, corneal epithelial remodeling, and expected biomechanical changes.⁶⁻⁸

Aspherical ablation profile or Q-value-adjusted or Custom-Q ablation algorithm is currently a widely used method, and both are based on the manifest refraction.⁹ In this study, we compared two methods of corneal ablation performed using femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) in myopic eyes with or without astigmatism. We conducted a prospective randomized controlled study between two eyes in the same individual. For each patient, one eye was treated with ray-tracing and the contralateral eye was treated with Custom-Q. Both methods required the use of the WaveLight EX500 (Alcon Laboratories, Inc) excimer laser system.

PATIENTS AND METHODS

PATIENTS

This prospective, randomized, comparative study was conducted at the Peking University Third Hospital from September 2023 to January 2024. The study was approved by the ethics committee of the Peking University Third Hospital (#M2024275) and was conducted in accordance with the tenets of the Declaration of Helsinki. A written informed consent was obtained from each patient prior to the surgical procedure.

The study included patients aged 21 to 43 years of both sexes with myopia with or without astigmatism, with corrected distance visual acuity (CDVA) no worse than 20/25, with a documented refractive stability for a minimum period of 1 year, and with discontinuation of soft contact lenses for at least 2 weeks. Exclusion criteria were: anisometropia greater than 1.50 D in the spherical equivalent, corneal thickness of less than 500 μm , or predictive postoperative residual stromal bed less than 280 μm , topographic and/or tomographic evidence of corneal ectasia, previous ocular surgery, history of herpetic eye disease, corneal scarring, collagen vascular disease, pregnancy, and lactation.

PREOPERATIVE EXAMINATIONS

Preoperative evaluation included uncorrected distance visual acuity (UDVA) and CDVA, manifest cycloplegic and noncycloplegic refraction, slit-lamp biomicroscopy, and dilated fundus evaluation. The measurements including biometry, wavefront refraction, whole eye aberrometry, and tomography were captured by the InnovEyes SightMap (Alcon Laboratories, Inc). The asphericity and corneal HOAs were measured using WaveLight Topolyzer Vario software (Alcon Laboratories, Inc). The total corneal aberrations and optic quality in a 6-mm zone were obtained from the corneal topography and tomography (Sirius; CSO). Parameters of corneal aberrations and optical quality included optical path difference (OPD), root mean square (RMS) of HOAs, corneal astigmatism, spherical aberration (SA), coma, and Strehl ratio.

SURGICAL PROCEDURES

All surgeries were performed by an experienced refractive surgeon (YC) under topical anesthesia. All flaps were created using the WaveLight FS200 femtosecond laser (Alcon Laboratories, Inc). The flap/canal/hinge parameters were flap thickness of 110 μm , flap diameter of 8.5 to 9 mm, side-cut angle of 100°, hinge angle of 50°, and canal width of 1.3 mm. Following blunt dissection and flap lifting, the stromal bed was ablated with an excimer laser (EX500 WaveLight) using an optical zone of 6.5 mm with a 1.25-mm transition zone under automatic angle kappa and cyclotorsion compensation.

The ray-tracing ablation profile was constructed from measurements wherein the wavefront sphere at 4 mm and subjective sphere were aligned within 0.50 diopters (D). No nomogram adjustments were applied within this cohort. The excimer laser treatment was performed using a WaveLight EX500 with a treatment zone of 6.5 mm and the ablation profile based on the ray-tracing technology was automatically generated.⁶

The preoperative examinations by the Topolyzer were transferred to an EX500 excimer laser workstation and used to plan the Custom-Q ablation profile. The postoperative Q-target was programmed to be equal to the preoperative physiological Q. The refraction data used for the eyes randomized to the Custom-Q group were the subjective manifest refraction. The ablation profile was centered on an estimated visual axis determined by the topographer (taking 75% of the pupil toward the corneal vertex [offset value]), which closely approximates the visual axis.

POSTOPERATIVE CARE AND FOLLOW-UP

Postoperatively, all eyes received treatment with 0.1% fluorometholone (FML; Allergan Pharmaceuticals)

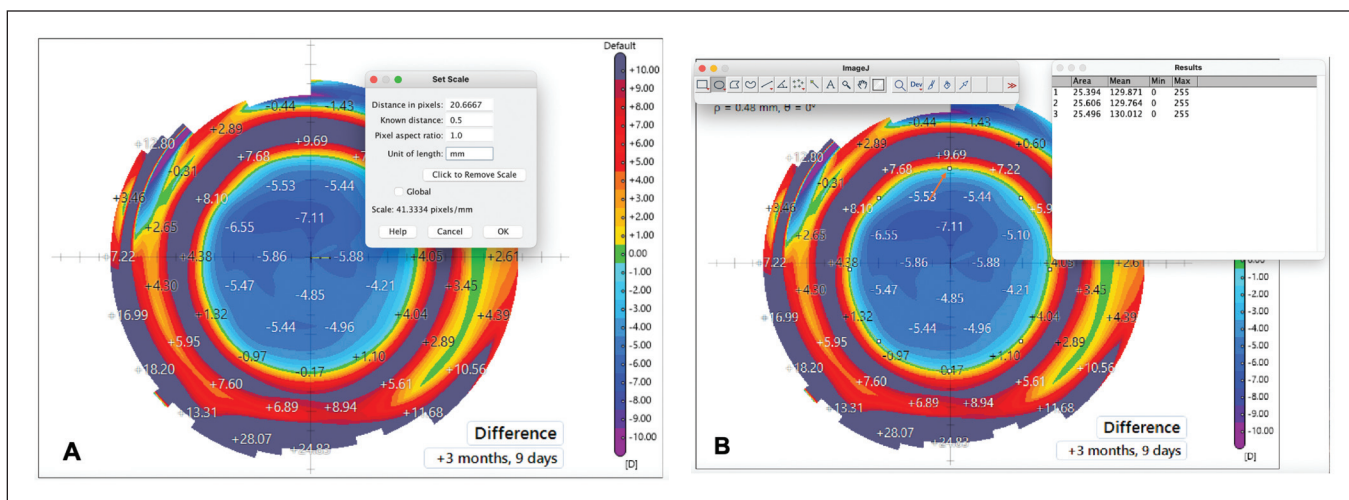


Figure 1. Analyzing effective optical zone (EOZ) with ImageJ software (National Institutes of Health). (A) Draw a straight line along the x-axis and set the scale. (B) Draw a circle along zero diopter on the tangential curvature, adjust 8 anchor points (orange arrow) to outline the green area, and click the measure function to obtain the size.

in tapering dose for 4 weeks, 0.5% levofloxacin (Cravit; Santen Pharmaceutical (China) Co Ltd) four times a day for 2 weeks, and lubricating drops four times a day for at least 4 weeks. The follow-up visits data had been obtained for stability of at least 3 months. The follow-up examinations involved measurements of UDVA, slit-lamp examination, manifest refraction, CDVA, and combined corneal topography and tomography.

EFFECTIVE OPTICAL ZONE (EOZ) MEASUREMENT

The Sirius combined corneal topography and tomography system was used to measure the EOZ with preoperative–postoperative tangential difference map. As previously described,^{10,11} EOZ was considered as the area outlined by a change of zero diopter on the tangential curvature difference map.

EOZ measurements were obtained using the National Institutes of Health ImageJ software.¹² The protocol for analysis (**Figure 1**) was:

1. Upload the screenshot from the Sirius (tangential curvature difference map) to ImageJ.
2. Draw a straight line along the x-axis and set the scale. Each image contained a scale bar (the length of each segment = 0.5 mm).
3. Using the Circle tool in ImageJ, adjust 8 anchor points to outline the green area (zero diopter).
4. Click on Measure to obtain the area of each EOZ. For accuracy and reproducibility, each sample should be performed three times and the average taken.
5. The EOZ was calculated as:

$$2 \times \sqrt{\text{EOZ area}/\pi}$$

STATISTICAL ANALYSIS AND SAMPLE SIZE CALCULATION

All statistical analyses were performed using SPSS version 25.0 software (version 25.0; SPSS, Inc). A *P* value of less than .05 was considered statistically significant. Continuous variables were checked for normality using the Kolmogorov-Smirnov test. Measurements were expressed as mean ± standard deviation (range). The paired *t*-test was used to compare the two data sets, where variables that did not conform to a normal distribution were compared using the Wilcoxon signed-rank test. Comparison of the percentage of eyes between the preoperative and the postoperative used the Fisher's exact test. Linear regression analyses were performed to compare achieved versus attempted outcomes. In corneal vector analysis, the keratometric refractive index (1.3375) was used. The results were based on the standard for reporting astigmatism outcomes of refractive surgery.

According to the results of previous study,^{9,13} the 3-month postoperative UDVA in the ray-tracing and Custom-Q groups were -0.14 ± 0.06 and -0.08 ± 0.05 logMAR, respectively. With a power of 0.95 and type I error of 0.05, the estimated sample size was calculated as 24 in each group. Considering the drop-off rate of 15% at each visiting time point (1 week, 1 month, and 3 months), the sample size was 40. Therefore, 40 patients were recruited at the beginning, 6 of them were lost to follow-up before the 3-month visit, and 34 of them were analyzed for 3 months.

The results were based on the standard for reporting astigmatism outcomes of refractive surgery.¹⁴

RESULTS

CHARACTERISTICS OF THE PATIENTS

This study included 68 eyes of 34 patients (29 women and 5 men). No procedure-related complications,

TABLE 1
Comparison of Preoperative Parameters, Mean $\pm$ SD (Range)

Parameter	IE (n = 34)	Custom-Q (n = 34)	P
Sphere (D)	-5.01 $\pm$ 1.54 (-8.50 to -1.75)	-5.55 $\pm$ 1.64 (-9.00 to -2.50)	.186
Cylinder (D)	-1.07 $\pm$ 0.83 (-3.00 to 0.00)	-0.98 $\pm$ 0.79 (-3.50 to 0.00)	.333
MRSE (D)	-5.55 $\pm$ 1.64 (-9.00 to -2.25)	-5.69 $\pm$ 1.71 (-9.00 to -2.00)	.239
CDVA (logMAR)	-0.09 $\pm$ 0.04 (-0.18 to 0.00)	-0.09 $\pm$ 0.04 (-0.18 to 0.00)	> .999
Ablation depth-maximum (μ m)	100.97 $\pm$ 20.78 (57.60 to 154.04)	85.24 $\pm$ 21.89 (36.61 to 123.89)	< .001 ^a
Ablation depth-central (μ m)	100.96 $\pm$ 20.79 (57.60 to 154.04)	85.24 $\pm$ 21.89 (36.61 to 123.89)	< .001 ^a
AL (mm)	25.60 $\pm$ 0.88 (23.65 to 27.58)	25.68 $\pm$ 0.86 (23.87 to 27.43)	.112

AL = axial length; CDVA = corrected distance visual acuity; Custom-Q = the refraction data planned with Q-factor customized corneal ablation treatment; D = diopters; IE = the refraction data planned based on the ray-tracing technology; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refraction spherical equivalent

^aSignificantly different between IE and Custom-Q groups using paired t-test and Wilcoxon signed-rank test.

TABLE 2
Comparison of Refractive Outcomes at 3 Months Postoperatively, Mean $\pm$ SD (Range)

Parameter	IE (n = 34)	Custom-Q (n = 34)	P
UDVA (logMAR)	-0.10 $\pm$ 0.05 (-0.20 to 0.00)	-0.09 $\pm$ 0.07 (-0.18 to 0.10)	.040 ^a
Sphere (D)	0.38 $\pm$ 0.35 (0.00 to 1.50)	0.10 $\pm$ 0.28 (-0.25 to 1.25)	.001 ^a
Cylinder (D)	-0.24 $\pm$ 0.33 (-1.00 to 0.00)	-0.13 $\pm$ 0.23 (-1.00 to 0.00)	.028 ^a
MRSE (D)	0.26 $\pm$ 0.27 (-0.13 to 1.00)	0.03 $\pm$ 0.29 (-0.25 to 1.25)	.001 ^a
CDVA (logMAR)	-0.12 $\pm$ 0.05 (-0.20 to -0.04)	-0.11 $\pm$ 0.05 (-0.18 to -0.04)	.182
EOZ area (mm ²)	26.18 $\pm$ 3.26 (20.41 to 36.77)	23.23 $\pm$ 2.50 (19.58 to 28.77)	< .001 ^a
EOZ (mm)	5.77 $\pm$ 0.35 (5.10 to 6.84)	5.43 $\pm$ 0.29 (5.00 to 6.05)	< .001 ^a
TIA	-1.07 $\pm$ 0.83 (-3.00 to 0.00)	-0.98 $\pm$ 0.79 (-3.50 to 0.00)	.333
SIA	-1.24 $\pm$ 0.35 (-4.00 to 0.00)	-1.02 $\pm$ 0.35 (-3.60 to 0.00)	.045 ^a
DV	-0.24 $\pm$ 0.33 (-1.00 to 0.00)	-0.13 $\pm$ 0.23 (-1.00 to 0.00)	.028 ^a
CI	1.08 $\pm$ 0.20 (0.83 to 1.65)	1.04 $\pm$ 0.17 (0.70 to 1.70)	.136

CDVA = corrected distance visual acuity; CI = correction index; Custom-Q = the refraction data planned with Q-factor customized corneal ablation treatment; D = diopters; DV = difference vector; EOZ = effective optical zone; IE = the refraction data planned based on the ray-tracing technology; logMAR = logarithm of the minimum angle of resolution; MRSE = manifest refractive spherical equivalent; SD = standard deviation; SIA = surgically induced astigmatism; TIA = target induced astigmatism; UDVA = uncorrected distance visual acuity

^aSignificantly different between IE and Custom-Q groups using paired t-test and Wilcoxon signed-rank test.

corneal haze, diffuse lamellar keratitis, or epithelial ingrowth were observed.

Table 1 lists the two groups' preoperative parameters. No significant differences were observed in preoperative sphere, cylinder, manifest refraction SE, and CDVA between the two groups except for ablation depth-maximum and ablation depth-central.

VISUAL ACUITY, EFFICACY, SAFETY, AND EOZ

Compared to preoperative parameters, the ray-tracing group showed a better UDVA than that in the Custom-Q group ($P = .04$) (**Table 2**). However, significant disparities were observed in sphere, cylinder, manifest refraction SE, surgically induced astigmatism, and difference vector (DV) between the two groups.

The programmed optical zone was 6.5 mm in diameter in both groups, but the ray-tracing group created a significantly larger EOZ ($P < .001$) compared to Custom-Q postoperatively.

The standardized graphs in **Figure 2** demonstrate the visual and refractive outcomes. **Figure 2A** shows the distribution of monocular postoperative UDVA and preoperative CDVA. The preoperative CDVA was 20/20 or better in all eyes in both groups. The postoperative UDVA was 20/16 or better in 32 eyes (94%) in the ray-tracing group compared with 29 eyes (85%) in the Custom-Q group. No significant differences were observed between the two groups ($P = .064$).

Figure 2B shows the differences between preoperative CDVA and postoperative UDVA. At the 3-month

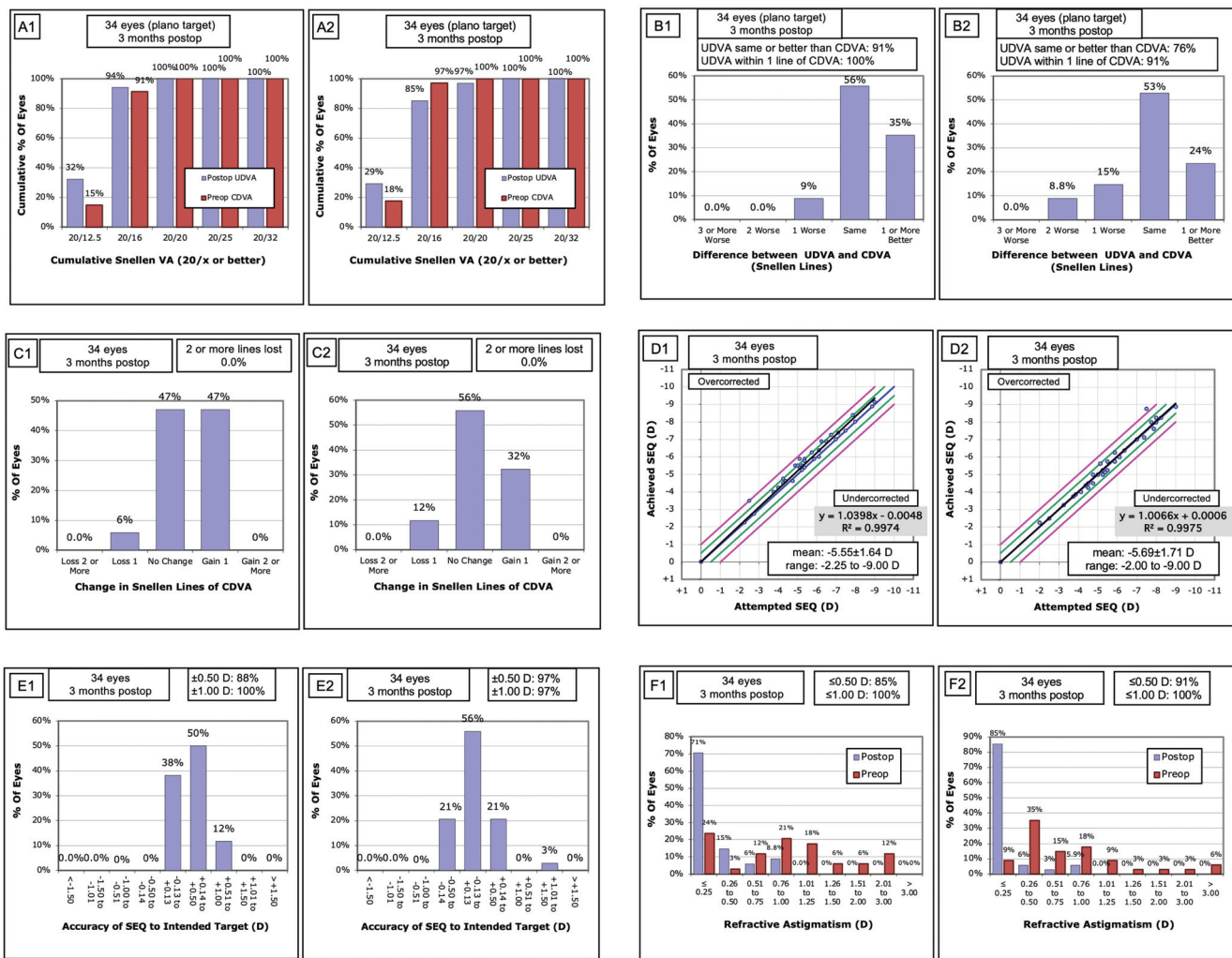


Figure 2. Visual outcomes after ray-tracing (A1-F1) and Custom-Q (A2-F2) femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK). (A) Cumulative 3-month postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA). Changes in the Snellen lines of postoperative (B) UDVA and (C) CDVA, compared with preoperative CDVA. (D) The relationship between the attempted and achieved spherical equivalent (SEQ). (E) The accuracy of the SEQ compared with the intended target. (F) The comparative distribution of preoperative and 3-month postoperative astigmatism. D = diopters

follow-up visit, 12 eyes (35%) in the ray-tracing group (B1) and 8 eyes (24%) in the Custom-Q group (B2) gained one or more Snellen lines of UDVA compared with the preoperative CDVA. No significant differences were observed between the two groups ($P = .121$).

Figure 2C shows the changes in monocular CDVA. Sixteen eyes (47%) in the ray-tracing group (C1) and 11 eyes (32%) in the Custom-Q group (C2) gained one or more Snellen lines of postoperative CDVA compared with the preoperative CDVA. The result was significantly better in the ray-tracing group ($P = .043$).

ACCURACY

Figure 2D shows the relationship between the attempted and achieved SE (coefficient of determination

$R^2 = .997$ in the ray-tracing group and $R^2 = .998$ in the Custom-Q group).

Figure 2E shows the accuracy of SE to the intended target. At the 3-month follow-up visit, 13 eyes (38%) in the ray-tracing group and 19 eyes (56%) in the Custom-Q group achieved an SE between -0.13 and $+0.13$ D, respectively. The outcome was notably higher in the Custom-Q group ($P = .016$).

Figure 2F shows the distribution of monocular preoperative and postoperative astigmatism. Twenty-four eyes (71%) in the ray-tracing group and 29 eyes (85%) in the Custom-Q group achieved a postoperative refractive astigmatism of 0.25 D or less. Less postoperative astigmatism was observed in the Custom-Q group ($P = .026$).

TABLE 3
Comparison the Difference of Corneal Aberrations and Visual Quality Preoperatively (6-mm), Mean $\pm$ SD (Range)

Parameter	IE (n = 34)	Custom-Q (n = 34)	P
OPD (μ m)	1.34 $\pm$ 0.71 [0.42 to 3.10]	1.36 $\pm$ 0.73 [0.30 to 3.21]	.793
RMSH (μ m)	0.43 $\pm$ 0.12 [0.26 to 0.73]	0.46 $\pm$ 0.15 [0.23 to 0.82]	.321
AST RMS (μ m)	1.24 $\pm$ 0.75 [0.16 to 3.01]	1.26 $\pm$ 0.76 [0.09 to 3.17]	.831
Coma RMS (μ m)	0.26 $\pm$ 0.13 [0.01 to 0.60]	0.26 $\pm$ 0.12 [0.08 to 0.63]	.681
SA RMS (μ m)	0.20 $\pm$ 0.07 [0.04 to 0.33]	0.21 $\pm$ 0.08 [0.08 to 0.41]	.344
SR	0.12 $\pm$ 0.07 [0.04 to 0.30]	0.12 $\pm$ 0.06 [0.04 to 0.30]	.837

AST RMS = the root mean square of higher order aberrations of corneal astigmatism; Coma RMS = the root mean square of coma; Custom-Q = the refraction data planned with Q-factor customized corneal ablation treatment; IE = the refraction data planned based on the ray-tracing technology; OPD = optical path difference; RMSH = root mean square of higher order aberrations; SA RMS = the root mean square of higher order aberrations of spherical aberration; SD = standard deviation; SR = Strehl ratio

TABLE 4
Comparison the Difference of Corneal Aberrations and Visual Quality Postoperatively (6-mm), Mean $\pm$ SD (Range)

Parameter	IE (n = 34)	Custom-Q (n = 34)	P
OPD (μ m)	0.90 $\pm$ 0.26 [0.44 to 1.49]	1.08 $\pm$ 0.34 [0.55 to 2.17]	.040 ^a
RMSH (μ m)	0.74 $\pm$ 0.30 [0.34 to 1.43]	0.79 $\pm$ 0.21 [0.33 to 1.29]	.177
AST RMS (μ m)	0.44 $\pm$ 0.20 [0.01 to 0.83]	0.66 $\pm$ 0.41 [0.14 to 1.92]	.011 ^a
Coma RMS (μ m)	0.53 $\pm$ 0.28 [0.11 to 1.19]	0.46 $\pm$ 0.24 [0.08 to 0.99]	.182
SA RMS (μ m)	0.30 $\pm$ 0.20 [0.01 to 0.93]	0.43 $\pm$ 0.20 [0.05 to 1.17]	< .001 ^a
SR	0.16 $\pm$ 0.03 [0.10 to 0.24]	0.15 $\pm$ 0.03 [0.09 to 0.23]	.494

AST RMS = the root mean square of higher order aberrations of corneal astigmatism; Coma RMS = the root mean square of coma; Custom-Q = the refraction data planned with Q-factor customized corneal ablation treatment; IE = the refraction data planned based on the ray-tracing technology; OPD = optical path difference; RMSH = root mean square of higher order aberrations; SA RMS = the root mean square of higher order aberrations of spherical aberration; SD = standard deviation; SR = Strehl ratio

^aSignificantly different between IE and Custom-Q groups using paired t-test and Wilcoxon signed-rank test.

HOAs

Tables 3-4 demonstrate the changes in corneal aberrations and Strehl ratio in the 6-mm optical zone in both groups. No significant differences were observed between the two groups preoperatively. At 3 months postoperatively, the ray-tracing group showed a significantly better result in OPD, the root mean square of corneal astigmatism (AST RMS), and the root mean square of HOAs of spherical aberration (SA RMS) than that in the Custom-Q group.

VECTOR ANALYSIS

Vector analysis of astigmatism was performed using the Alpains method. Table 2 presents the results of target induced astigmatism, surgically induced astigmatism, DV, and correction index at 3 months postoperatively. There were no significant differences in target induced astigmatism and correction index between the two groups. However, there was a statistically significant variance in surgically induced astigmatism,

which was -1.24 and -1.02 D in the ray-tracing group and the Custom-Q group, respectively ($P = .045$). Additionally, DV was significantly higher in the ray-tracing group ($P = .028$).

The single-angle polar plots of corneal vector analysis were generated using the AstigMATIC software and are shown in Figures 3-4.¹⁵

DISCUSSION

The objective of refractive surgery is to provide optimal postoperative visual performance for patients. Various improved excimer laser ablation algorithms have been designed for the purpose.¹⁶⁻¹⁸ However, addressing the disparity between corneal astigmatism and the refractive cylinder has led to different combinations and continual discourse.^{19,20} A decade ago, ray-tracing-based LASIK was introduced with the aim of developing personalized treatments tailored to individualized eye models.^{3,5} It was developed as a concept to overcome the limitations of traditional treatments and was expected

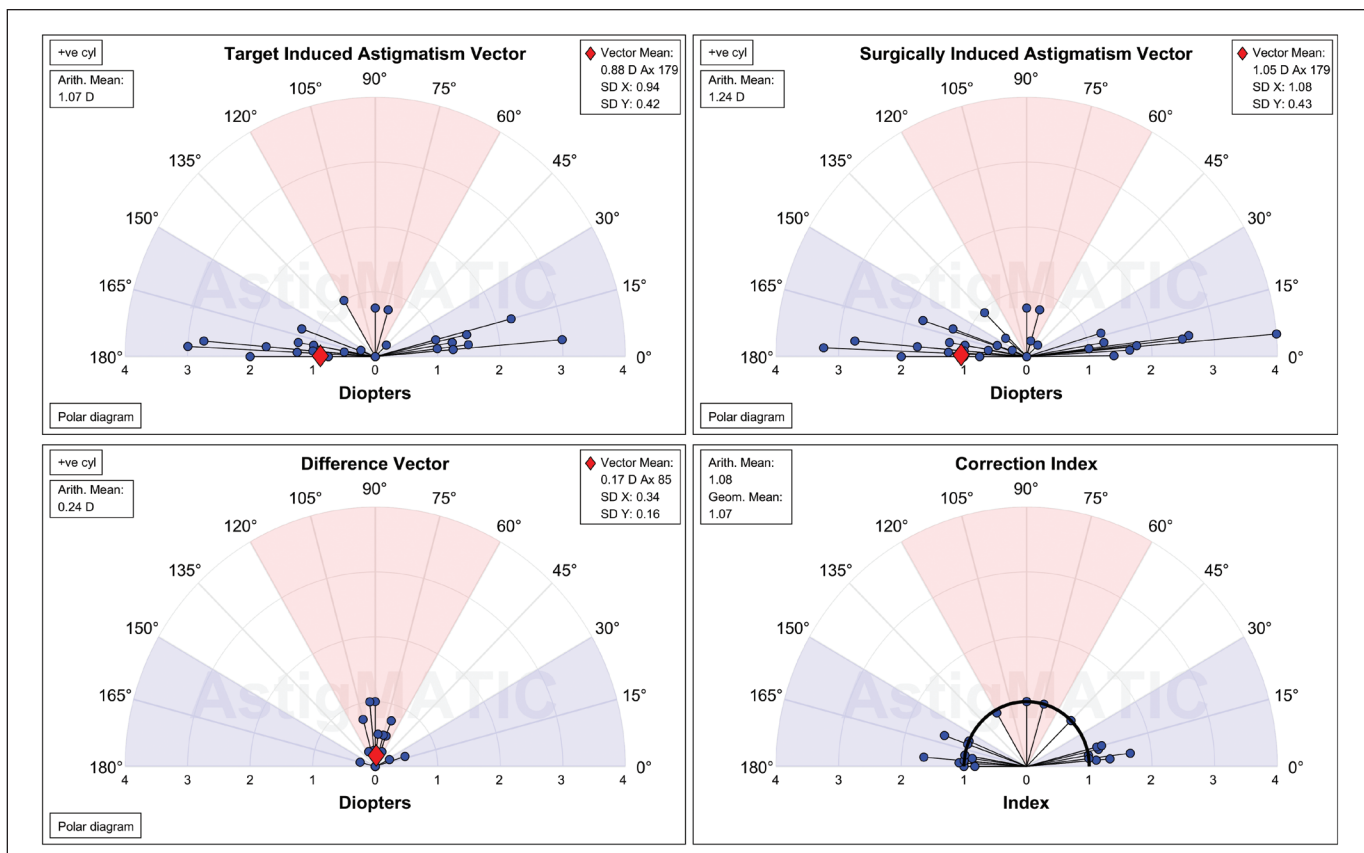


Figure 3. Ray-tracing group vector analysis. (A) Single-angle polar plots of corneal vector analysis of the target induced astigmatism vector, (B) surgically induced astigmatism vector, (C) difference vector, and (D) correction index. The vector means are plotted as a red diamond (calculated in double-angle vector space) and the standard deviations for the X and Y directions are displayed in the call-out box.

to yield better results. The main objective of our study was to compare the effectiveness, safety, predictability, accuracy, and corneal optical quality between the two surgical techniques (ray-tracing and Custom-Q) in the correction of myopia with or without astigmatism. To our knowledge, no prior study has compared outcomes between these two surgical techniques.

Previous clinical studies had evaluated the safety and efficacy of the ray-tracing algorithm. The first clinical data with ray-tracing optimization of the refraction was published in 2020, and used the current version of the ray-tracing algorithm with the InnovEyes SightMap and WaveLight EX500 excimer laser, noting that 40 of 40 (100%) eyes achieved UDVA of 20/20 or better at 6 months and 65% of eyes gained one line of vision and 38% gained two lines.⁶ He and Bala¹³ observed that half of the eyes achieved 20/12.5 or better UDVA, and 8% achieved 20/10 postoperatively in ray-tracing-guided LASIK. Kanellopoulos et al⁸ reported that UDVA was 20/20 or better in 208 of 212 (98.1%) eyes and 76 of 212 (35.8%) eyes gained one or more line of CDVA. Alves et al⁹ reported that 87% in the Custom-Q group had a UDVA of 20/16 at the

end of 12 months, with 9 eyes (30%) in the Custom-Q group gaining of one line of visual acuity. Our study showed that 94% in the ray-tracing group and 85% in the Custom-Q group had 20/16 or better UDVA postoperatively. Forty-seven percent gained one or more Snellen lines of CDVA in the ray-tracing group and 27% in the Custom-Q group. Compared to those previous studies, the current study showed a similar result in both groups. Because there were no significant preoperative differences between the two groups, we found that the ray-tracing group performed better in postoperative UDVA and the changes in monocular CDVA. However, postoperative sphere, cylinder, and manifest refraction SE indicated a potential overcorrection with wavefront refraction. Previous studies found similar refractive outcomes,¹³ possibly because of the accuracy of the built-in nomogram, epithelial wound healing compensation algorithm, or fogging function of InnovEyes SightMap. This needs to be confirmed through a larger cohort and an extended follow-up period. Additionally, a more effective compensation method for ray-tracing may be required to achieve more precise refractive outcomes.

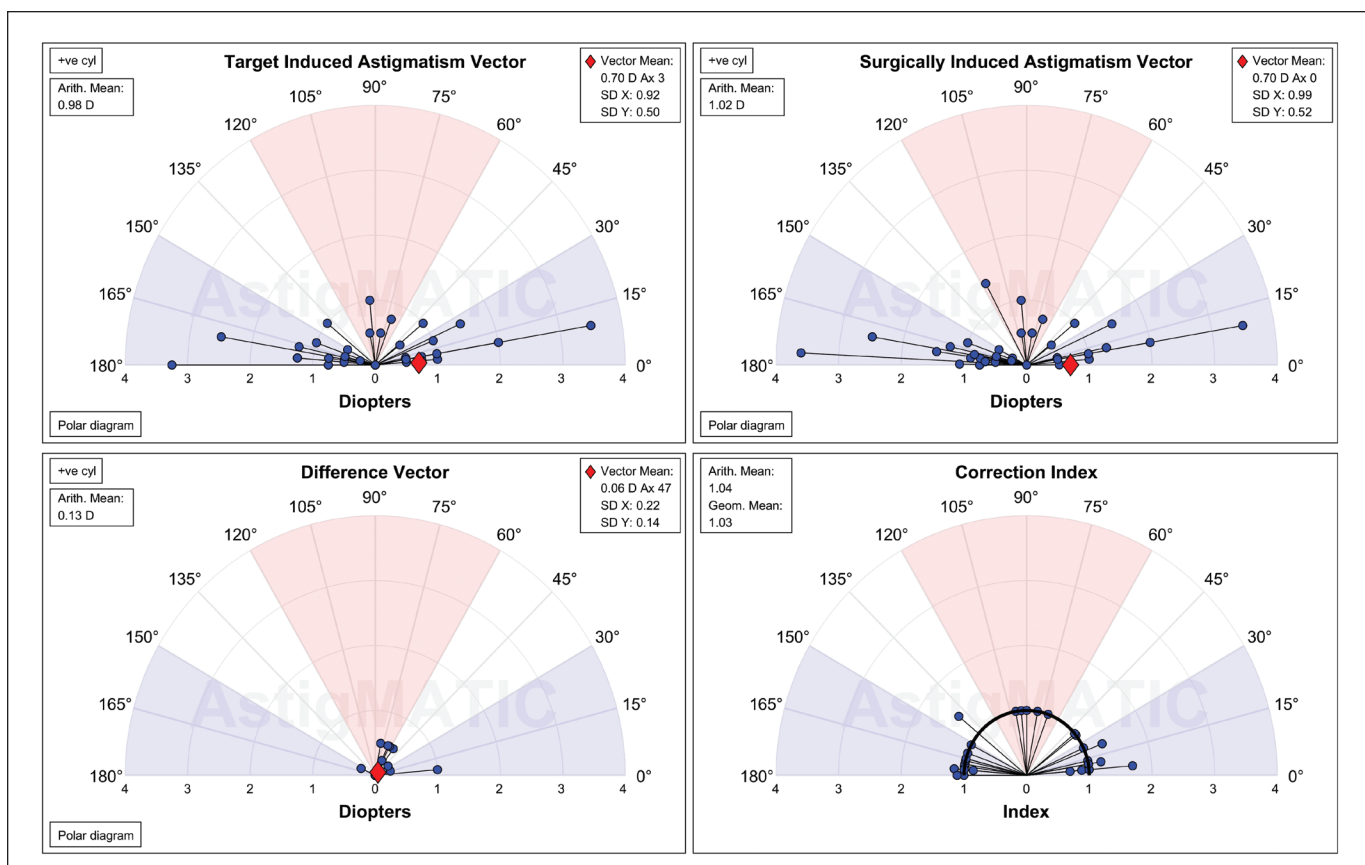


Figure 4. Custom-Q group vector analysis. (A) Single-angle polar plots of corneal vector analysis of the target induced astigmatism vector, (B) surgically induced astigmatism vector, (C) difference vector, and (D) correction index. The vector means are plotted as a red diamond (calculated in double-angle vector space) and the standard deviations for the X and Y directions are displayed in the call-out box.

The corneal aberrations and Strehl ratio were found to be correlated with visual outcomes after refractive corneal surgery. In this study, because the parameters were well matched between the two groups preoperatively, the postoperative OPD, AST RMS, and SA RMS in the ray-tracing group were better than in the Custom-Q group. The postoperative values of the corneal aberrations were consistent with the results that postoperative UDVA was higher in the ray-tracing group. The variance could be explained by the ablation algorithm: Custom-Q ablation attempted to maintain the original asphericity of the cornea, which is directly related to postoperative spherical aberration.⁹ Previous studies demonstrated that the Custom-Q technique results in a smaller change in the Q-value compared to traditional optimized ablation methods, leading to a reduced induction of SA.²¹ However, the ray-tracing algorithm yielded better results in this study. Previously, He and Bala¹³ found that the ray-tracing algorithm led to a decrease in SA at 5.5-mm pupil diameter, although 21% of the treated cohort had greater than 5.00 D sphere. In the current study, despite 67.7% of the treated cohort having a sphere

greater than 5.00 D, a significant decrease in spherical aberration at the 6-mm pupil diameter was also noted. This result can likely be attributed to the ray-tracing treatment concept, which created a fully customized ablation profile,⁶ as well as the size of the EOZ.

Corneal EOZ refers to the central region of the cornea that has been treated during refractive ablation surgery, providing the intended optimal postoperative visual acuity.²² Many studies had proved that factors influencing EOZ size include preoperative corneal shape, degree of myopia, and astigmatism, as well as the type of surgical procedure.^{11,23} Variations can also arise due to the use of different platforms within the same type of surgical procedure. Li et al²⁴ reported that the EX500 Contoura LASIK ablated the smaller EOZ compared with the AMARIS excimer laser platform, with a similar plan optical zone. In this study, ray-tracing group achieved a larger EOZ, which theoretically resulted in smaller HOA, including SA and vertical coma.^{8,25} A recent study also demonstrated that maintaining a larger surgical EOZ size resulted in less induction of SA and total HOAs, reducing subsequent glare and halos.²⁵ That could explain the good

postoperative UDVA and reduced corneal aberrations observed in the ray-tracing group. However, based on the Munnerlyn law, a larger optical zone will cause more corneal tissue ablation (ie, a larger optical zone will use more tissue).²⁶ This study demonstrated that the ray-tracing algorithm ablated corneal tissue approximately 18.5% more than the Custom-Q algorithm, which suggested that there were statistically significant differences in the ablating results in the two groups. Whether the loss of corneal tissue is cost-effective requires further investigation and discussion.

Although ray-tracing-guided FS-LASIK developed as a concept to overcome the limitations of traditional treatments and was expected to yield superior outcomes, the existing technology and algorithms still present areas with potential for improvement. As the ray-tracing algorithm required, the ablation profile was constructed from measurements wherein the wavefront sphere at 4 mm and subjective sphere were aligned within 0.50 D. However, this rule excluded nearly half of the patients. Additional modifications to the nomogram or the implementation of a more effective fogging function may be necessary to overcome ocular accommodation.

This study had several limitations, such as the small sample size in this single-center trial and the short follow-up period. A longer-term evaluation would facilitate the evaluation of refraction stability, effectiveness of long-term epithelial remodeling, and the anticipated biomechanical changes. In addition, we only compared visual acuity, refraction, and corneal aberrations between the two groups; more data such as subjective satisfaction were not available.

Ray-tracing-guided FS-LASIK in clinical practice was found to be safe and effective for myopic correction with or without astigmatism. Approximately 94% in the ray-tracing group achieved UDVA of 20/16 or better and 32% achieved 20/12.5 with fewer corneal HOAs and less OPD than that in Custom-Q. The ray-tracing algorithm ablated more corneal tissue because of the larger EOZ compared with Custom-Q, with a similar plan optical zone. However, ray-tracing was not as accurate as Custom-Q, with a potential overcorrection. Further comprehension of the ablation algorithms and optimization nomogram is necessary to develop a more precise design method for ray-tracing.

AUTHOR CONTRIBUTIONS

Study concept and design (YFY, RYZ, YZ, YGC); data collection (ZZW, YXW); writing the manuscript (YFY, RYZ); critical revision of the manuscript (YFY, RYZ, ZZW, YXW, YZ, YGC); statistical expertise (YXW); administrative, technical, or material support (YZ, YGC); supervision (YZ, YGC)

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