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Study of the InnovEyes Sightmap Platform in Comparing Ray-Tracing–Guided LASIK and Topography-Guided LASIK

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ABSTRACT

PURPOSE: To evaluate the performance of the InnovEyes Sightmap platform (Alcon Laboratories, Inc) in refractive surgery by comparing the visual acuity and higher order aberrations (HOAs) between ray-tracing–guided laser in situ keratomileusis (LASIK) and topography-guided LASIK.

METHODS: This prospective study enrolled participants who underwent either ray-tracing–guided LASIK or topography-guided LASIK. Comprehensive ophthalmic evaluations were performed preoperatively, as well as at 1 day, 2 weeks, 1 month, and 3 months postoperatively. Patients in the ray-tracing–guided LASIK group underwent wavefront, tomography, and biometry assessment using the InnovEyes Sightmap diagnostic device. Assessments included visual acuity, manifest refraction, and whole-eye HOAs.

RESULTS: A total of 42 eyes treated with ray-tracing–guided LASIK and 42 eyes treated with topography-guided LASIK were analyzed. Both strategies demonstrated comparable good refraction accuracy and refractive stability ($P > .05$). The ray-tracing–guided LASIK group exhibited significantly better postoperative uncorrected distance visual acuity (UDVA) compared to the topography-guided LASIK group (-0.12 ± 0.05 vs -0.07 ± 0.04 logarithm of the minimum angle of resolution, respectively; $P < .05$), with 48% of eyes achieving a UDVA of 20/12.5 or better. Ray-tracing–guided LASIK induced a small but statistically significant increase in HOAs and vertical coma aberration, along with a significant reduction in spherical aberration ($P < .05$). In contrast, topography-guided LASIK resulted in a significant increase in vertical coma ($P < .05$) without significant changes in overall HOAs or spherical aberration ($P > .05$). At 3 months postoperatively, spherical aberration was significantly different between the two groups (-0.021 ± 0.031 vs 0.054 ± 0.122 µm, respectively; $P < .05$).

CONCLUSIONS: The InnovEyes Sightmap platform's ray-tracing–guided LASIK demonstrated potential advantages in visual acuity outcomes compared to topography-guided LASIK. The observed negative shift in spherical aberration, characterized by a lower absolute value, may have contributed to the enhanced visual acuity results.

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In the past three decades, corneal refractive surgery has solidified its position as a widely adopted and safe intervention, with laser in situ keratomileusis (LASIK) being extensively practiced worldwide.[1] Throughout this period, substantial progress has been achieved in theoretical comprehension, diagnostic capabilities, and technological advancements within this field. These developments have significantly contributed to the enhancement of precise calculation methodologies, including wavefront-guided, Q-value–guided, topography-guided, and ray-tracing–guided modes for excimer ablation.

Topography-guided LASIK is designed to achieve a more regular corneal shape, thereby reducing higher order aberrations (HOAs) during the correction of refractive errors.[2-4] Studies have indicated that topography-

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guided LASIK results in fewer induced HOAs, leading to reductions in ocular trefoil, coma, and total corneal HOAs.[5] Several clinical investigations have reported favorable outcomes following this approach.[6,7] However, the ablation profile in topography-guided LASIK is derived from topography data using the Gullstrand model eye as the reference for treatment.

To enhance the precision of custom ablations and improve optical quality, it is essential to consider all anatomical structures of the patient's eye.[8] The InnovEyes Sightmap (Alcon Laboratories, Inc), which was commercially launched in December 2023, has emerged as a potentially game-changing tool in this domain. It aims to revolutionize the way corneal refractive surgeries are planned and executed by integrating multiple essential diagnostic measurements into a single device. Previous studies have provided valuable insights into the efficacy and safety of different LASIK modalities. However, the InnovEyes Sightmap brings a new dimension to the table by offering a more comprehensive and personalized approach. It not only measures the traditional parameters but also uses advanced algorithms to create a virtual eye model, which is crucial for optimizing the ablation profile,[9] allowing for the calculation of both lower order aberrations (myopia with or without astigmatism) and HOAs through an automated ray-tracing algorithm.[10] Preliminary pre-launched trials have demonstrated that ray-tracing–guided LASIK was safe and effective in correcting myopia, both with and without astigmatism, with visual acuity of many eyes markedly improved from baseline.[10,11] In addition, ray-tracing–guided LASIK, with its ability to trace the path of light from the anterior corneal surface to the fovea at multiple points, allows for a more precise calculation of the target corneal curvature at multiple points and then creation of the ablation profile. In contrast, using the mean value of corneal curvature and asphericity to calculate the lower order aberration ablation profile may not be as accurate. Therefore, ray-tracing–guided LASIK also theoretically reduces bias and offers a more refined approach.

To evaluate the potential advantages of ray-tracing–guided LASIK using the InnovEyes algorithm compared to the topography-guided methodology, we conducted a dual-arm, randomized controlled, prospective trial. This study compared visual acuity outcomes and HOAs between the two LASIK procedures. A comprehensive review of the current literature indicates a lack of relevant studies or reports addressing this specific comparison.

PATIENTS AND METHODS

Study Design and Participants

This prospective study enrolled a consecutive series of patients scheduled for therapeutic refractive surgery at Hangzhou MSK Eye Hospital from December 2023 to January 2024. Approval for the study protocol was granted by the medical research ethics committee of Hangzhou MSK Eye Hospital (approval number: #MSKLL20231213), and the study complied with the principles outlined in the Declaration of Helsinki. The study was registered with clinical trial registration number ChiCTR2300078709. Written informed consent was obtained from each participant prior to their inclusion in the study.

Inclusion and Exclusion Criteria

Inclusion criteria encompassed individuals aged 18 to 40 years with myopia ranging from -0.50 to -8.00 diopters sphere (DS), refractive astigmatism from 0.00 to -3.00 diopters cylinder (DC), and corrected distance visual acuity (CDVA) of Snellen 20/20 or better. Exclusion criteria comprised the presence of keratoconus, abnormal intraocular pressure, cataract, uveitis, severe dry eye affecting refraction and visual outcomes, history of ocular or intraocular surgery within the study period, follow-up duration less than 3 months, corneal opacities or infections, and any contraindications to corneal refractive surgery.

Study Group

Participants were allocated to either the ray-tracing–guided group or the topography-guided group through randomization facilitated by SPSS software's random number generation function, employing a double-masked approach. The ray-tracing–guided group implemented the ZZ InnovEyes strategy, which integrated factors such as age, preoperative refraction, InnovEyes automated refraction, and target refractive power to determine the intended correction. Conversely, the topography-guided group used the fitting-Shape-based ZZ AR strategy to calculate the intended correction. All patients were targeted for emmetropia.

Preoperative and Postoperative Examinations

Preoperative and postoperative assessments were conducted comprehensively at multiple time points: 1 day, 2 weeks, 1 month, and 3 months following surgery. These evaluations encompassed various parameters including uncorrected distance visual acuity (UDVA), CDVA, slit-lamp biomicroscopy, intraocular pressure measurement, objective and manifest refraction, as well as assessments of wavefront analysis, corneal tomography, and biometry using the InnovEyes Sightmap system (Alcon Laboratories, Inc). All examinations were performed by a qualified and independent ophthalmologist. The wavefront or topography values with high repeatability were used for strategic planning of two procedures. High repeatability was defined as

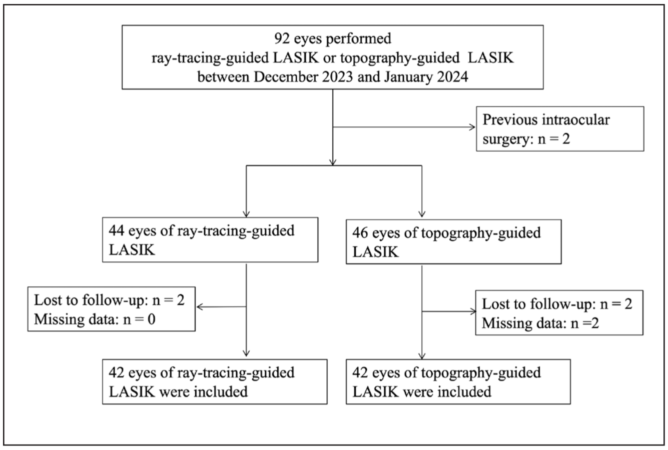

Figure 1. Flowchart showing enrolment of the study participants. LASIK = laser in situ keratomileusis

InnovEyes Sightmap refraction or anterior corneal curvature difference of less than 0.50 D.

Surgical Technique

Ray-Tracing–Guided LASIK. Bilateral sequential LASIK flaps were created at a depth of 100 µm using a WaveLight FS200 (Alcon Laboratories, Inc) with an 8.6-mm diameter. The excimer laser treatment was conducted with the WaveLight EX500 (Alcon Laboratories, Inc) using a 6.5-mm treatment zone and applying the ablation profile derived from the InnovEyes Sitemap data. All surgical procedures were executed by a single experienced surgeon (JZ).

Topography-Guided LASIK. The corneal flap was created using the WaveLight FS200 (Alcon Laboratories, Inc), targeting a diameter of 8.6 mm and a flap thickness of 100 µm. Subsequently, following flap elevation, stromal ablation was conducted using the WaveLight EX500 excimer laser equipped with Contoura software, focusing on a 6.5-mm treatment zone. The flap was then meticulously repositioned over the ablated stroma. All surgical procedures were carried out under the expertise of a single experienced surgeon (JZ).

Data Collection

Data collection encompassed measurements of UDVA, CDVA, photopic manifest refraction, root mean square of HOAs, vertical coma (Z^3_{-1}), horizontal coma (Z^3_1), and spherical aberration (Z^4_0) within the 5-mm optical zone. Evaluations were conducted both preoperatively and at each subsequent postoperative follow-up visit.

Statistical Analysis

Statistical analyses were conducted using Microsoft Excel 2010 (Microsoft Corporation) and SPSS 19.0 (IBM Corporation). The Kolmogorov-Smirnov test assessed the normality of continuous variables. Data were presented as means ± standard deviation or medians (range) based on normality. For normally distributed continuous variables, the independent-sample *t*-test and paired *t*-test were used for inter-group and intra-group comparisons, respectively. The Wilcoxon signed-rank test was used for skewed distributions. Categorical variables were presented as numbers and percentages and analyzed using the chi-square test. A two-sided *P*-value of less than .05 was considered statistically significant. The sample size was calculated using PASS 15.0 software (NCSS LLC).

RESULTS

Patient Characteristics

The study initially included 92 eyes from 46 patients who underwent either ray-tracing–guided LASIK or topography-guided LASIK. For the final analysis, 84 eyes from 42 patients were included (**Figure 1**). The ray-tracing–guided LASIK cohort included 21 patients (42 eyes), with a mean age of 27.64 ± 6.43 years; 52% of participants were men. Similarly, the topography-guided LASIK cohort consisted of 21 patients (42 eyes), with a mean age of 28.95 ± 7.53 years; 48% were men. Baseline characteristics for each group are summarized in **Table 1**. No statistically significant differences were observed in any preoperative variables between the two treatment groups. All surgical procedures proceeded without complications, and no intraoperative or postoperative issues such as flap complications, infections, or diffuse lamellar keratitis were reported.

Visual Acuity and Refraction Analysis

Figure 2 presents standardized graphical representations of visual and refractive outcomes. At the 3-month follow-up, both study groups exhibited statistically significant improvements in UDVA compared to baseline ($P < .05$). Postoperatively, the ray-tracing–guided LASIK cohort achieved superior UDVA outcomes compared to the topography-guided LASIK cohort (-0.12 ± 0.05 vs -0.07 ± 0.04 logMAR, respectively; $P < .05$). Moreover, a higher proportion of patients in the ray-tracing–guided group achieved UDVA of 20/12.5 or better (48% vs 5%, $P < .05$). Trends favored the ray-tracing–guided approach for achieving UDVA of 20/16 or better (98% vs 90%, $P = .36$) (**Figure 2A**). Loss of lines from preoperative CDVA to 3-month UDVA were numerically lower in the ray-tracing–guided group (0.00%) compared to the topography-guided group (5%, $P = .49$) (**Figure 2B**). Both techniques demonstrated strong correlations between attempted and achieved manifest refraction spherical equivalent ($R^2 = 0.977$ and 0.989, respectively) with low rates of overcorrection (0.17 ± 0.30 vs 0.18 ± 0.20 D, *P*

TABLE 1

Baseline Patient Data

Parameter	Ray-tracing–Guided LASIK	Topography-Guided LASIK	P
Eyes (no. of patients)	42 (21)	42 (21)	–
Gender (male:female)	11:10	10:11	–
Age (years)	27.64 ± 6.43	28.95 ± 7.53	.541
Axial length (mm)	25.51 ± 1.02	25.49 ± 1.07	.916
Central corneal thickness (µm)	538 ± 33	537 ± 25	.976
IOP (mm Hg)	14.25 ± 2.27	14.12 ± 2.45	.810
Manifest refraction			
Spherical (D)	-4.76 ± 2.02	-4.83 ± 1.94	.850
Cylindrical (D)	-1.05 ± 0.73	-1.30 ± 0.70	.104
Spherical equivalent (D)	-5.28 ± 1.95	-5.49 ± 1.78	.607
UDVA (logMAR)	1.21 ± 0.26	1.23 ± 0.34	.853
CDVA (logMAR)	-0.06 ± 0.03	-0.06 ± 0.04	.531

CDVA = corrected distance visual acuity; D = diopters; IOP = intraocular pressure; LASIK = laser in situ keratomileusis; logMAR, logarithm of minimum angle of resolution; UDVA = uncorrected distance visual acuity

= .90) (**Figure 2C**). No significant differences were observed in absolute residual astigmatism between the two treatment groups (0.38 ± 0.24 vs 0.43 ± 0.34 D, $P = .35$). Additionally, both groups exhibited similar accuracy in spherical equivalent refraction, cylindrical correction, and refractive stability (**Figures 2D-2F**).

HOA Analysis

Table 2 and **Figure 3** depict the alterations in aberrations across the 5-mm analytical zone postoperatively. There were no statistically significant differences in HOAs, spherical aberration, or coma between the two groups prior to surgery (all $P > .05$). Following ray-tracing–guided LASIK, a significant increase in HOAs and vertical coma aberration was observed (all $P < .05$), accompanied by a significant reduction in spherical aberration ($P < .05$). Conversely, topography-guided LASIK led to a significant increase in vertical coma aberration ($P < .05$), with no significant changes in HOAs or spherical aberration (all $P > 0.05$). At the 3-month follow-up, no statistically significant differences were detected between the ray-tracing–guided and topography-guided groups in terms of HOAs, vertical coma, or horizontal coma (All $P > .05$) (**Table 2**). Notably, spherical aberration exhibited a significant difference between the two groups (-0.021 ± 0.031 vs 0.054 ± 0.122 µm, respectively; $P < .05$).

Corneal Parameters

The ray-tracing–guided LASIK tended to achieve a deeper ablation depth compared to the topography-guided LASIK (106 ± 31 vs 96 ± 23 µm, $P = .07$). After undergoing ray-tracing–guided LASIK, the Q-value of the anterior corneal surface within the 5-mm zone remained negative, with the absolute value significantly increasing from -0.163 ± 0.111 preoperatively to -0.375 ± 0.295 postoperatively ($P < .05$). Conversely, the topography-guided LASIK induced a significant shift in the Q-value of the anterior corneal 5-mm zone, changing from a negative (-0.192 ± 0.153) preoperative value to a positive (0.008 ± 0.547) postoperative value ($P < .05$). At the 3-month follow-up, the difference in the Q-value between the two groups was statistically significant ($P < .05$).

DISCUSSION

This study represents the initial comparison of visual acuity and HOAs between ray-tracing–guided LASIK and topography-guided LASIK in clinical settings. The ray-tracing–guided group demonstrated superior postoperative UDVA compared to the topography-guided group, with a higher percentage of eyes achieving UDVA of 20/12.5 or better ($P < .05$). Spherical aberration was found to be significantly different between the two groups at the 3-month follow-up ($P < .05$), with ray-tracing–guided LASIK resulting in a notable decrease in spherical aberration ($P < .05$), whereas topography-guided LASIK showed no significant change in spherical aberration. Moreover, both treatment strategies exhibited comparable outcomes in terms of refraction accuracy and refractive stability.

Topography-guided custom ablation aims to optimize corneal curvature based on precise corneal topography measurements.[12] This approach not

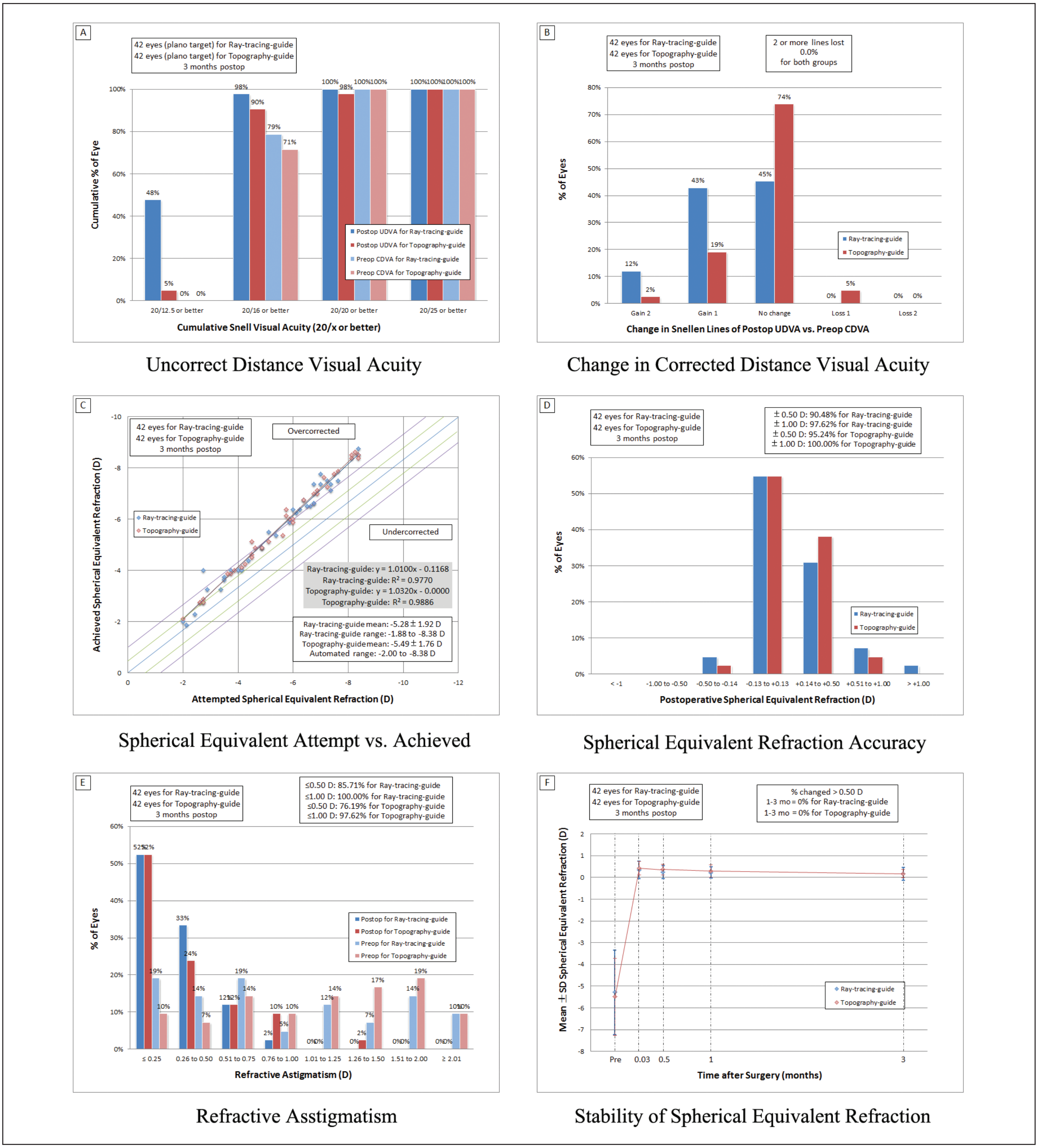

Figure 2. Standard graphs for reporting refractive surgery outcomes. (A) Uncorrected distance visual acuity (UDVA). (B) Change in corrected distance visual acuity (CDVA). (C) Spherical equivalent (SEQ) attempted versus achieved. (D) SEQ refraction accuracy. (E) Refractive astigmatism. (F) Stability of SEQ refraction. D = diopters

only corrects manifest sphere and cylinder but also addresses corneal irregular astigmatism and aberrations. Previous research by Kim et al[13] demonstrated that topography-guided LASIK results in

TABLE 2

Comparison of HOAs Across the 5-mm Analytical Zone Between the Two Groups

Parameter (μm), Mean ± SD	Ray-tracing–Guided LASIK	Topography-Guided LASIK	*P*
Preoperative			
HOAs	0.223 ± 0.063	0.249 ± 0.073	.083
Spherical aberration	0.056 ± 0.045	0.062 ± 0.053	.582
Vertical coma aberration	0.012 ± 0.114	0.003 ± 0.122	.720
Horizontal coma aberration	0.001 ± 0.054	0.006 ± 0.068	.696
Postoperative 1 day			
HOAs	0.310 ± 0.098	0.251 ± 0.100	.008[a]
Spherical aberration	-0.152 ± 0.095	-0.049 ± 0.114	< .001[a]
Vertical coma aberration	-0.058 ± 0.119	0.006 ± 0.135	.024[a]
Horizontal coma aberration	0.074 ± 0.127	-0.004 ± 0.096	.002[a]
Postoperative 2 weeks			
HOAs	0.271 ± 0.096	0.255 ± 0.113	.489
Spherical aberration	-0.081 ± 0.087	-0.013 ± 0.110	.002*
Vertical coma aberration	-0.150 ± 0.112	-0.071 ± 0.122	.003[a]
Horizontal coma aberration	0.052 ± 0.089	-0.021 ± 0.113	.002[a]
Postoperative 1 month			
HOAs	0.275 ± 0.120	0.250 ± 0.106	.315
Spherical aberration	-0.038 ± 0.043	0.031 ± 0.100	< .001[a]
Vertical coma aberration	-0.172 ± 0.139	-0.106 ± 0.124	.026[a]
Horizontal coma aberration	0.038 ± 0.097	-0.013 ± 0.110	.027[a]
Postoperative 3 months			
HOAs	0.271 ± 0.086	0.280 ± 0.130	.722
Spherical aberration	-0.021 ± 0.031	0.054 ± 0.122	< .001[a]
Vertical coma aberration	-0.151 ± 0.104	-0.101 ± 0.132	.059
Horizontal coma aberration	0.025 ± 0.100	-0.014 ± 0.119	.111

HOAs = higher order aberrations; LASIK = laser in situ keratomileusis; SD = standard deviation
[a]Significant difference between groups (P < .05).

fewer HOAs, and significant reductions in ocular trefoil, corneal total HOAs, and coma. However, the topography-guided algorithm has inherent limitations. First, it lacks an effective strategy for managing spherical aberration,[14] a finding supported by our study, which showed no significant changes in HOAs or spherical aberration following topography-guided LASIK. Topography-guided LASIK can adjust spherical aberration by modifying the fitting Q-value. However, the absence of a target Q-value algorithm and adequate spherocylindrical compensation limits the practical application of this feature. Second, this approach does not account for individual variations in multiple refractive elements beyond the cornea.[9] It is known that corneal aberrations account for nearly 80% of all aberrations of the eye.[2,15] Therefore, currently, topography-guided LASIK theoretically addresses approximately 80% of total ocular HOAs, exclusive of spherical aberration.

Ray-tracing-guided LASIK, using advanced algorithms, represents a significant advancement over earlier methodologies, promising enhanced clinical outcomes.[16] This approach is founded upon an optical model of the eye,[11] where data from a single diagnostic device, the InnovEyes Sitemap, integrates corneal tomography (using the Scheimpflug principle), biometry (partial coherence interferometry), and total eye wavefront analysis (Hartmann-Shack). The proprietary software generates a comprehensive model and recommends the most suitable ablation profile automatically. This integrated approach minimizes manual treatment planning and potential measurement errors associated with multiple equipment use. However, we also acknowledge that like any measurement device,

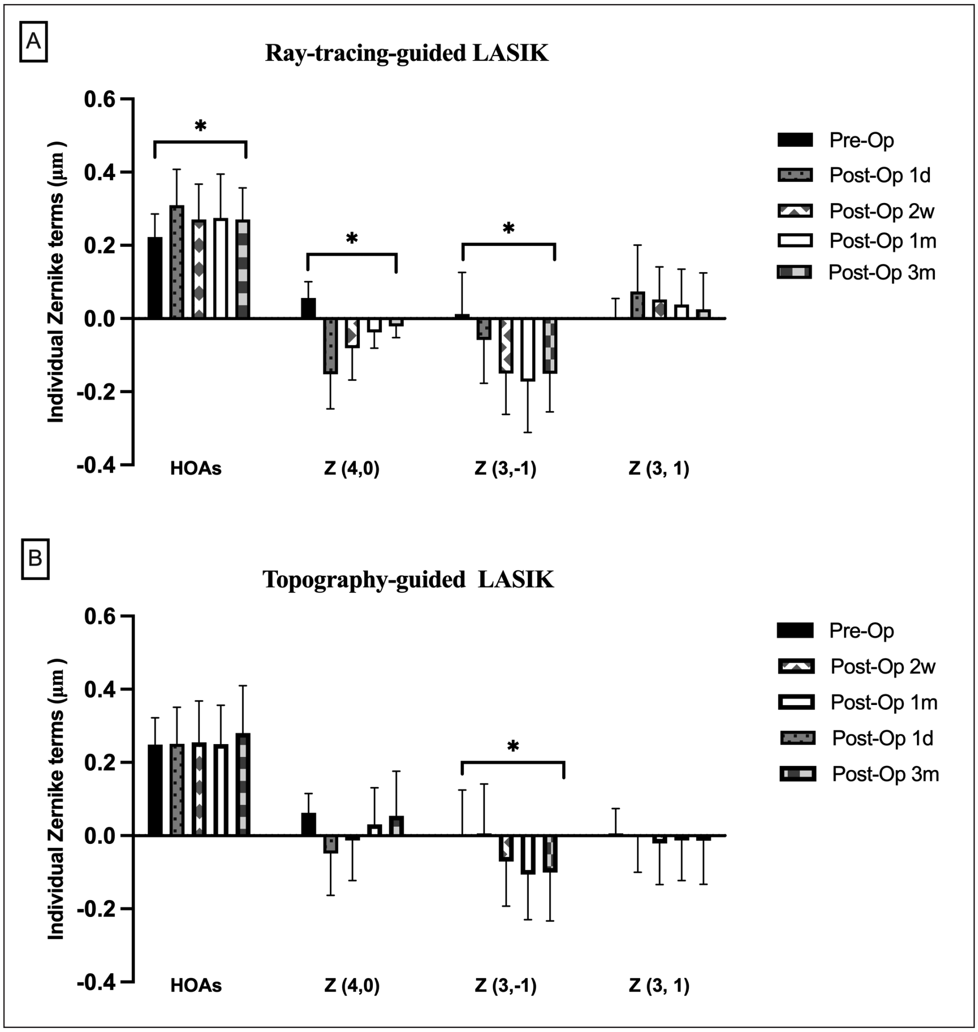

Figure 3. Individual Zernike terms over the 5-mm analytical zone for (A) ray-tracing–guided laser in situ keratomileusis (LASIK) and (B) topography-guided LASIK. *Significant difference between preoperative data and postoperative 3-month data. HOAs = higher order aberrations; Z^4_0 = spherical aberration; Z^3_{-1} = vertical coma aberration; Z^3_1 = horizontal coma aberration

there may be some degree of variability, and further studies may be needed to fully understand and minimize this variability.

The treatment profile includes adjustments for excimer laser efficiency, corneal biomechanics, and wound healing response, optimizing outcomes.[10] By calculating the wavefront using this optical model, the path of light is traced from the anterior corneal surface to the fovea, allowing virtual treatment of anterior corneal tomography to achieve optimal postoperative wavefront outcomes. This personalized approach is anticipated to yield superior results. The disparity in corneal Q-value alterations corresponded to the variations in corneal morphological changes, thereby confirming the distinct ablation profile of the two treatment strategies. In current practice, ray-tracing–guided LASIK theoretically targets achieving zero total ocular HOAs. Thus, it addresses not only the spherical aberration but also approximately 20% of the intraocular HOAs beyond what is addressed by topography-guided treatment. Additionally, the ablation pattern of ray-tracing–guided LASIK also takes tilt into consideration. The above factors may contribute to the increased ablation depth in ray-tracing–guided LASIK. Given the above discussion on correcting HOAs, it is necessary to further compare the differences between ray-tracing–guided LASIK and wavefront-guided LASIK. Compared to wavefront-guided LASIK, ray-tracing–guided LASIK offers several advantages. First, whereas corneal tissue can only be ablated and not augmented, differences in ablation pattern algorithms ensure that the lower order aberration component of ray-tracing–guided LASIK remains unaffected by the correction of HOAs, thereby preserving postoperative visual quality. Second, hardware upgrades enable the ablation and calculation center of HOAs to shift from the traditional pupil center to the corneal vertex, reducing surgically induced coma caused by kappa eccentricity. Third, ray-tracing–guided LASIK includes iris recognition, mitigating biases induced by factors such as ocular rotation.

In our study, the ray-tracing–guided group demonstrated superior postoperative UDVA compared to the topography-guided group. Specifically, 48% achieved UDVA of 20/12.5 or better, 98% achieved 20/16 or better, and all achieved 20/10 or better. These findings are consistent with those reported by He and Bala.[11]

HOAs are critical determinants of visual quality,[2] often manifesting as glare, halos, and reduced contrast sensitivity, especially in low light conditions.[17] Among Zernike HOA components, primary coma of relatively low order and primary spherical aberration positioned centrally exert significant influence on visual quality.[18,19] Therefore, our focus was on observing and comparing total HOAs, coma, and spherical aberration. Ray-tracing–guided LASIK demonstrated a tendency toward increased total HOAs, yet exhibited a negative shift in spherical aberration, maintaining a lower absolute value, which correlates with greater improvement in postoperative UDVA compared to preoperative CDVA. This underscores the substantial impact of spherical aberration among all HOAs.[20]

Additionally, ray-tracing–guided LASIK consistently exhibited a higher absolute value for the negative shift in vertical coma, indicative of a slight upward displacement in the ablation center relative to the corneal vertex. Similar observations were noted in topography-guided LASIK. Potential explanations may involve gravitational effects leading to changes in the kappa angle from seated to supine positions.

The current study is subject to several limitations. First, the sample size in this single-center trial was small, necessitating larger, multi-center studies to validate the findings. Second, the follow-up duration was short, and future investigations will incorporate longer-term assessments to evaluate the stability of refractive accuracy and aberration changes over time. Third, conducting a comparative analysis of clinical outcomes and aberration changes between the ray-tracing–guided algorithm and earlier custom-guided methodologies, including wavefront-guided and Q-value–guided algorithms, will offer insights into their distinct advantages. Such analyses are crucial for guiding clinical decision-making and selecting the optimal procedure tailored to individual patient needs.

Ray-tracing–guided LASIK demonstrated superior postoperative UDVA compared to topography-guided LASIK, with a greater proportion of eyes achieving UDVA of 20/12.5 or better. Ray-tracing–guided LASIK resulted in a small but statistically significant increase in HOAs and vertical coma aberration, accompanied by a significant reduction in spherical aberration. Conversely, topography-guided LASIK led to a significant increase in vertical coma without notable changes in HOAs or spherical aberration. Differences in spherical aberration between the two groups remained statistically significant at the 3-month follow-up. The observed negative shift in spherical aberration, characterized by a lower absolute value, likely contributed significantly to the enhanced visual acuity outcomes observed in the ray-tracing–guided LASIK group.

AUTHOR CONTRIBUTIONS

Study concept and design (JZ, XFC); data collection (JS, XFC, YGZ); analysis and interpretation of data (JZ, XFC, LZ); writing the manuscript (XFC); critical revision of the manuscript (JZ, JS, YGZ, LZ); statistical expertise (JZ, JS, XFC, LZ); administrative, technical, or material support (JZ, JS, XFC, YGZ); supervision (JZ, LZ)

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