· Clinical Research ·

One-year clinical efficacy evaluation of selective corneal wavefront aberration-guided FS-LASIK correction in patients with high myopia

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Abstract

● **AIM:** To evaluate the effectiveness, safety, predictability, precision and changes of higher-order aberrations (HOAs) on corneal front surface of selective corneal wavefront aberration-guided femtosecond laser-assisted *in situ* keratomileusis (CW-FS-LASIK) in patients with high myopia 1-year postoperatively.

● **METHODS:** Totally 74 eyes of 37 patients with high myopia or myopic astigmatism in both the eyes who underwent the CW-FS-LASIK procedure in Xi'an Gaoxin Hospital from January 2021 to June 2021 were included. The changes of uncorrected distance visual acuity (UDVA), best corrected visual acuity (BCVA), spherical equivalent refraction (SER), astigmatism, HOAs and Strehl ratio (SR) on the anterior surface of the cornea after 1y of the surgery were analyzed.

● **RESULTS:** At postoperative 1y, the UDVA (logMAR) of 74 eyes (100%) reached 0 or better, including 0 in 8 eyes (10.81%), -0.1 in 45 eyes (60.81%), and -0.2 in 21 eyes (28.38%). The effectiveness index was 1.29±0.134. There was no decrease in postoperative BCVA compared with preoperative BCVA in all patients. Postoperative BCVA was the same in 44 eyes (59.46%) as preoperative BCVA, increased by 1 line in 23 eyes (31.08%) and increased by 2 lines in 7 eyes (9.46%) compared with preoperative BCVA. The safety index was 1.11±0.159. The estimated corrected SER before surgery was (-7.76±1.21) D, and the actual corrected SER was (-7.83±1.25) D (Y=0.9811X+0.2156, R^2=0.9084). There was a high correlation between the estimated corrected SER and the actual corrected SER. The postoperative SER in 74 eyes (100%) was within ±0.75 D. The postoperative astigmatism of all was within -0.75 D to 0. Root mean square (RMS) HOAs of spherical aberration and SR within 5 mm of the corneal front surface were all increased compared with those before operation (P<0.01). The total coma, horizontal coma and vertical coma were all decreased compared with those before operation (P<0.01). There was no statistically significant difference in horizontal trefoil and vertical trefoil compared with preoperative ones (P>0.05).

● **CONCLUSION:** Selective CW-FS-LASIK for correction of high myopia is effective, safe, predictive, and accurate. For patients with preoperative RMS HOAs over 0.25 defocus equivalent, postoperative coma aberration can be significantly reduced, and SR value can be increased, thus corneal imaging quality can be improved.

● **KEYWORDS:** corneal aberration; FS-LASIK; effectiveness; safety; predictability; precision

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INTRODUCTION

High myopia refers to refractive errors with myopia degree of -6 D or above. Femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) has been favored by more and more surgeons with refractive error due to its good safety, effectiveness and stability, especially patients with high myopia, and has become one of the mainstream procedures for laser vision correction to correct refractive error[1]. Studies had shown that the higher the diopter of FS-LASIK surgery corrected patients, the thicker the corneal stroma ablated, and the greater the introduction of surgical higher-order aberration (HOA)[2-3]. As laser corneal refractive surgery continues to be optimized and the demand for better visual quality increases, many personalized laser-assisted *in situ* keratomileusis (LASIK) surgical ablation patterns have been proposed in recent years[4-6]. The corneal wavefront aberration-guided femtosecond laser-assisted *in situ* keratomileusis (CW-FS-LASIK) converts corneal topographic information collected by the Keratron Scout corneal topographer (Optikon 2000, Rome, Italy) into corneal wavefront aberration data. It uses the SCHWIND CAM Amaris - optimal refractive corneal ablation management system - to design the surgical plan and Amaris 1050RS (SCHWIND, Germany) excimer laser surgery system to accurately ablate the corneal stroma, selectively correct HOAs that affect visual quality, and maximize the saving of corneal tissue, thereby improving the postoperative visual quality of patients. There are many studies on personalized LASIK surgery around the world[4-6]. However, there are few reports of LASIK surgery using SCHWIND CAM software to select corneal aberration protocols automatically. We hope to verify the long-term clinical efficacy of CW-FS-LASIK surgery through this study. In this study, the changes in uncorrected distance visual acuity (UDVA), best corrected visual acuity (BCVA), spherical equivalent refraction (SER), astigmatism, HOAs on the anterior surface of the cornea and Strehl ratio (SR) were analyzed and observed one year after CW-FS-LASIK surgery, which provided a reference for the clinical application of CW-FS-LASIK surgery.

SUBJECTS AND METHODS

Ethical Approval The study protocol was approved by Xi'an Gaoxin Hospital Medical Ethics Committee (approval No.GXYYEC-2021001) and adhered to the Declaration of Helsinki. Written informed consent was obtained from all patients before the surgery.

Materials This case-series study retrospectively enrolled 37 patients (74 eyes) with myopia or myopic astigmatism in both the eyes aged 18 to 39y (28.45±7.58y) who received CW-FS-LASIK surgery between January 2021 and June 2021 at the Department of Ophthalmology of Xi'an Gaoxin Hospital, including 18 males (36 eyes) and 19 females (38 eyes). Their preoperative SER were from -9.63 to -6.00 D (-7.76±1.21 D). The root mean square (RMS) values of total HOAs on the anterior corneal surface before surgery were 0.25 to 0.50 defocus equivalent (DEq; 0.32±0.05 DEq). Inclusion criteria were: 1) preoperative thinnest corneal thickness more than 450 μm, postoperative remaining corneal stromal bed thickness more than 300 μm; 2) discontinuing soft contact lens wear for over 2wk, rigid contact lens wear for over 1mo or orthokeratology lens wear for over 3mo prior to the procedure; 3) the refractive error has been relatively stable for the past two years (myopia increasing by less than 0.50 D per year by objective examination); 4) corneal aberration by iTrace was greater than the intraocular aberration, and the RMS HOAs on the anterior surface of the cornea by Keratron Scout corneal topographer was over 0.25 DEq. Exclusion criteria were: 1) active ocular disease; 2) keratoconus or suspicious corneal topography; 3) history of ocular surgery or trauma; 4) pregnancy or lactation.

Examination Methods for HOAs and SR on the Anterior Surface of the Cornea The Keratron Scout corneal topographer was applied to examine the HOAs and SR of the anterior corneal surface of the patient before and one year after surgery. Under natural lighting conditions, the patient was asked to sit in front of the instrument and place the lower jaw on the mandibular rest, adjust the patient's eye position height using the scale on the headrest and then position the head correctly to avoid the difference between the left and right eye. Next, the patient was instructed to look into the eye cone and slowly push the cone forward until the focuser jumps to the position of the indicator line. Then, the patient was guided to blink momentarily and open the eye wide; at this point, depress the foot pedal or press and hold the OK button, and the instrument will automatically take the image. The measurement is repeated four times, and one image is selected from the results for analysis, converting the corneal topography morphology data into Zernike aberration data and obtaining HOAs and SR values within 5 mm of the anterior corneal surface.

CW-FS-LASIK Surgical Design Plan The patient's Zernike aberration data was transmitted to the SCHWIND CAM Amaris. The Pyramid Manager in the corneal wavefront ablation mode was used to design the surgical plan. The Depth Minimize module in the Pyramid Manager was used to select the HOAs to be corrected automatically, and the personalized result was used as the surgical plan.

Surgical Procedures and Postoperative Management Before surgery, 4 g/L of oxybuprocaine hydrochloride eyedrops were used for surface anaesthesia. VisuMax femtosecond laser (Carl Zeiss, Germany) was used to create the corneal flap. The hinge of the flap was located at 90°, the thickness was 100 μm, the diameter was 8.1 mm, and the flap margin incision angle was 90°. Then, the patient was transferred to the excimer laser treatment area. The corneal stromal ablation was performed using the Amaris 1050RS excimer laser. The diameter of the optical zone was 6.0-6.5 mm. The planned eye needed to perform Static Cyclotorsion Compensation (SCC), uncover the corneal flap, perform stromal ablation according to the preset surgical plan, automatically open the dynamic cyclotorsion compensation (DCC) during the ablation process, reset the corneal flap after the laser scanning was completed, and wash the corneal layers with balanced salt solution. After flattening the corneal flap, a sterile eye mask was used to wrap the treated eye. To ensure consistent results, all surgeries were performed by the same experienced surgeon.

The postoperative regimen included administration of topical 0.5% levofloxacin eyedrops (Tarivid; Santen, Inc., Japan),

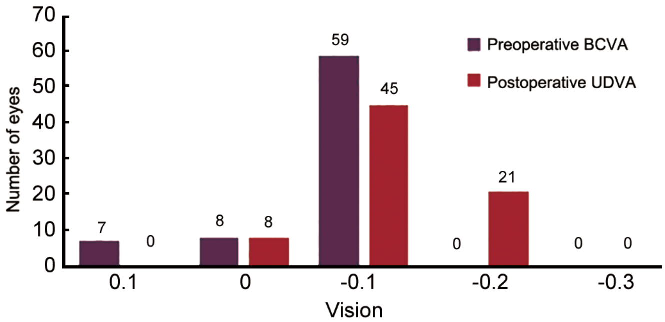

Figure 1 Effectiveness of 1y after surgery BCVA: Best-corrected distance visual acuity; UDVA: Uncorrected distance visual acuity.

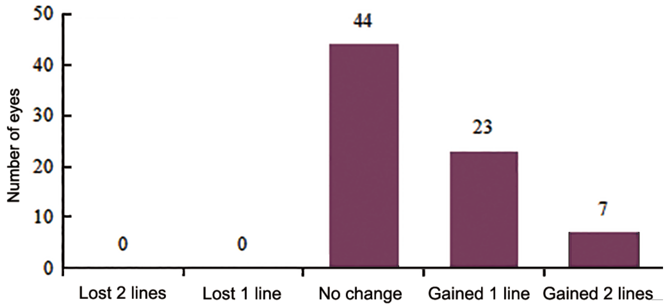

Figure 2 Safety of 1y after surgery.

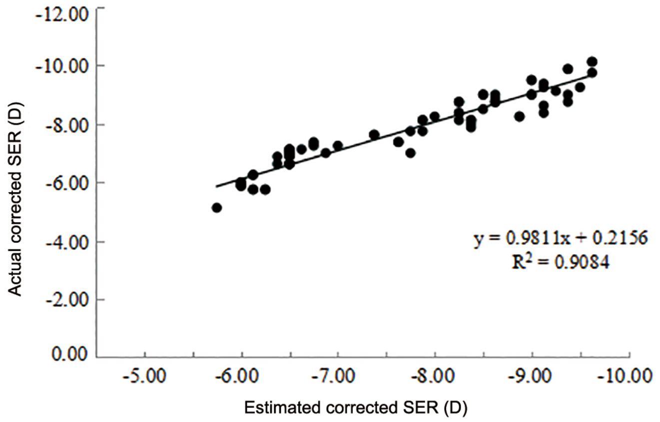

Figure 3 Predictability of 1y after surgery SER: Spherical equivalent refraction.

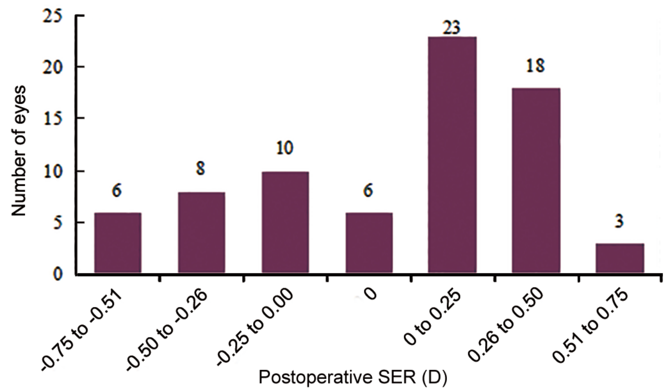

Figure 4 Precision of 1y after surgery SER: Spherical equivalent refraction.

0.25% tobramycin and dexamethasone eyedrops (Maxidex; Alcon Laboratories, Inc.) four times per day for 1wk; and 0.1% fluorometholone eyedrops (Tarivid; Santen, Inc., Japan) four times per day for 3wk. In addition, preservative-free lacrimal substitutes were used as needed.

Postoperative Follow-up Observation Patients were advised to have regular postoperative follow-ups and to exam their UDVA, BCVA, SER, astigmatism, RMS HOAs within 5 mm of the anterior corneal surface, spherical aberration, total coma, horizontal coma, vertical coma, horizontal trefoil, tilted trefoil and SR. UDVA and BCVA were checked with the international standard visual acuity chart, and convert it to a logarithm of the minimum angle of resolution (logMAR) scale for analysis. The value of SER and astigmatism were measured by manifest refraction.

Statistical Analysis All data were tested with the Kolmogorov-Smirnov test for evaluation of data normal distribution. Mean±standard deviation and count data were used for quantitative variables. Effectiveness=postoperative UDVA/ preoperative BCVA. Safety=postoperative BCVA/preoperative BCVA. Paired *t*-test was used to compare the changes between the preoperative and postoperative data. Statistical analysis was performed using SPSS (GLM UNIVARIATE, version 20, IBM). *P*-value<0.05 was regarded as significant.

RESULTS

Effectiveness and Safety Postoperative UDVA was 0 and above in 74 eyes (100%), with 8 eyes (10.81%) at 0, 45 eyes (60.81%) at -0.1 and 21 eyes (28.38%) at -0.2 logMAR. The effectiveness index was 1.29±0.134 (Figure 1). Totally 74 eyes (100%) had a postoperative BCVA that met or exceeded the preoperative BCVA, 44 eyes (59.46%) were consistent with the preoperative BCVA, 23 eyes (31.08%) had one line more than the preoperative BCVA, and 7 eyes (9.46%) had two lines more than the preoperative BCVA. The safety index was 1.11±0.159 (Figure 2).

Predictability The preoperative estimated corrected SER was (-7.76±1.21) D and the actual corrected SER was (-7.83±1.25) D, which were highly linearly correlated (Y=0.9811X+0.2156, R^2=0.9084; Figure 3).

Precision At one year postoperatively, SER was -0.75 to -0.51 D in 6 eyes (8.11%), -0.50 to -0.26 D in 8 eyes (10.81%), -0.25 to -0.01 D in 10 eyes (13.51%), 0 in 6 eyes (8.11%), +0.01 to +0.25 D in 23 eyes (31.08%), +0.26 to +0.50 D in 18 eyes (24.32%), and 3 eyes (4.05%) for +0.51 to +0.75 D (Figure 4).

Astigmatism One Year after Surgery There were 15 eyes with 0 astigmatism (20.27%), 28 eyes with -0.01 to -0.25 D (37.84%), 26 eyes with -0.26 to -0.50 D (35.11%) and 5 eyes with -0.51 to -0.75 D (6.76%; Figure 5).

Comparison of Preoperative and One-year Postoperative Corneal Anterior Surface HOAs and SR At one year after surgery, RMS HOAs, spherical aberration and SR on the anterior surface of the cornea were all greater than those of preoperation, with statistically significant differences

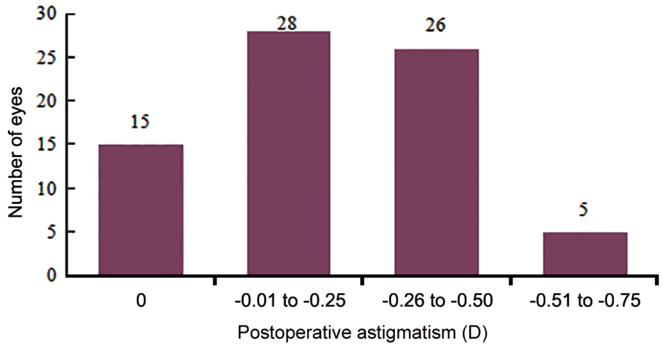

Figure 5 Astigmatism 1y after surgery.

Table 1 Comparison of HOAs and SR on anterior corneal surface before and one year after CW-FS-LASIK

Parameters	Preoperatively	One year postoperatively	*t*	*P*
Number of eyes	74	74		
RMS HOAs	0.287±0.047	0.359±0.105	-5.813	<0.01
Spherical aberration	0.144±0.040	0.243±0.086	-10.912	<0.01
Total coma	0.196±0.069	0.120±0.569	12.187	<0.01
Horizontal coma	-0.080±0.159	-0.043±0.089	10.315	<0.01
Vertical coma	0.047±0.213	0.002±0.120	10.610	<0.01
Horizontal trefoil	0.007±0.071	0.014±0.080	-0.578	0.565
Tilted trefoil	-0.033±0.070	-0.005±0.075	0.850	0.398
SR	0.029±0.016	0.059±0.036	-8.069	<0.01

RMS HOAs: Root mean square of higher-order aberrations ; SR: Strehl ratio; CW-FS-LASIK: Corneal wavefront aberration-guided femtosecond laser-assisted *in situ* keratomileusis.

($P<0.01$); total coma, horizontal coma and vertical coma were all less than those of preoperation, with statistically significant differences ($P<0.01$); horizontal and tilted trefoil were not statistically significant compared with those of preoperative ($P>0.05$; Table 1).

DISCUSSION

FS-LASIK surgery was performed by using a femtosecond laser to create a corneal flap. Excimer laser ablates the corneal stroma to change the shape of the anterior surface of the cornea to achieve the purpose of correcting vision. Because of its exemplary safety and effectiveness, it has become one of the mainstream procedures for correcting refractive error[7]. There are many indicators to evaluate visual quality, among which HOAs can reflect the imaging quality of corneal refractive surgery relatively objectively and truthfully[8]. In addition, since laser corneal refractive surgery changes the morphology and thickness of the cornea, it can cause changes in corneal aberrations, which further affect the visual quality after surgery. Wang *et al*[2] and Chen *et al*[3] found that the higher the diopter of FS-LASIK surgery corrected patients, the thicker the corneal stroma ablated, and the greater the introduction of surgical HOA. Ren *et al*[9] reported that total HOA, spherical aberration and horizontal coma on the anterior surface of the cornea increased at 6mo after FS-LASIK compared to the preoperative period and were higher in the high myopia group than in the mild to moderate myopia group. Therefore, visual quality issues such as monocular diplopia, glare, halos and night vision loss in high myopic patients after FS-LASIK remain a significant concern for surgeons. Conventional LASIK surgery can only correct lower-order aberrations in the operated eye, but not the HOAs that were already present before surgery. With the advancement of science and technology and people's pursuit of better visual quality, modern laser corneal refractive surgery has gradually transitioned from the traditional conventional ablation mode to a more accurate and "eye customization" personalized ablation mode. As a result, various personalized surgeries have emerged, including Q adjustment, corneal topography guidance, and wavefront aberration-guided personalized corneal refractive surgery[4-6]. The HOAs of the human eye mainly root in the corneal periphery. We convert the morphological data collected by corneal topographic map into Zernike corneal aberration data, which is relatively simple, more comprehensive and reproducible. Furthermore, the examination method is not affected by eye accommodation and pupil size, and its results are more stable than the whole ocular aberrations. In addition, corneal topography-guided and wavefront aberration-guided surgery cannot selectively eliminate aberrations. However, they can only correct the aberrations measured before surgery in an untargeted manner, which means ablating more corneal tissue. We applied the Depth Minimize module in SCHWIND CAM Amaris software to automatically select HOAs that have an impact on visual quality, retain clinically meaningless corneal aberrations, and avoid unnecessary tissue consumption when correcting HOAs in the case of limited corneal thickness, which can not only maximize corneal tissue savings but also improve the visual quality of patients after surgery.

In this study, UDVA of all patients reached or exceeded the preoperative BCVA one year after surgery, and postoperative BCVA did not decrease compared with that before surgery. The possible reason is that CW-FS-LASIK not only corrects the ametropia, but also corrects the HOAs that have an impact on visual quality, and improves the corneal image quality, thus improving the postoperative BCVA. 100% of the surgical eye SER was within ±0.75 D, and the postoperative astigmatism of all patients was within -0.75 D to 0, and 93.24% within -0.50 D to 0. Studies have reported that due to the complex relationship between lower-order aberrations and HOAs, there may be obvious over-correction or under-correction after corneal aberration-guided personalized surgery. The HOAs that existed before correction may impact the postoperative refractive status. If the surgical design is not adjusted accordingly, the expected effect of the surgery may not be achieved[10-11]. According to the safety interval required by SCHWIND CAM

Amaris software, the maximum ablation depth difference between corneal wavefront aberration mode and Aberration-Free (AF) wavefront optimization mode should not exceed 13 μm (equivalent to 0.75 D). The results of this study were consistent with the recommended values for equipment use, confirming the safety, effectiveness, accuracy and predictability of CW-FS-LASIK surgery. Amaris 1050RS surgical platform tracks the eyeball during the operation through iris recognition technology. Many scholars, such as Tang and Ma[12] and Febbraro *et al*[13] used iris recognition technology to perform LASIK surgery and found that the residual astigmatism after surgery was significantly reduced compared with preoperative. This study was consistent with the above results.

The refractive system of the human eye is not perfect, and there will be a specific deviation between the actual wavefront after the point light source passes through the human eye and the ideal wavefront, that is wavefront aberration. Aberrations can be quantitatively expressed using Zernike polynomials, divided into lower-order aberrations and HOAs. Yang and Long[14] believed that corneal aberration measurement will not be interfered with by accommodation, pupil size and intraocular aberrations compared with the whole ocular aberration. In addition, corneal aberration can precisely and accurately analyze apparent or minor irregularities on the corneal surface, especially corneal HOAs are essential factors affecting the quality of retinal imaging, among which coma, spherical aberration, and trefoil aberration have a more significant impact on imaging clarity. Corneal RMS HOAs over 0.25 DEq have been suggested to be clinically corrective[15]. Most of the studies on HOAs use "μm" as the unit, so the results of this study were expressed in "μm". DEq is the amount of defocus required to produce the same wavefront aberration, and both DEq and μm are units of HOAs. They can be converted to each other. Zhao *et al*[16] compared the HOAs under different pupil diameters of 3mo after FS-LASIK surgery in patients with an optical region diameter range of 6.0-6.5 mm. They found that the results of HOAs under 5 mm compared with 3 mm pupil diameter were more significant, so this research selected aberration data within 5 mm on the anterior surface of the cornea for study. Corneal topography-guided FS-LASIK converts corneal topography morphology data into corneal wavefront aberration data. It uses RMS values to evaluate the corneal optical quality. The Zernike aberration data used in CW-FS-LASIK was also derived from corneal topography morphology data, both of which were processed to convert the corneal aberration data into a matching laser ablation protocol. Tang and Ma[12] compared the results 3mo after corneal topography-guided FS-LASIK with conventional FS-LASIK. They found that the total HOAs, spherical aberration and coma RMS values were significantly lower after corneal topography-guided FS-LASIK than conventional surgery at 5 mm pupil diameter, with no statistically significant difference in trefoil and SR values. Compared with conventional FS-LASIK, corneal topography-guided FS-LASIK resulted in better corneal surface regularity and better visual quality. Kang and Wang[17] observed the results of 3mo after corneal topography-guided FS-LASIK. They found that the coma decreased significantly after operation, and the total HOAs and spherical aberration were significantly increased compared to preoperative. Yao *et al*[18] used VisuMax femtosecond laser to create the corneal flap. The corneal hinge was located at 90°, thickness was 100 μm, the flap margin incision angle was 90°. Mel 80 excimer laser (Carl Zeiss, Germany) was used for stromal ablation, and they observed the corneal aberrations within 5 mm of the pupil diameter of 8 patients (14 eyes) after FS-LASIK one year, it was found that the postoperative spherical aberration and total HOAs increased, and there was no significant change in coma and trefoil. Wang *et al*[2] applied the Swiss Ziemer LDV femtosecond laser to create a corneal flap with the flap hinge located above and a thickness of 100 μm. They used the Amaris 500 Hz excimer laser for corneal stromal ablation. In a study of 68 patients (134 eyes, including 2 monocular cases) with myopia or myopic astigmatism undergoing FS-LASIK, it was found that total HOAs, spherical aberration and vertical coma increased on the anterior surface of the cornea at 1mo postoperatively, with no significant change in a horizontal coma or trefoil. Wang *et al*[19] used the VisuMax femtosecond laser to create a corneal flap with the corneal flap hinge located above and a thickness of 110 μm. The Amaris 1050RS excimer laser was used for corneal stromal ablation with an optical zone diameter of 6.5 mm. The Keratron Scout corneal topographer was applied to examine the HOAs on the anterior surface of the patient's cornea. Their study found that 1mo after FS-LASIK, spherical aberration, horizontal coma and tilted trefoil increased and vertical coma decreased compared to the preoperative period. Chen *et al*[3] followed up on 15 patients (26 eyes) with wavefront aberration-guided FS-LASIK surgery for 3mo. They found that the horizontal coma after surgery was significantly increased compared with the preoperative period, and the vertical coma remained stable. Our results of this study showed that the total HOAs and spherical aberration within 5 mm of the anterior surface of the cornea increased compared with the preoperative period. However, the total coma, horizontal coma and vertical coma decreased compared with the preoperative period, and there was no significant change in trefoil aberration. The results were consistent with previous studies[17,20-21]. The difference in HOAs results after FS-LASIK is mainly related to the surgical design plan, center location, the angle of the corneal flap hinge and the postoperative healing response. In addition, FS-

LASIK surgery changes the asphericity of the cornea, resulting in an increase in corneal spherical aberration. At the same time, it has been suggested that the ablation morphology of the transition zone in LASIK surgery also causes an increase in spherical aberration[22]. Therefore, introducing additional spherical aberration and HOAs after FS-LASIK surgery is inevitable. This study found that the proportion of coma was higher in patients with greater preoperative RMS HOAs. CW-FS-LASIK could significantly reduce the corneal coma in patients with high myopia. The Pyramid Manager in the corneal wavefront ablation mode identifies and corrects greater aberration automatically and selectively. At the same time, a good laser tracking system is essential for successfully implementing personalized surgery. In most patients, when switching from a seated to a recumbent position, the eyeball may spin to rotate the precorrected HOAs site, and the presence of the Kappa angle and intraoperative eye alignment may cause a decentered ablation that affects postoperative visual quality[23]. The Amaris 1050RS automatically corrects the laser ablation centre according to the size of the Kappa angle during surgery. In addition, by adjusting the illumination brightness of the operating room and equipment, the intraoperative pupil size is as close as possible to the preoperative examination results, and the offset of the pupil centre can be reduced. As a result, Intraoperative SCC and DCC can compensate for the static and dynamic rotation of the eyeball, eliminate the error caused by eye rotation through iris recognition technology, and reduce the impact on the surgical effect due to patient cooperation from seven directions, all of which help to ensure the accuracy and safety of personalized cutting[24].

In 1894, K. Strehl proposed the SR, which is a quantitative expression of the point spread function (PSF), which can comprehensively and objectively evaluate the optical quality, standard between 0-1; the more significant the value, the better the visual quality[25]. Since corneal aberrations account for 80% of whole ocular aberrations, and CW-FS-LASIK surgery operating on the cornea, it is of great clinical significance to study the SR value of the cornea alone to assess the effect of surgery on visual quality. Tang and Ma[12] found that the SR value of 5 mm pupil diameter at 3mo after corneal topography-guided FS-LASIK surgery was not significantly different from conventional surgery. Our study found that the SR of the anterior corneal surface at postoperative one year was higher than that before surgery, which further confirmed that CW-FS-LASIK surgery could improve the imaging quality of the cornea. Although the total HOAs of the cornea increased after surgery, it did not adversely affect the optical imaging quality of the surgical eye.

In summary, the use of Pyramid Manager of SCHWIND CAM Amaris software for CW-FS-LASIK surgery has good effectiveness, safety, predictability and precision, and for patients with RMS HOAs over 0.25 DEq on the anterior surface of the cornea preoperatively, the value of the coma can be significantly reduced, the SR value can be increased, and the imaging quality of the cornea can be improved after CW-FS-LASIK surgery. However, the number of cases in this study was limited, the follow-up time was short, and it was not compared and analyzed with conventional FS-LASIK surgery. Therefore, the specific results need to be further studied. In the follow-up work, based on expanding the sample size, we will apply a combination of subjective and objective evaluation to evaluate the surgical effect comprehensively, at the same time, use the new wavefront measurement technology to analyze the source of preoperative aberrations and the effects between different surgical methods of patients, and conduct a more detailed study on the targeted correction of HOAs by CW-FS-LASIK surgery.

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