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RESEARCH

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Long-term changes in classified higher-order aberrations after implanting an EVO intraocular collamer lens

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Abstract

Purpose To evaluate changes in intraocular, corneal, and whole-eye higher-order aberrations (HOAs) after EVO intraocular collamer lens (ICL) implantation.

Methods In this retrospective study, we enrolled 53 eyes of 53 patients and measured their refractive parameters and intraocular, corneal, and whole-eye HOAs using OPD scanning preoperatively and 1 month, and 3 years postoperatively. All statistical analyses were performed using SPSS software.

Results The safety index was 1.31 ± 0.15, and the efficacy index was 1.02 ± 0.24 3 years postoperatively. The best linear fit curve of the attempted versus achieved correction was y = 0.96x + 0.08 at 3 years postoperatively. The mean spherical equivalent decreased from − 8.53 ± 2.49 D preoperatively to -0.09 ± 0.25 D and − 0.34 ± 0.41 D at 1 month and 3 years postoperatively, respectively ($P < 0.05$). The whole-eye trefoil and total HOAs, intraocular trefoil, corneal trefoil increased significantly at 1 month ($P < 0.05$) but did not change significantly at 3 years ($P > 0.05$) postoperatively compared to the preoperative value. The intraocular spherical aberration and total HOAs increased significantly at 1 month and 3 years postoperatively ($P < 0.05$). The whole-eye coma or spherical aberration, intraocular coma, corneal coma or spherical aberration or total HOAs did not differ from those observed at 1 month and 3 years postoperatively ($P > 0.05$).

Conclusions Long-term EVO-ICL implantation is safe, effective, predictable, and stable. The intraocular and corneal trefoils increased significantly in the early postoperative period but can be recovered to the preoperative level in the long term. The intraocular spherical aberration increases slightly in the long term postoperatively, but the whole-eye spherical aberration does not change significantly.

Keywords Implantable collamer lens, EVO-ICL, Higher-order aberrations, Myopia, OPD

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Introduction

The intraocular collamer lens (ICL) is the most widely used posterior chamber phakic intraocular lens to correct refractive errors, such as myopia, hyperopia, and astigmatism [1–4]. With rapid technological developments in recent years, EVO-ICL has gradually replaced the original ICL V4. Compared to ICL V4, EVO-ICL is designed with a 0.36-mm central hole, which helps the aqueous humor flow from the posterior to the anterior chamber, and the flow direction is closer to the physiological state, such that postoperative pupil block and cataracts occur less frequently and additional peripheral iridotomy is not required [5–7]. Safety, efficacy, and changes in visual quality after implantation are of great concern to researchers and surgeons. ICL implantation is safe, effective, and stable, and patients achieve good visual outcomes postoperatively [1–4]. Intraocular refractive surgeries and corneal laser refractive surgeries have become the mainstream surgeries for myopia correction [8–10].

Aberrations can be divided into lower-order aberrations (LOAs) and higher-order aberrations (HOAs), which are collectively known as wavefront aberrations. LOAs are refractive errors that can be corrected by wearing glasses, such as myopia, astigmatism, and hyperopia, while HOAs are aberrations that cannot be corrected by wearing glasses, such as coma, trefoil, and spherical aberration [11, 12]. Because of the existence of HOAs, the image formed on the retina is a diffused speck rather than a clear image, and the visual quality of the patient is significantly reduced, particularly at night. Some patients cannot see things clearly even when the degree of myopia is not high. HOAs are an important index for evaluating the objective visual quality of the human eyes [13]. HOAs change with changes in the cornea and intraocular refractive interstitium [11–13]; therefore, the detection of HOAs before and after refractive surgery can be used for visual quality evaluation.

Most evaluations of HOAs for EVO-ICL implantation simply evaluated whole-eye or corneal aberrations. However, unlike corneal refractive surgeries, EVO-ICL is implanted into the eye through a corneal incision, thereby affecting both corneal and intraocular HOAs. Therefore, in this study, we measured intraocular, corneal, and whole-eye HOAs and aimed to analyze postoperative changes in coma, trefoil, spherical aberration, and total HOAs compared to their preoperative values to explore causes of postoperative HOAs and understand changes in the objective visual quality after EVO-ICL implantation.

Materials and methods

Patients

This study was performed in conformance with the Declaration of Helsinki and was approved by the Ethics Committee of the Fudan University Eye and ENT Hospital. All patients voluntarily participated in the study and signed informed consent forms after the possible risks and benefits of the study had been explained to them.

The inclusion criteria were: (1) stopped wearing contact lenses for over 1 week preoperatively; (2) stable refraction, with an annual increase of < 0.50 D for at least 2 years; (3) anterior chamber depth of ≥ 2.8 mm; (4) endothelial cell density (ECD) ≥ 2,000 cells/mm^2; and (5) spherical equivalent (SE) > – 18.00 D.

The exclusion criteria were: (1) ocular inflammation, obvious refractive interstitial opacity, a history of ocular surgery, glaucoma, cataract, and other ocular diseases; (2) systemic connective tissue and autoimmune diseases, such as systemic lupus erythematosus, rheumatoid arthritis, multiple sclerosis, and diabetes; and (3) mental or psychological abnormalities and unrealistic expectations.

Observation indicators for the 3-year follow-up were uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refractive errors, axis length, intraocular pressure (IOP), ECD, vault, coma, trefoil, spherical aberration, and total HOAs.

Finally, 53 eyes of 53 patients were followed up for 1 month and 3 years postoperatively. Due to the closure of the COVID-19, the follow-up of the intermediate periods were not all completed. Then 23 eyes of 23 patients completed the follow-up for 1 month, 6 months and 3 years postoperatively. Therefore, a subgroup analysis of this group was conducted to explore the rule of the aberration changes after ICL.

Aberration measurement

OPD-Scan III (Nidek Co., Ltd., Gamagori, Japan) was used to measure parameters in patients who underwent ICL implantation preoperatively and postoperatively, and the whole-eye, intraocular, and corneal aberrations were recorded with a 4-mm pupil size, including the coma, trefoil, spherical aberration, and total HOAs. The measurement was operated in a dark room, and the patients were adapted for 5 min. All parameters were measured for 3 times. Coma is the root mean square (RMS) of Z_3^{-1} and Z_3^1 trefoil is the RMS of Z_3^{-3} and Z_3^3 and spherical aberration is the RMS of Z_4^0.

Surgical techniques

All surgeries were performed by a single surgeon. The implanted lenses were all EVO-ICLs with an optic zone of 4.9–5.8 mm, a spherical power range of – 0.50 to – 18.00

DS, and a cylindrical power range of + 0.50 to + 6.00 DC. The available sizes were 12.1, 12.6, 13.2 and 13.7 mm.

Anti-inflammatory eye drops were administered 3 days preoperatively. Pupillary dilatation was initiated 30 min preoperatively. Topical anesthesia was administered to the operated eye, and routine disinfection and draping were performed, after which the eyelid was opened with an eyelid opener. A 3.0-mm corneal incision was made in the temporal region, and an EVO-ICL was inserted using an injector cartridge. After the ICL unfolded naturally, the foot loop was buried behind the iris using a special adjustment hook. Postoperatively, all patients were administered with the steroid medication Protek four times daily for 3 days, antibiotic eye drops four times daily for 1 week, non-steroidal anti-inflammatory eye drops four times daily for 2 weeks, and artificial tears four times daily for 1 month.

Statistical analysis

All statistical analyses were performed using SPSS 26.0 (SPSS Inc., IBM, USA). The Kolmogorov–Smirnov test was used to determine the normality of data distribution. The repeated-measures analysis of variance with bonferroni-adjusted post hoc comparisons was used to compare the RMS of total HOAs, coma, trefoil, and spherical aberrations between the preoperative and postoperative time points. The paired *t*-test was used to compare the differences in postoperative aberration increases. Pearson's correlation coefficient was used to explore the correlation between aberration increase and preoperative and postoperative parameters. Continuous variables are expressed as mean ± standard deviation. Statistical significance was set at $p < 0.05$.

Table 1 Distribution of preoperative characteristics

Parameter	Mean ± SD (range)
N, eyes	53
Age, years	25.78 ± 4.25 (18 to 33)
Gender (male: female)	8:45
logMAR CDVA	−0.03 ± 0.04 (-0.08 to 0.10)
Refractive errors (D)	
Spherical	−8.09 ± 2.32 (-2.50 to -15.25)
Cylindrical	−1.25 ± 0.74 (0.00 to -3.00)
Spherical equivalent	−8.72 ± 2.31 (-4.00 to -15.75)
Keratometric value (D)	
Flat K	42.27 ± 1.28 (41.20 to 45.90)
Steep K	44.84 ± 1.18 (42.20 to 47.10)
WTW diameter (mm)	11.97 ± 0.35 (11.40 to 12.60)
IOP (mm Hg)	15.78 ± 2.27 (10.20 to 20.00)
CCT (mm)	521.75 ± 41.88 (452.00 to 612.00)
ACD (mm)	3.26 ± 0.24 (2.80 to 3.71)
Axial length (mm)	26.85 ± 1.32 (24.13 to 31.86)
ECD (cells/mm^2)	2629.00 ± 202.61 (2146.00 to 2989.00)

N = number of eyes; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = diopters; K = keratometry; WTW = horizontal white-to-white diameter; IOP = intraocular pressure; CCT = central corneal thickness; ACD = anterior chamber depth; ECD = corneal endothelial cell density; SD = standard deviation

Results

Patient demographics

This study included 53 eyes (16 eyes with ICL and 37 with TICL) of 53 patients who underwent EVO-ICL implantation. The ratio of men to women was 8:45. The mean age was 25.78 ± 4.25 (18–33) years, and the preoperative spherical equivalent was − 8.53 ± 2.49 (− 4.00 to − 15.75) D. Table 1 summarizes the demographic characteristics and preoperative parameters of patients.

Refractive results

The safety indices (postoperative/preoperative CDVA) at 1 month and 3 years postoperatively were 1.23 ± 0.16 and 1.31 ± 0.15, respectively ($P > 0.05$, Fig. 1A). The best CDVA (logMAR) preoperatively and 1 month and 3 years postoperatively were − 0.03 ± 0.04, − 0.11 ± 0.05, and − 0.14 ± 0.06, respectively ($P > 0.05$). After a follow-up of 3 years, 5.66% of eyes had no change in CDVA; 60.38% of eyes gained one line of CDVA; 33.96% of eyes gained two lines of CDVA; and none of the eyes exhibited a loss of CDVA. The CDVA of 96.23% of the eyes was 20/20 or better preoperatively and 100.00% and 98.11% at 1 month and 3 years postoperatively, respectively. The CDVA of 100.00% of the eyes was 20/40 or better preoperatively and postoperatively.

The efficacy indices (postoperative UDVA/preoperative CDVA) at 1 month and 3 years postoperatively were 1.12 ± 0.18 and 1.02 ± 0.24, respectively ($P > 0.05$, Fig. 1B). The UDVAs (logMAR) at 1 month and 3 years postoperatively were − 0.07 ± 0.06 and − 0.02 ± 0.13, respectively ($P > 0.05$). At 1 month and 3 years postoperatively, 100.00% and 98.11% of the eyes had a UDVA of 20/40 or better, respectively, and 94.34% and 69.81% of the eyes had a UDVA of 20/20 or better, respectively.

Figure 1C shows the scatter plots of attempted and achieved corrections at 1 month and 3 years postoperatively; the best linear fit curves were y = x − 0.02 and 0.96x + 0.08, respectively. At 1 month and 3 years postoperatively, 94.34% and 77.36% were within ± 0.50 D, respectively, and 100.00% and 96.23% were within ± 1.00 D of the attempted correction, respectively. The mean spherical equivalent decreased from − 8.53 ± 2.49 D preoperatively to − 0.09 ± 0.25 D and − 0.34 ± 0.41 D at 1 month and 3 years postoperatively, respectively (($P < 0.05$, Fig. 1D).

Aberration results

For whole-eye aberration, the preoperative RMS of the whole-eye coma, trefoil, spherical aberration, and total HOAs were 0.06 ± 0.03, 0.11 ± 0.08, 0.03 ± 0.02, and 0.15 ± 0.07 μm, respectively; those 1 month

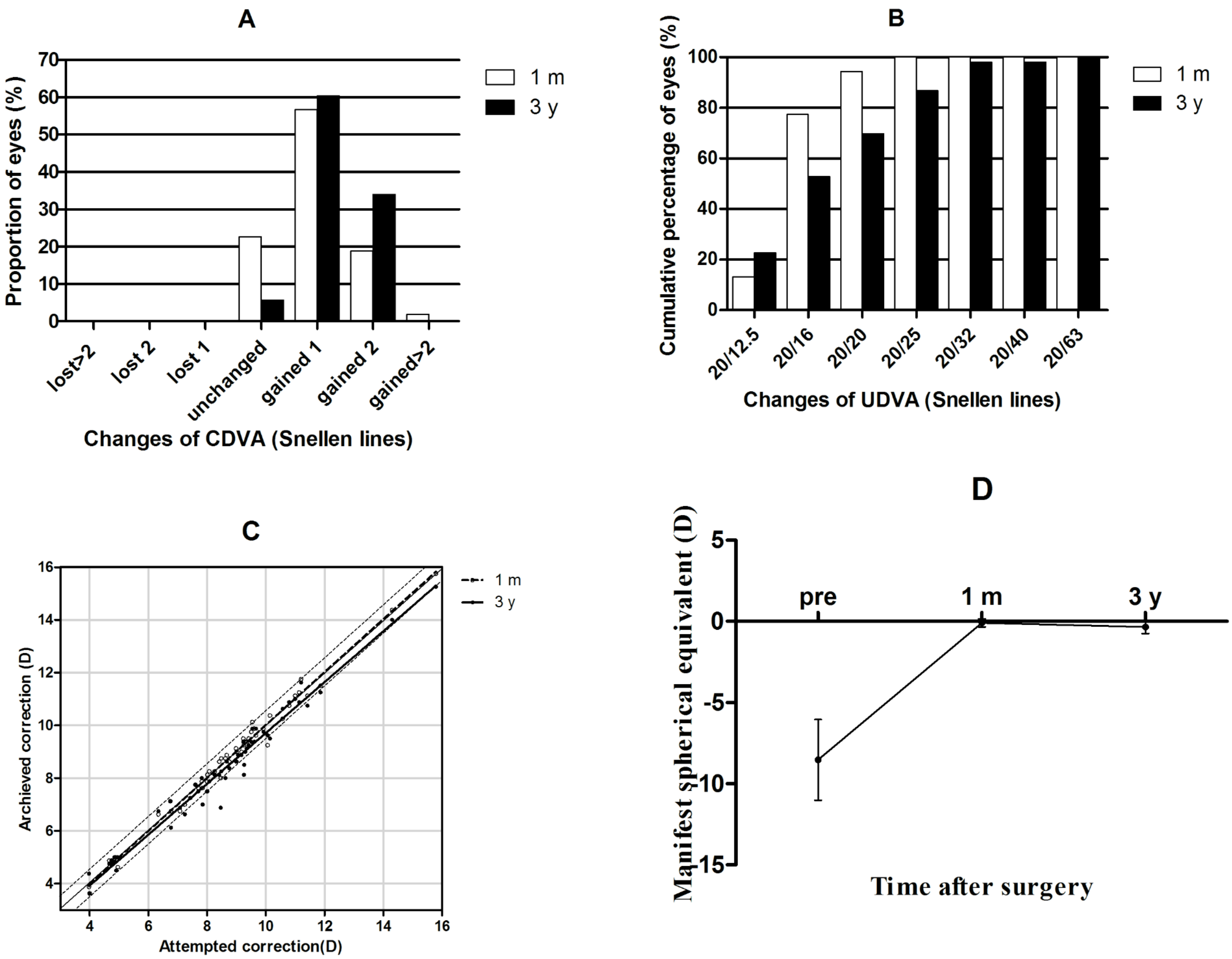

Fig. 1 Changes in corrected distance visual acuity (**A**) and uncorrected distance visual acuity (**B**) at different time points after EVO intraocular Collamer lens (ICL) implantation. Scatter plot of attempted and achieved correction after EVO ICL implantation (**C**). The black solid line in the middle represents y = x, and the black dotted lines on both sides represent y = x ± 1.00 D. Changes in manifest spherical equivalent over time after EVO ICL implantation (**D**)

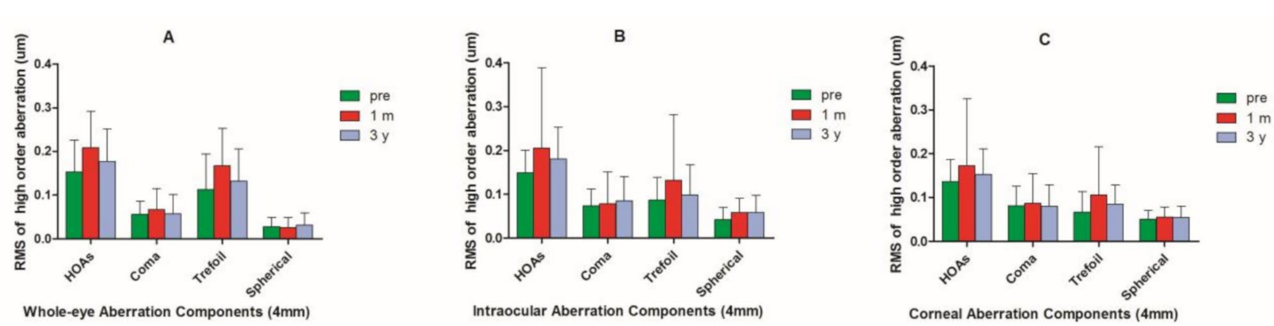

Fig. 2 Whole-eye aberrations components (**A**), intraocular aberrations components (**B**), and corneal aberrations components (**C**) at different time points with a 4-mm pupil. Coma is the root mean square (RMS) of Z_3^{-1} and Z_3^{1}, trefoil is the RMS of Z_3^{-3} and Z_3^{3}, and spherical aberration is the RMS of Z_4^{0}. HOAs = higher-order aberrations

postoperatively were 0.07 ± 0.05, 0.17 ± 0.09, 0.03 ± 0.02, 0.21 ± 0.08 μm, respectively; those 3 years postoperatively were 0.06 ± 0.04, 0.13 ± 0.07, 0.03 ± 0.03, and 0.18 ± 0.07 μm, respectively (Fig. 2A). The whole-eye trefoil and total HOAs increased significantly at 1 month ($P < 0.05$) but did not change significantly at 3 years ($P > 0.05$) postoperatively compared to the preoperative value. The preoperative whole-eye coma or spherical aberration did not differ from those observed at 1 month and 3 years postoperatively ($P > 0.05$).

Table 2 Subgroup analysis of whole-eye, intraocular, and corneal aberrations components at different time points with a 4-mm pupil

Parameters		pre	1 mo	6 mo	3 ye
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Whole-eye Aberration Components	Coma	0.06 ± 0.02	0.06 ± 0.03	0.05 ± 0.02	0.06 ± 0.03
	trefoil	0.11 ± 0.04	0.16 ± 0.04*	0.13 ± 0.05	0.12 ± 0.06
	spherical	0.03 ± 0.03	0.02 ± 0.02	0.03 ± 0.01	0.03 ± 0.02
	total HOAs	0.15 ± 0.03	0.20 ± 0.04*	0.17 ± 0.04	0.16 ± 0.03
Intraocular Aberration Components	Coma	0.06 ± 0.03	0.07 ± 0.02	0.07 ± 0.04	0.07 ± 0.02
	trefoil	0.09 ± 0.03	0.09 ± 0.05	0.09 ± 0.04	0.09 ± 0.05
	spherical	0.05 ± 0.03	0.06 ± 0.03	0.07 ± 0.03	0.05 ± 0.04
	total HOAs	0.14 ± 0.05	0.16 ± 0.05	0.15 ± 0.05	0.15 ± 0.03
Corneal Aberration Components	Coma	0.07 ± 0.03	0.07 ± 0.03	0.07 ± 0.02	0.07 ± 0.03
	trefoil	0.05 ± 0.03	0.10 ± 0.05*	0.08 ± 0.03	0.07 ± 0.03
	spherical	0.05 ± 0.02	0.06 ± 0.02	0.06 ± 0.03	0.05 ± 0.03
	total HOAs	0.12 ± 0.03	0.14 ± 0.03	0.13 ± 0.02	0.13 ± 0.02

SD = standard deviation; *$P < 0.05$

For intraocular aberration, the preoperative RMS of the intraocular coma, trefoil, spherical aberration and total HOAs were 0.07 ± 0.04, 0.09 ± 0.05, 0.04 ± 0.03, and 0.15 ± 0.05 μm, respectively; those 1 month postoperatively were 0.08 ± 0.07, 0.13 ± 0.15, 0.06 ± 0.03, and 0.21 ± 0.18 μm, respectively; those 3 years postoperatively were 0.08 ± 0.06, 0.10 ± 0.07, 0.06 ± 0.04, and 0.18 ± 0.07 μm, respectively (Fig. 2B). The 1-month postoperative intraocular trefoil increased significantly compared to the preoperative value ($P < 0.05$) but did not change significantly at 3 years postoperatively ($P > 0.05$). The intraocular spherical aberration and total HOAs at 1 month and 3 years postoperatively increased significantly compared to the preoperative values ($P < 0.05$). The intraocular coma did not differ significantly between preoperatively and at 1 month and 3 years postoperatively ($P > 0.05$).

For corneal aberration, the preoperative RMS of corneal coma, trefoil, spherical aberration and total HOAs were 0.08 ± 0.04, 0.07 ± 0.05, 0.05 ± 0.02, and 0.14 ± 0.05 μm, respectively; those a 1 month postoperatively were 0.09 ± 0.07, 0.11 ± 0.11, 0.06 ± 0.02, and 0.17 ± 0.15 μm, respectively; those a 3 years postoperatively were 0.08 ± 0.05, 0.0 ± 0.04, 0.05 ± 0.03, and 0.15 ± 0.06 μm, respectively (Fig. 2C). The corneal trefoil increased significantly at 1 month postoperatively ($P < 0.05$) but did not change significantly at 3 years postoperatively compared to the preoperative value ($P > 0.05$). The corneal coma, spherical aberration, and total HOAs, did not change significantly at 1 month and 3 years postoperatively ($P > 0.05$).

Compared to the preoperative values, the RMS of the whole-eye coma, trefoil, spherical aberration, and total HOAs increased by 0.01 ± 0.04, 0.05 ± 0.07, 0.00 ± 0.03, and 0.06 ± 0.07 μm at 1 month postoperatively, respectively, and increased by 0.00 ± 0.05, 0.02 ± 0.08, 0.00 ± 0.03, and 0.02 ± 0.08 μm at 3 years postoperatively, respectively. The increases in whole-eye trefoil, spherical aberration, and total HOAs differed significantly between the two time points postoperatively ($P < 0.05$), while the increase in whole-eye coma did not differ significantly between the two time points ($P > 0.05$). The RMS of the intraocular coma, trefoil, spherical aberration and total HOAs increased by 0.01 ± 0.08, 0.05 ± 0.15, 0.02 ± 0.03, and 0.06 ± 0.19 μm at 1 month postoperatively, respectively, and increased by 0.01 ± 0.06, 0.01 ± 0.07, 0.02 ± 0.04, and 0.03 ± 0.07 μm at 3 years postoperatively, respectively. The increase in intraocular HOAs did not differ significantly between the two postoperative time points ($P > 0.05$). The RMS of the corneal coma, trefoil, spherical aberration, and total HOAs increased by 0.01 ± 0.07, 0.04 ± 0.10, 0.00 ± 0.02, and 0.04 ± 0.15 μm at 1 month postoperatively, respectively, and increased by 0.00 ± 0.05, 0.02 ± 0.07, 0.00 ± 0.02, and 0.02 ± 0.07 μm at 3 years postoperatively, respectively. The increase in corneal HOAs did not differ significantly between the two time points postoperatively ($P > 0.05$).

The subgroup analysis of 23 eyes of 23 patients showed that the whole-eye trefoil and total HOAs, corneal trefoil increased significantly at 1 month ($P < 0.05$) but did not change significantly at 6 months and 3 years ($P > 0.05$) postoperatively compared to the preoperative value (Table 2). The whole-eye coma or spherical aberration, intraocular aberrations, corneal coma or spherical aberration.

or total HOAs did not differ from those observed at 1 month, 6 months and 3 years postoperatively ($P > 0.05$).

Factors related to aberrations

The increase in intraocular spherical aberrations at 1 month and 3 years postoperatively was significantly correlated with age, preoperative CDVA, and postoperative refractive astigmatism status ($P < 0.05$), whereas gender, preoperative refractive error, IOP, axial length, ICL size, ICL power, and postoperative vault were not significantly correlated ($P > 0.05$). The increase in intraocular and corneal trefoils at 1 month postoperatively did not significantly correlate with any preoperative or postoperative parameters ($P > 0.05$).

Discussion

In this retrospective study, we analyzed the visual and refractive outcomes after EVO-ICL implantation in 53 eyes of 53 patients and demonstrated that the EVO-ICL is safe, effective, predictable, and stable for correcting myopia and astigmatism. The results showed that the long-term safety index was improved after surgery, but the myopia progression led to the decline of UDVA and efficacy index, which was consistent with the previous study [1]. Although several articles [9, 10, 14] have reported changes in whole-eye HOAs after EVO-ICL implantation for myopic and astigmatic corrections, this was the first to investigate long-term changes in intraocular, corneal, and whole-eye HOAs after EVO-ICL implantation.

Herein, we evaluated whole-eye, intraocular, and corneal HOAs before and 1 month and 3 years after EVO-ICL implantation; the intraocular and corneal trefoils increased significantly at 1 month postoperatively compared to their preoperative levels and decreased to preoperative levels at 3 years postoperatively, resulting in an early postoperative increase in whole-eye trefoil, but decreased to the preoperative level in the long term. We believe that the increase in corneal trefoil in the early postoperative period was due to corneal incision, and the increase in intraocular trefoil was associated with the early postoperative intraocular reaction. With the incisional and intraocular recovery, the trefoil decreased to the preoperative level in the long term. At 1 month and 3 years postoperatively, the intraocular spherical aberrations increased compared to their preoperative values, but the whole-eye spherical and corneal spherical aberrations did not. The little increase in intraocular spherical aberrations might have been due to the ICL itself, but might have been neutralized by the other refractive media in the eye, resulting in no change in the whole-eye spherical aberration. Intraocular and corneal comas did not change significantly between the early and long-term postoperative periods; therefore, the whole-eye coma did not differ significantly from the preoperative coma. Briefly, the increase in total whole-eye HOAs in the early postoperative period was derived from the increase in whole-eye trefoil. Overall, the increase in total whole-eye HOAs in the early postoperative period after EVO-ICL implantation was derived from the increase in corneal and intraocular trefoils, and postoperative total whole-eye HOAs in the long-term were consistent with preoperative values.

Compared to other studies, Huseynova [6] reported that both EVO-ICL and ICL V4 increased HOAs 3 months postoperatively, but the increase in HOAs did not differ significantly between these two lenses, and eyes with a 6-mm pupil increased more in HOAs than in 4-mm pupils. Wei [15] compared the HOAs after implantation of TICL and ICL and found no significant difference in changes in HOAs between the two lenses, but the RMS of total HOAs and trefoil increased significantly at 6 months postoperatively ($P < 0.05$). In a study by SW KIM [16], patients with ICL implantation were divided into small- and large-incision groups. The spherical aberration and trefoil increased in the small-incision group postoperatively, and the total HOAs also increased postoperatively in the large-incision group. As similar trefoil increases have been observed in cataract surgery after Artisan and Artiflex implantations [17], KIM [16] assumed that the trefoil is caused by the incision itself, believing that incision changes can cause an increase in total HOAs and trefoil, while the increase in spherical aberration is caused by lenses. This is consistent with the findings of our separate analysis of corneal and intraocular HOAs, confirming the assumption of KIM.

Most studies [10, 14, 18, 19] have shown that the HOAs introduced by corneal laser surgeries are greater than those introduced by ICL implantation. In a study by Igarashi A [19], ICL introduced fewer higher-order wavefront aberrations compared to LASIK, and HOAs increased after LASIK surgery compared to preoperative values. Kamiya [18] compared HOAs after wavefront-guided LASIK and ICL implantation in moderate myopia and arrived at the same conclusion. Miao [20] also reported that the total HOAs of the cornea increased after SMILE surgery. In a review by O'Brart [21] for superficial ablation, whether PRK, LASIK, epi-LASIK, or trans-PRK, postoperative HOAs also increased compared to preoperative HOAs. Choi [22] proved that the RMS of HOAs, coma, and trefoil increased more after bioptic surgery than did the corresponding values after ICL implantation. Compared to that associated with corneal refractive surgeries, the increase in HOAs after ICL implantation is less because it preserves the integrity and prolate shape of the cornea, whereas corneal refractive surgeries cut the cornea to make it flat. When the safety, efficacy, and improvement of postoperative refractive results of laser surgeries are similar to those of ICL implantation, EVO-ICL is associated with better postoperative visual quality than that associated with corneal refractive surgeries for the correction of medium and high myopia.

This study had several limitations. First, the sample size was insufficient. Few studies have reported on changes in HOAs after EVO-ICL implantation, with contradictory or controversial results. Studies with larger sample sizes and longer follow-up durations are required for comparison. Second, our patients had a wide range of spherical powers, and the eyes were not classified based on the degree of myopia. Besides, this study only had three data points and the rate of missed follow-up in the intermediate period was high because of the COVID-19 situation. But the subgroup analysis of the intermediate period was conducted. There were no statistically significant differences in high-order aberrations between 6 months and 3 years postoperatively.

In conclusion, EVO-ICL implantation provides safe, effective, predictable, and stable outcomes. The intraocular and corneal trefoils increased significantly in the early postoperative period but can be recovered to the preoperative level in the long term. The intraocular spherical aberration increases slightly in the long term postoperatively, but the whole-eye spherical aberration does not change significantly.

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Author contributions
The authors were involved in the conception or design of the work, the acquisition, analysis or interpretation of data for the work (XC, HMM, BLL, MRC, ICL, YDL, YJJ, XYW, XTZ); drafting the work or revising it critically for important intellectual content (XC, HMM); final approval of the version to be published (XYW, XTZ); agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (XC, HMM, BLL, MRC, ICL, YDL, YJJ, XYW, XTZ). All authors read and approved the final manuscript.

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Data availability
Data and materials are available upon request from the corresponding author at doctxiaoyingwang@163.com or doctzhouxingtao@163.com.

Declarations

Ethics approval and consent to participate
This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethical Committee Review Board of Fudan University Eye and ENT Hospital (2016038). All patients voluntarily participated in the study and signed informed consent forms after the possible risks and benefits of the study had been explained to them.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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