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ORIGINAL RESEARCH

Long-Term Evaluation of Contrast Sensitivity and Vision Quality for High and Extreme High Myopia After EVO ICL Implantation

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Purpose: To determine the contrast sensitivity (CS) and vision quality of patients with high and extreme high myopia following long-term evolution implantable collamer lens (EVO ICL) implantation.

Patients and Methods: Thirty-five patients (60 eyes) with a myopia range of −7.25 D to −18.50 D were enrolled. Participants were categorized into the high myopia (HM) (spherical equivalent>-12.0 D) and extreme high myopia (EHM) (spherical equivalent≤-12.0 D) groups. Routine examinations, including measurements of endothelial cell density and anterior chamber parameters, were performed. CS and vision quality were assessed over a long-term follow-up period, with an average final follow-up time of 7.29±0.82 years.

Results: All surgical procedures were completed without any significant complications. No statistical differences for the CS parameters at the six different spatial frequencies in the corrected and uncorrected conditions were identified between the two groups ($P>0.05$). The vision quality questionnaire results indicated both groups reported concerns regarding the frequency of halos (HM group 57.6%, EHM group 63%). Driving was identified as the most distressing postoperative daily life activity. Further analysis revealed a negative correlation between driving distress and CS ($B=-0.40$, $P<0.01$). The preoperative axial length was found to be correlated with CS ($B=-0.39$, $P<0.01$).

Conclusion: Patients with HM and EHM maintained good long-term CS and vision quality after EVO ICL implantation. Halos and driving distress were the most common complaints.

Keywords: contrast sensitivity, high myopia, implantation, lens, vision

Introduction

The incidence of myopia is increasing globally and prevalences of both high and low myopia are the largest in East Asia, including China[1,2] Extreme high myopia (EHM) leads to a decline in patients' vision and inconvenience in their daily life. Refractive surgeries, particularly implantable collamer lens (ICL) implantation, offer significant therapeutic benefits for correcting high myopia in adults. ICL implantation is widely effective for correcting refractive errors with good refractive stability and a favourable safety profile.[3–5]

Due to the increasing popularity of evolution implantable collamer lens (EVO ICL) implantation, designed to improve aqueous humour circulation, its impact on vision quality has received widespread attention. Since EVO ICL introduces few higher order aberrations, it can achieve better visual quality compared to other refractive surgeries.[6] However, glare and halos are common visual issues following ICL implantation, which may significantly impact

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a patient's daily life.[7,8] Studies have shown that this may be related to pupil size, ICL optical zone and white-to-white (WTW).[9] In addition, the optical distortion caused by the inner wall of the central hole may be one of the other factors leading to visual problems.[10] Several methods have been used to assess vision quality; questionnaires are used to quantify patient subjective visual perception, whereas contrast sensitivity (CS) represents an objective measurement of the spatial vision quality that detects the minimum contrast required to discriminate objects at a specific spatial frequency. Lu et al reported that the visual acuity and CS both decline in conjunction with the progression of myopia.[11] A meta-analysis demonstrated that, compared to corneal laser surgery, ICL implantation resulted in superior postoperative vision quality.[12] However, the long-term impact of EVO ICL implantation on visual quality remains poorly understood.

The aim of this study was to ascertain the long-term postoperative impact of EVO ICL implantation on vision quality using a combination of objective and subjective measurements (CS and questionnaires, respectively).

Materials and Methods

Study Design

Participants who met the indications for surgery and required ICL implantation were included in this study. The participant inclusion criteria were: (1) high and extreme high myopia (spherical equivalent [SE] <-6.0 D), with the myopia degree within the EVO ICL correctable range; (2) anterior chamber depth (ACD) >2.8 mm; (3) endothelium cell density (ECD) >2,000/mm2; (4) absence of ocular and systemic diseases such as glaucoma and cataract, except for refractive errors; and (5) absence of other ocular surgeries. The participants were further categorized according to SE into high myopia (HM) (−12.0 D<SE≤-6.0 D, 33 eyes) and an extreme high myopia (EHM) (SE≤-12.0 D, 27 eyes) groups.

This study was approved by the EENT Ethics Committee and conducted in accordance with the Declaration of Helsinki (No. 2016038). The patients were fully informed of the details of the procedure details and provided written consent.

EVO ICL Implantation

The EVO ICL (STAAR Surgical, Nidau, Switzerland) power was calculated using the modified apex formula. Topical antibiotic drops were administered pre-operatively for several days. On the day of surgery, after adequate pupil dilation and surface anaesthesia, the EVO ICL was implanted after injection of a viscoelastic into a small 3-mm incision in the cornea. After the EVO ICL was placed to the appropriate position, the viscoelastic material was rinsed with a balanced salt solution. Subsequently, 1% fluticasone eye drops were routinely administered four times a day for the first 3 days, propranolol eye drops four times a day for 2 weeks, moxifloxacin eye drops four times a day for 1 week, and artificial tears 4 times a day for at least 1 month. All surgical procedures were conducted by a surgeon with extensive experience in the field (XTZ).

Ocular Examinations

All participants underwent complete ophthalmic examinations by qualified examiners (LL N, YH Y) who were blinded to the study group assignment and the preoperative information. Subjective refraction, uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA) were measured using an RT-5100 phoropter (Nidek Technologies, Gamagori, Japan). Intraocular pressure (IOP) was measured with a Canon Full Auto Tonometer TX-F (Canon, Inc., Tokyo, Japan). Axial length (AL) was obtained using IOL Master 700 (Carl Zeiss AG, Jena, Germany). Pentacam HR (Oculus Optikgerate Wetzlar, Wetzlar, Germany) was used to ascertain the following postoperative values: white-to-white (WTW), anterior chamber depth (ACD), anterior chamber volume (ACV), anterior chamber angle (ACA), central corneal thickness (CCT), and vault.

CS was measured using a specific device with a digital monitor (Gension & Waltai Digital Video System Co., Ltd., Beijing, China). To test CS at six different spatial frequencies, patients were required to identify three numbers on a screen that was 3 m away, as described in our previous study (Ye). The area under the curve between 1.5 and 18 LogCSF was defined as the AULCSF. The size of the optotype at a contrast threshold of 100% was defined as the acuity.

The vision quality questionnaire was adapted from previously reported and evaluated questionnaires.[13–15] The questionnaire comprises a comprehensive range of vision quality-related symptoms, including glare, halos, starbursts, visual haziness, visual blurring, visual distortion, diplopia, fluctuating visual acuity, difficulty in focusing, and difficulty in accurately judging distance or depth. The frequency, degree, and distress of each visual symptom are subjectively rated on a scale of 0–3, with 0 indicating the absence of symptoms, 1 indicating symptoms of mild degree, 2 indicating symptoms of moderate degree, and 3 indicating symptoms of severe degree. The extent of dry eye, overall improvement in vision quality, and satisfaction level was determined. In addition, specific factors that affect the participants daily lives after refractive surgery were recorded. The investigators (YM, TF) explained the contents of the questionnaire to the patients, and then the patients will complete the questionnaire independently. The vision quality questionnaire is provided in Supplementary 1.

Statistical Analyses

SPSS was utilized for statistical analyses (version 20.0; IBM Corp., Armonk, NY, USA). The sample size of 60 participants was calculated by G*power 3.1 software, with the objective of ensuring a significance level (α) of 0.05, power (β) of 0.2, and a correlation among repeated measures of 0.5.[16] Normality tests were performed on all data. The *t*-test was performed for continuous variables that conformed to normality, the Mann–Whitney *U*-test was performed for non-normally distributed variables, and the chi-square test was performed for ordinal variables. Multiple linear regression as well as Spearman's rank correlation were used for correlation analysis, and Bonferroni adjustment was used for binocular enrolment. Statistical significance was set at $P < 0.05$.

Results

Demography Information

Thirty-five patients (60 eyes) were included in this study. The preoperative age was 39.85±8.97 years in the HM group (33 eyes) and 41.11±7.25 years in the EHM (27 eyes, P=0.56) group. The SE was −10.27±1.16 D and −13.80±2.18 D preoperatively in the HM and EHM groups, respectively (P<0.01). All preoperative baseline parameters were matched between the two groups, except for spherical D and AL. SE was −1.00±0.89 D and −1.51±0.82 D (P=0.02) in two groups, respectively (P=0.02) at the last follow up. Table 1 lists the demographic information before and after EVO ICL implantation.

Table 1 Basic Information on Demography

	Preoperative			**Postoperative**		
	HM (33 Eyes)	**EHM (27 Eyes)**	**P**	**HM (33 Eyes)**	**EHM (27 Eyes)**	**P**
Spherical diopter (D)	−9.67±1.13 [−11.50, −7]	−12.86±2.03 [−17.75, −10.50]	**<0.01**	−0.67±0.94 [−4.00, +1.00]	−1.19±0.74 [−2.50, 0]	**0.03**
Cylinder (D)	−1.21±0.96 [−4, 0]	−1.80±1.46 [−5.0, 0]	0.07	−0.65±0.46 [−1.75, 0]	−0.66±0.49 [−2.00, 0]	0.96
SE (D)	−10.27±1.16 [−11.50, −7.25]	−13.80±2.18 [−18.50, −12.0]	**<0.01**	−1.00±0.89 [−4.125, 0.625]	−1.51±0.82 [−2.75, −0.25]	**0.02**
CDVA	1.04±0.14 [0.8, 1.2]	0.96±0.18 [0.6, 1.2]	0.06	1.20±0.16 [0.8, 1.5]	1.13±0.19 [0.8, 1.5]	0.11
IOP (mmHg)	14.98±2.50 [10.4, 19.2]	15.90±2.99 [10.9, 21.4]	0.20	13.65±2.67 [9.7, 20.0]	15.47±3.98 [9.4, 24.2]	**0.04**
ECD (/mm2)	2860.76±469.57 [2085, 3971]	2931.33±408.81 [2210, 3709]	0.54	2567.97±257.14 [2107, 3142]	2557.6±211.59 [2044, 2886]	0.87
AL (mm)	27.25±1.14 [25.05, 30.42]	28.93±1.49 [26.02, 32.96]	**<0.01**	27.50±1.30 [25.22, 30.87]	29.33±1.62 [26.21, 33.31]	**<0.01**
WTW (mm)	11.95±0.99 [11.1, 12.7]	11.77±0.46 [11.1, 12.6]	0.40	11.56±0.22 [11.2, 12.0]	11.62±0.45 [10.9, 12.4]	0.62
CCT (μm)	520.36±28.01 [472, 574]	532.81±25.81 [456, 563]	0.08	519.21±26.66 [479, 573]	530.52±27.31 [462, 567]	0.10

(*Continued*)

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Table 1 (Continued).

	Preoperative			Postoperative		
	HM (33 Eyes)	**EHM (27 Eyes)**	**P**	**HM (33 Eyes)**	**EHM (27 Eyes)**	**P**
ACD (mm)	3.11±0.21 [2.80, 3.55]	3.15±0.20 [2.80, 3.50]	0.45	2.86±0.20 [2.48, 3.38]	2.88±0.25 [2.37, 3.33]	0.73
ACV (mm3)	188.71±26.63 [126, 258]	180.54±51.47 [134, 247]	0.45	107.57±16.54 [78, 135]	111.38±19.41 [70, 146]	0.43
ACA (°)	38.55±4.68 [31.6, 50.4]	40.07±9.58 [31.9, 56.8]	0.45	22.17±4.32 [14.4, 32.8]	24.40±5.47 [11.4, 36.0]	0.10
Vault (μm)	NA	NA		319.88±219.73 [100, 1070]	435.00±250.86 [120, 1030]	0.07

Notes: Values with statistical significance are shown in bold.
Abbreviations: SE, spherical equivalent; CDVA, corrected distance of visual acuity; IOP, intraocular pressure; ECD, endothelial cells density; AL, axial length; WTW, white to white; CCT, central corneal thickness; ACD, anterior chamber depth; ACV, anterior chamber volume; ACA, anterior chamber angle; HM, high myopia group; EHM, extreme high myopia group.

Refractive Information

The safety index (post CDVA/pre CDVA) for all participants was 1.18±0.17; 1.16±0.14 and 1.20±0.21 for the HM and EHM groups, respectively (P=0.45). The overall efficacy index (post UDVA/pre CDVA) for all participants was 0.71±0.26; 0.76 ±0.27 and 0.65±0.24 in two groups, respectively (P=0.12). All eyes in the HM had a UDVA of 20/25 or better, and 14 eyes in the EHM group had a UDVA of 20/25 or better (Figure 1A). Four eyes in the HM and eight eyes in the EHM groups achieved two or more lines of CDVA. Neither group exhibited a loss of two or more lines of CDVA (Figure 1B). Figure 1C shows the linear regression formula of SE-attempted versus SE-achieved at the final follow-up. About 15.2% patients in the HM and 14.8% patients in the EHM achieved postoperative SE within ±0.50D (Figure 1D). The refractive astigmatism results showed that 19 eyes in the HM and 14 eyes in the EHM were within ±1.0 D (Figure 1E). Figure 1F shows the changes in the SE.

Contrast Sensitivity

In the uncorrected condition, AULCSF was 0.72±0.36 among all participants without significant difference between the two groups (0.76±0.36 in the HM vs 0.66±0.36 in the EHM, P=0.30). Acuity was 12.59±8.01 cpd among all participants, and the acuity for the HM and EHM were 13.92±8.46 cpd and 10.97±7.24 cpd, respectively (P=0.16). In the corrected condition, AULCSF was 1.10±0.20 among all participants; 1.11±0.17 and 1.10±0.23 for the HM and EHM groups, respectively (P=0.89). Acuity was 20.88±6.81 cpd among all participants; 21.17±6.34 in the HM group and 20.54±7.42 cpd in the EHM group (P=0.73). Table 2 presents the CS at different spatial frequencies, without statistical differences between the two groups.

Visual Acuity Questionnaire

No statistical discrepancies were identified between the two groups (HM and EHM) with respect to the responses provided to each question. The most common complaint for participants with HM was halo frequency, with 57.6% of the participants reporting mild or worse halo symptoms. In the HM group, 24.2% of the participants reported impaired driving ability, and 12.1% felt distressed reading at night. Dry eye symptoms were reported in 24.2% of the participants with HM. The most common complaint from the participants with EHM was halo frequency and degree, with 63.0% of participants reporting mild or worse halo symptoms. Among the participants with EHM, 25.9% felt distressed while driving, 7.4% experienced disturbed reading at night, and 25.9% experienced dry eye symptoms.

Correlation Analysis

CS parameters were analysed using the results of the vision quality questionnaire. None of the CS coefficients correlated significantly with vision quality satisfaction or the occurrence of dry eyes ($P > 0.05$). However, driving disturbance was found to be significantly correlated with ACLCSF in the uncorrected ($B=-0.41$, $P<0.01$) and corrected ($B=-0.47$, $P<0.01$) conditions, and acuity in the uncorrected ($B=-0.41$, $P<0.01$) and corrected ($B=-0.39$, $P<0.01$) conditions. Only AL had a significant negative correlation with the CS parameters. Table 3 presents the detailed outcomes of the correlation analyses.

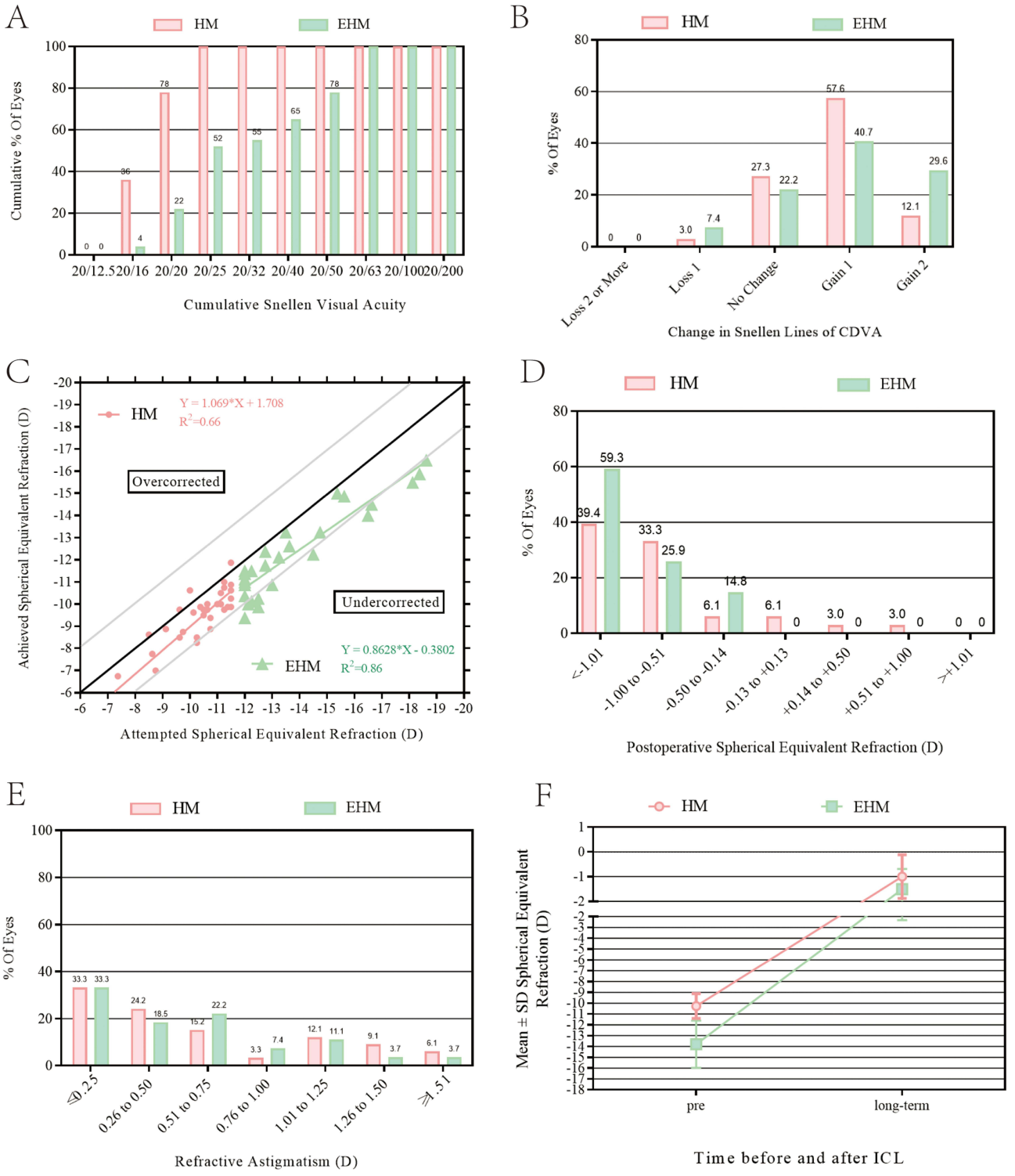

Figure 1 Refractive outcomes of patients extreme high myopiaEHMfollowing EVO ICL implantation, including the uncorrected distance visual acuity (**A**), the change in corrected distance visual acuity (**B**), the formula of spherical equivalent attempted versus achieved (**C**), the spherical equivalent refractive accuracy (**D**), the refractive astigmatism (**E**), the change of spherical equivalent refraction (**F**).

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Table 2 Different Spatial Frequencies of Contrast Sensitivity Between the High Myopia Group and Extreme High Myopia Group

	Uncorrected Condition			Corrected Condition		
	HM	SHG	P	HM	SHG	P
1.0cpd	1.19±0.18	1.11±0.17	0.12	1.20±0.13	1.79±0.12	0.27
1.5cpd	1.17±0.19	0.10±0.21	0.20	1.25±0.13	1.27±0.13	0.66
3.0cpd	1.01±0.37	0.89±0.43	0.23	1.28±0.13	1.29±0.16	0.92
6.0cpd	0.68±0.45	0.53±0.49	0.22	1.43±1.69	1.11±0.25	0.34
12.0cpd	0.29±0.35	0.19±0.29	0.27	0.65±0.26	0.62±0.36	0.72
18.0cpd	0.09±0.19	0.06±0.13	0.37	0.25±0.24	0.24±0.24	0.83

Abbreviations: HM: high myopia group; SHG, extreme high myopia group.

Table 3 Correlation Analysis Between Contrast Sensitivity Parameters and Preoperative Baseline Information

	AULCSF (Uncorrected)		Acuity (Uncorrected)		AULCSF (Corrected)		Acuity (Corrected)	
	B	P	B	P	B	P	B	P
Age (years old)	−0.25	0.14	−0.19	0.29	−0.09	0.59	0.01	0.96
IOP (mmHg)	0.07	0.64	0.05	0.73	0.06	0.66	0.06	0.69
ECD (/mm2)	−0.12	0.44	−0.09	0.58	−0.07	0.67	−0.18	0.25
AL (mm)	−0.29	**0.04**	−0.28	0.06	−0.39	**<0.01**	−0.39	**<0.01**
WTW (mm)	−0.04	0.81	0.04	0.82	0.04	0.76	0.05	0.71
CCT (μm)	0.06	0.72	0.05	0.76	0.36	0.07	0.25	0.10
ACD (mm)	−0.04	0.80	−0.11	0.50	0.15	0.31	0.27	0.08

Notes: Values with statistical significance are shown in bold.
Abbreviations: IOP, intraocular pressure; ECD, endothelial cells density; AL, axial length; WTW, white to white; CCT, central corneal thickness; ACD, anterior chamber depth.

Discussion

The objective of this study was to evaluate the visual acuity of patients in the extended postoperative phase after EVO ICL implantation. Good safety and efficacy were observed 7 years postoperatively. The outcomes of the CS and vision quality questionnaires revealed no significant differences between the HM and EHM groups. However, the observed correlation between CS and driving distress indicated the need for postoperative vision quality assessment.

In both HM and EHM groups, a safety index of over 1.15 and stable endothelial cell values (within the safe range) were observed. These findings substantiate the continued favourable safety profile and stability of EVO ICL implantation, 7 years after the initial ICL implantation. The efficacy index was low in both groups, and patients with a higher degree of myopia tended to have more refractive regression at postoperative follow-up. A study on refractive regression after ICL implantation by Kamiya et al[17] showed that patients with longer preoperative AL exhibited a greater propensity for refractive regression. Consistent with previous study results,[18,19] in the present study, patients with EHM exhibited more pronounced under-correction with AL growth. It has been hypothesized that the postoperative efficacy index is related to the progression of HM. In this study, all patients exhibited notable enhancement in their BCVA and reached a level of 20/25 or above, which indicated a substantial improvement in their visual performance.

CS is a useful index for assessing postoperative vision quality which can reflect the integrated ability of the entire visual pathway, including the optical system, retina and brain. Thus it has the potential to evaluate visual quality deficits caused by

underlying diseases. HM results in a reduction in retinal optical images, which can be attributed to its effect on intraocular scattering.[20] Wang et al observed a reduction in CS in patients with HM and identified a significant correlation between cone density and reduced AULCSF.[21] Conversely, patients with HM who underwent refractive correction demonstrated postoperative improvement in BCVA. Studies have demonstrated that refractive surgery results in a transient decrease in CS postoperatively, which typically returns to preoperative levels or even improves further within 1 year.[22,23] However, in our study, no statistically significant long-term CS difference was observed between the HM and EHM groups following EVO ICL implantation. Furthermore, CS was superior at low to medium spatial frequencies compared to high spatial frequencies in both groups. Given that patients with EHM exhibit lower retinal magnification and more pronounced hyperopic astigmatism, it has been postulated that these patients demonstrate greater improvement in CS than patients with HM.[24] Further exploration and validation of this hypothesis in the future is warranted. Additionally, modulation transfer function (MTF) reflects the objective estimation of visual quality. Since it can directly evaluate the visual quality of the optic system, studies have shown that MTF could improve significantly after EVO ICL implantation.[25] Combining MTF and CSF can provide a more comprehensive evaluation of patients' visual quality, accurately locating the root cause of postoperative visual quality problems.

Our study revealed no significant differences in individual vision quality symptoms between patients with HM and EHM. In both groups, of the primary adverse effect was halo formation after ICL implantation. Numerous studies have demonstrated that halos are a prevalent visual aberration following ICL implantation.[7,8] This phenomenon may be associated with factors such as pupil size, WTW, and visual field diameter of the implanted ICL.[9] Although not severe, patients reported driving and night-time reading to be the main problematic activities after surgery. Further analysis revealed a significant association between CS and driving distress, which is consistent with the findings of Ang et al.[26] However, no correlation was observed between CS and daily activities such as night reading and exercise. The correlation between CS and AL is consistent with previous findings, which suggests that the incongruence between AL and luminosity may result in a decline in vision quality.[17,27]

This study had a few limitations. First, it should be noted that the cohort of patients in this study who had undergone EVO ICL surgery for a period exceeding 7 years lacked preoperative CS testing owing to device limitations. Second, the sample size was relatively small. However, the results of this study can still provide reference values provided that the preoperative baseline data are consistent.

Conclusion

We demonstrated that EVO ICL was safe, efficacious, and stable in the long-term following surgery. CS did not differ significantly between patients with HM and EHM postoperatively. The most frequent postoperative symptom was the presence of halos, which had a detrimental impact on daily living, such as driving and reading distress at night.

Data Sharing Statement

All data used and analysed during the study are available upon reasonable request.

Ethics Statement

This study was approved by the EENT Ethics Committee and conducted in accordance with the Declaration of Helsinki (No. 2016038). The patients were fully informed of the details of the procedure details and provided written consent.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no competing interests in this work.

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