

# **Evaluation of visual quality after EVO-ICL implantation for hypermyopia**

# An observational study

Qin Qin, MD<sup>a,b,c,d</sup>, Zhengcan Wu, MD<sup>e</sup>, Lianyun Bao, MD<sup>a</sup>, Hui Chen, MD<sup>a</sup>, Liping Yang, MD<sup>c,d</sup>, Zifang He, MD<sup>a</sup>, Zhenping Huang, MD<sup>c,d,\*</sup>

## Abstract

The purpose of this retrospective study was to evaluate the visual quality, objective scattering index, aberration, etc after Implantable Collamer Lens with center hole (EVO-ICL) implantation to treat patients with hypermyopia (diopter > -10D).

A total of 30 eyes underwent EVO-ICL implantation. The uncorrected distance visual acuity (UDVA), best-corrected visual acuity (BCVA), equivalent spherical degree, aberration, visual quality parameters, and corneal endothelial cell density were compared preoperative and postoperative. Fill in the National Eye Institute Refractive Error Quality of Life Instrument-42 before and after surgery.

The modulation transfer function (MTF), Optical Quality Analysis System (OQAS) II values (OV 100%, 20%, 9%), and Stahl ratio 1 and 3 months after surgery were higher than the respective preoperative values. The objective scatter index value increased 1 week after surgery, but decreased 1 and 3 months after surgery compared with the preoperative values. Total aberration (TA), total low-order aberration (tLOAs), and defocus decreased at 1 week and 3 months after EVO-ICL implantation. Total high-order aberration (tHOAs) and spherical aberration were significantly increased 1 week after surgery and decreased 3 months after surgery, and the difference was statistically significant. Astigmatism, coma, and clover were not significantly different in each time period. TA, tLOAs, tHOAs, defocus, and spherical aberration were higher at 1 week than 3 months after surgery. At 3 months after surgery, the scores of the patients' NEI-RQL-42 scale were all improved except that the glare was lower than that before surgery. There was no significant difference in the density of corneal endothelial cells before and 3 months after surgery.

For patients with hypermyopia, the postoperative subjective and objective visual quality of EVO-ICL implantation was better than preoperative.

**Abbreviations:** BCVA = best-corrected visual acuity, ECD = endothelial cell density, EVO-ICL = Implantable Collamer Lens with center hole, MTF = modulation transfer function, TA = total aberration, tHOAs = total high-order aberration, tLOAs = total low-order aberration.

Keywords: EVO-ICL, hypermyopia, visual quality

# 1. Introduction

Myopia refers to a situation in which the light through eyes is focused in front of the retina.<sup>[1]</sup> Due to the increasing high prevalence over the past few decades, myopia remains a significant public health issue in some areas of the world, especially East Asia.<sup>[2]</sup> Myopia is measured in diopters and divided into 4 status groups (low, moderate, high, and severe)

based on the pathogenesis.<sup>[3,4]</sup> There are more and more patients with hypermyopia ( $\geq$ -10.0D). At present, there is no unified standard for hypermyopia, which is usually defined as myopia with refractive power  $\geq$ -10.0D and axial length  $\geq$ 27.0mm. In this study, hypermyopia was defined as myopic patients with refractive power  $\geq$ -10.0D and excluding serious fundus complications such as retinal detachment and keratoconus.

Copyright © 2019 the Author(s). Published by Wolters Kluwer Health, Inc.

Editor: Khaled Abdulrahman.

ZW is the co-first author.

Funding: Project was supported by Medical Science and Technology Development Foundation, Nanjing Department of Health (YKK17078).

The funding agencies had no role in the design or conduct of this study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; or in the decision to submit the manuscript for publication.

The authors have no conflicts of interest to disclose.

<sup>&</sup>lt;sup>a</sup> Department of Ophthalmology, Nanjing Drum Tower Hospital, Affiliated to Nanjing University Medical School, <sup>b</sup> Department of Ophthalmology, Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University, <sup>c</sup> Department of Ophthalmology, Jinling Medical School of Nanjing Medical University, <sup>d</sup> Department of Ophthalmology, Jinling Hospital, <sup>e</sup> Department of Radiology, Nanjing First Hospital, Nanjing Medical University, Nanjing, Jiangsu Province, China.

<sup>\*</sup> Correspondence: Zhenping Huang, Department of Ophthalmology, Jinling Medical School of Nanjing Medical University, 305 East Zhongshan Road, Nanjing, 210002 Jiangsu Province, People's Republic of China (e-mail: hzp19633@126.com).

This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC), where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

How to cite this article: Qin Q, Wu Z, Bao L, Chen H, Yang L, He Z, Huang Z. Evaluation of visual quality after EVO-ICL implantation for hypermyopia. Medicine 2019;98:44(e17677).

Received: 6 August 2019 / Accepted: 30 September 2019 http://dx.doi.org/10.1097/MD.000000000017677

Although treatments including implantable collamer lens (ICL) and small-incision lenticule extraction (SMILE) have been widely used to correct near-sightedness; however, the surgical options for patients with hypermyopia are still very limited. Currently, the known surgical methods are lens replacement and intraocular lens implantation.

The Visian ICL<sup>TM</sup> (STAAR Surgical, Nidau, Switzerland) is a posterior chamber phakic intraocular lens (IOL).<sup>[5-7]</sup> These years, a novel ICL operation based on an artificial hole (Implantable Collamer Lens with center hole, EVO-ICL) has been developed. Previous work shows that EVO-ICL implantation is satisfactory in terms of safety.<sup>[8,9]</sup> Moreover, EVO-ICL implantation is similar to the traditional ICL implantation with regard to inducing the higher-order aberrations and contrast sensitivity function.<sup>[10]</sup> The laser-assisted in situ keratomileusis (LASIK), SMILE, and some other corneal laser surgery is not very suitable for patients with severe high myopia, because there will be a greater risk. Eventhough the parameters for optical quality as well as intraocular scattering are valuable for the subsequent satisfaction and postoperative visual performance in hypermyopia, the subjective and objective visual quality of hypermyopia after EVO-ICL implantation needs to be further analyzed.

In the present study, the double-pass technique (via OQAS<sup>TM</sup> II, Optical Quality Analysis System [OQAS], Visiometrics, Spain) was used to assess optical quality parameters and intraocular scattering in patients with hypermyopia who had undergone EVO-ICL implantation (Fig. 1). i-Ttrace visual function analyzer (TRACEY, United States) was used to evaluate the aberration of the patients, and National Eye Institute Refractive Error Quality

of Life Instrument-42 (NEI-RQL-42) was used to evaluate the subjective visual perception of the patients. This clinical study assessed the application scope of EVO-ICL implantation to treat hypermyopia. The findings of this study might help us to select the most appropriate and security surgical method for patients with hypermyopia.

### 2. Methods

#### 2.1. Patients

From February 2018 to October 2018, totally 30 eyes from 15 consecutive patients (8 women, 7 men; aged 21-34 years) who underwent the implantation of the posterior chamber phakic ICL with a 0.36-mm central artificial hole (EVO-ICL, STAAR Surgical) of hypermyopia (manifest refraction spherical equivalent to -10.25 to -18.0 diopters [D], manifest cylinder < 0.5 D, chamber depth  $\geq 3.0 \text{ mm}$ , endothelial cells  $\geq 2500/\text{mm}^2$ ) were assessed. The D stability of these patients was more than 2 years (the increase less than -0.5 D every year). All the operations in the current study were done at the Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University. Patients with a history of ocular surgery, severe dry eye, progressive corneal degeneration, cataract, or uveitis were excluded. Based on OCULYZERII (WaveLight, Alcon, Fort Worth, TX), eyes with keratoconus were excluded. The institutional review board at Nanjing Medical University approved this study, which followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.



Figure 1. Optical Quality Analysis System (OQAS) II detection figure.

#### 2.2. Operation procedure and follow-up period

Before surgery, noncycloplegic autorefraction, coreal topography, the uncorrected visual acuity, the best-corrected visual acuity (BCVA), cycloplegic refraction, intraocular pressure, axial length, visual quality, and scotopic pupil size were checked. Anterior chamber depth, white-to-white distance, ciliary sulcus spacing, and corneal endothelial cell counts were measured.<sup>[9]</sup> i-Trace visual function analyzer (TRACEY) was used to evaluate the aberrations of patients, including total aberration (TA), total low-order aberration (tLOAs), defocusing, astigmatism, total high-order aberration (tHOAs), spherical aberration, coma, and clover. All aberrations are represented by root mean square (RMS). All patients are required to perform at least 30 minutes dark adaptation before examination, and the pupil diameter needs to be more than 5.5 mm, which is uniformly converted into an RMS value of 5.0mm using the machine's own software operating system (version 3.1). The NEI-RQL-42 was completed before and 3 months after operation. Antibiotic eye drops were used 3 times a day preoperatively. In this study, the same doctor was in charge of all surgeries.

The manufacturer performed the ICL power calculation (STAAR Surgical) by the modified vertex formula based on the ICL Power Calculation Software (http://en.informer.com/iclpower-calculation-software/, version 3.0). To decrease the preoperative refractive errors in each patient's eye, the target refraction was based on emmetropia. The panoramic ultrasound biomicroscope (UBM), which used to the study of anterior segment structures of human eye, could measure central corneal thickness (CCT), central anterior chamber depth (CACD), and anterior chamber angle etc.<sup>[11]</sup> The manufacturer also decided the ICL size according to the parameter of horizontal corneal diameter, which was measured with a vernier caliper and the sulcus-to-sulcus (STS) distance using a panoramic UBM. We calculated the ideal ICL size as STS+0.7mm. The CCT, CACD, and corneal curvature were also measured with OCULYZERII (WaveLight, Alcon).

On the day of their surgery, patients were administered dilating and cycloplegic agents. After peribulbar anesthesia, an EVO-ICL was inserted through a 3 mm clear corneal incision by the injector cartridge (STAAR Surgical) after the placement of hyaluronate (Shandong Bausch & Lomb Freda Company) into the anterior chamber. After surgery, steroidal (1% prednisolone acetate; Allergan, Ireland) and a 0.5% antibiotic (levofloxacin; Santen, Japan) were given 4 times every day for 2 weeks, after which the dose was decreased gradually.

#### 2.3. Detection of visual quality parameters in OQAS II

After surgery, the optical quality and objective intraocular scattering measurements were performed with OQAS<sup>TM</sup> II (Optical Analysis System, Visiometrics, Spain) in a dark environment (approximately 25 lux) preoperatively and at 1 week, 1 month, and 3 months (for a 4.0 mm pupil). The device (OQAS II) has acceptable reliability, and the eye's realignment does not alter the measurements.<sup>[12,13]</sup> The double-pass technique enables the assessment of the retinal image quality only with 1 specific pupil diameter per measurement; an additional measurement is required for other desired pupil sizes. Therefore, retinal image quality measures were assessed with a 4.0 mm pupil in this study. This standard size is often used to analyze ocular aberrations and it more closely simulates visual acuity measurements performed with an undilated pupil.<sup>[14]</sup>

The instrument automatically corrected spherical ametropia between +6 and -8D. Ametropia beyond the spherical range or higher than the 0.5 D cylinder required an additional lens on the instrument insert frame. The patient blinked a few times before each inspection to spread evenly over the tear film. The instrument was based on the double-pass technique to directly obtain a point-source retinal image analysis, and then the point spread function (PSF) was analyzed. The objective visual analysis system of OQAS II is based on the double-pass retinal imaging technique used in this study. The distribution of light intensity in the retina of the 780nm infrared acquisition point-source imaging, with a description of the point-source resolution of the PSF of optical system expression analysis of intraocular optical imaging quality, and modulation transfer function (MTF) was obtained by PSF. The optical quality and objective intraocular scattering parameters were analyzed by PSF, including cut-off frequency of the MTF, Strehl ratio, OQAS under different contrast value (OQAS values [OV] 100%, 20%, 9%), and the objective scatter index. OQAS values under 100%, 20%, and 9% contrast ratio are below the MTF cut-off frequency, and the 0.05 and 0.01 MTF values are segmented by 30C/deg, respectively.

#### 2.4. Statistical analysis

SPSS 20.0 was used as the statistical software in the current study. UDVA, BCVA, spherical equivalent, optical quality, scattering function results, aberration, NEI-RQL-42 scores, and corneal endothelial cell density (ECD) were compared before and after operation using generalized estimation equation. A *P*-value of <.05 was considered significant.

#### 3. Results

#### 3.1. Follow-up and baseline comparison

No patients in this study were lost prior to the 3-month follow-up (Table 1). Our study found that none of the patients had obvious complications during surgery. Ocular pain and corneal edema were observed in 1 eye with high intraocular pressure after EVO-ICL implantation. However, the symptoms disappeared 24 hours after intravenous infusion of mannitol. The intraocular pressure in another patient was 26 to 30 mm Hg (1 mm Hg = 0.133 kPa) 2 weeks after surgery. Carteolol hydrochloride eye drops were administered twice per day, and the intraocular pressure recovered 5 days later (15 mm Hg). One month after surgery, the intraocular pressure was stable. In addition, none of the patients in the group exhibited serious complications, such as infectious keratitis, postoperative secondary intraocular hemor-

Table 1			
Preoperative demographics of the eyes undergoing EVO-ICL.			
	EVO-ICL (-10.25 D~-18 D)		
Age, y	24 y (21–34 y)		
Gender	Male: female $=$ 7:8		
Spherical	-13.87±2.16 -		
Equivalent (D)	(-10.25~-18.0)		
LogMAR UDVA	$2.10 \pm 0.17$		
LogMAR CDVA	$0.06 \pm 0.13$		

CDVA=corrected distance visual acuity, D=diopter, EVO-ICL=Implantable Collamer Lens with center hole, LogMAR=logarithm of the minimal angle of resolution, UDVA=uncorrected distance visual acuity.

 Fe 1	a1	r – 1	~
	24		

Postoperative period				
	Preoperative	1 wk	1 mo	3 mo
LogMAR UDVA	2.10±0.17	$0.07 \pm 0.12$	$0.01 \pm 0.10$	$-0.02 \pm 0.11$
P value		$P_1 < .0001^*$	$P_2 < .0001^*$	$P_3 < .0001^*$
LogMAR BCVA	$0.06 \pm 0.13$	$0.05 \pm 0.13$	$-0.01 \pm 0.10$	$-0.04 \pm 0.07$
P value		$P_1 = .451$	$P_2 = .006^*$	$P_3 = .001^*$
spherical equivalent (D)	$-13.87 \pm 2.16$	$0.06 \pm 0.31$	$0.06 \pm 0.26$	$0.05 \pm 0.27$
P value		$P_1 < .0001^*$	$P_2 < .0001^*$	$P_3 < .0001^*$

 $P_1 = P$ -value of the difference between the preoperative and 1 wk values;  $P_2 = P$ -value of the difference between the preoperative and 1 mo values;  $P_3 = P$ -value of the difference between the preoperative and 3 mo values. \*P < .05 = significant difference. BCVA = best-corrected distance visual acuity, D=diopter, EVO-ICL=Implantable Collamer Lens with center hole, LogMAR=logarithm of the minimal angle of resolution, UDVA= uncorrected distance visual acuity.

rhage, decompensation of corneal endothelium, endophthalmitis, or lens opacity.

#### 3.2. Safety and efficacy

All procedures showed acceptable safety and efficacy after surgery, and the patients did not experience BCVA loss. The safety indexes of the EVO-ICL implantation group was  $1.01 \pm 0.02$ . The efficacy index of the EVO-ICL implantation group was  $1.01 \pm 0.01$ .

The postoperative visual acuity and refractive power before and after surgeries are shown in Table 2. The UDVA in the EVO-ICL implantation groups 3 months after surgery increased compared to preoperative UDVA values, and the difference was significant (P < .0001). The 3-month postoperative BCVA values of the EVO-ICL implantation groups were higher than the preoperative values, and these differences were significant (P=.006, .001). The equivalent spherical Ds 3 months after surgery in the EVO-ICL group were lower than their respective preoperative values, and these differences were significant (P < .0001).

# 3.3. Visual quality comparison before and after surgery in the EVO-ICL group

The comparison of visual quality in the EVO-ICL implantation group before surgery as well as 1 week, 1 month, and 3 months

after surgery was listed in Table 3. There was no significant difference in the visual quality parameters before and 1 week after surgery, but there was significant difference in most of the visual quality parameters before and 1 month, 3 months after surgery (P < .05).

# *3.4.* Aberration comparison before and after surgery in the EVO-ICL group

Table 4 shows that the TA, tLOAs, and defocus decreased at 1 week and 3 months after EVO-ICL implantation. The tHOAs and spherical aberration increased significantly at 1 week after operation and decreased at 3 months after operation. And compared with the preoperative value, the difference was statistically significant. There was no significant difference in astigmatism, coma, and clover in each time period. The values of TA, tLOAs, tHOAs, defocus, and spherical aberration at 1 week after operation were higher than those at 3 months after operation, and the difference was statistically significant.

### 3.5. Scores of NEI-RQL-42

Table 5 shows a comparison of NEI-RQL-42 scores before and 3 months after EVO-ICL ( $-10.25 D \sim -18.0 D$ ) implantation. At 3 months after operation, except glare decreased before operation, the other indexes were higher than those before operation, the difference was statistically significant (P < .0001).

Table 3

Time courses of the optical quality parameters after EVO-ICL (-10.25 D~-18 D).

Postoperative period					
	Preoperative	1 wk	1 mo	3 mo	
MTF cutoff frequency, cpd	37.932±4.457	37.891 ± 4.446	42.707±3.841	43.265±3.801	
P value		$P_1 = .794$	P <sub>2</sub> < .0001*	$P_3 < .0001^*$	
Strehl ratio	$0.198 \pm 0.041$	$0.193 \pm 0.046$	$0.229 \pm 0.062$	$0.235 \pm 0.061$	
P value		$P_1 = .396$	$P_2 = .016^*$	$P_3 = .008^*$	
OV 100%	$1.32 \pm 0.30$	$1.30 \pm 0.31$	$1.30 \pm 0.30$	$1.48 \pm 0.32$	
P value		$P_1 = .721$	$P_2 = .013^*$	$P_3 = .247$	
OV 20%	$1.01 \pm 0.25$	$0.97 \pm 0.26$	$1.09 \pm 0.23$	$1.13 \pm 0.25$	
P value		$P_1 = .416$	$P_2 = .094$	$P_3 = .008^*$	
OV 9%	$0.56 \pm 0.13$	$0.60 \pm 0.13$	$0.70 \pm 0.19$	$0.72 \pm 0.18$	
P value		$P_1 = .207$	$P_2 < .0001^*$	$P_3 < .0001^*$	
OSI	$0.74 \pm 0.35$	$0.82 \pm 0.51$	$0.61 \pm 0.34$	$0.61 \pm 0.35$	
P value		$P_1 = .305$	$P_2 = .048^*$	$P_3 = .041^*$	

 $P_1 = P$ -value of the visual quality parameters statistically compared between preoperative and 1 wk postoperative;  $P_2 = P$ -value of the visual quality parameters statistically compared between preoperative and 1 wn postoperative;  $P_3 = P$ -value of the visual quality parameters statistically compared between preoperative and 3 mo postoperative. \*P < .05 = the difference was statistically significant. EVO-ICL = Implantable Collamer Lens with center hole, MTF = modulation transfer function, OSI = objective scattering index, OV = Optical Quality Analysis System (OQAS) value.

Table 4

Time courses of the	aberration	parameters	after EVO-ICL	(−10.25 D~−18 D).

	Preoperative	1 wk postoperative	3 mo postoperative	P value
TA/D	$5.977 \pm 0.025$	$1.846 \pm 0.006$	$1.527 \pm 0.005$	$P_1 < .0001^*$
	5 942 + 0 012	1.016 + 0.250	1 654 + 0 015	$P_2 < .0001^*$ $P_3 < .0001^*$
ILUAS/D	5.643±0.013	1.910±0.250	1.054±0.015	$P_1 < .0001^*$ $P_2 < .0001^*$ $P_2 = .010^*$
Defocus/D	$5.787 \pm 0.005$	$1.351 \pm 0.031$	$1.342 \pm 0.045$	$P_3 = .010$ $P_1 < .0001^*$ $P_2 < .0001^*$
Astigmatism/D	$0.413 \pm 0.005$	0.412±0.003	0.413±0.003	$P_3 = .323$ $P_1 = .299$ $P_2 = 1,000$
tHOAs/D	$0.485 \pm 0.004$	$0.512 \pm 0.002$	$0.476 \pm 0.003$	$P_2 = 1.000$ $P_3 = .064$ $P_1 < .0001^*$ $P_2 < .0001^*$
Coma/D	$0.283 \pm 0.003$	$0.286 \pm 0.027$	$0.280 \pm 0.005$	$P_2 < .0001^*$ $P_3 < .0001^*$ $P_1 = .744$ $P_2 = .105$
Spherical Aberration/D	$0.255 \pm 0.003$	$0.258 \pm 0.003$	$0.238 \pm 0.002$	$P_3 = .434$ $P_1 < .0001^*$ $P_2 < .0001^*$
Clover/D	$0.264 \pm 0.002$	$0.265 \pm 0.004$	$0.263 \pm 0.003$	$P_3 < .0001$ $P_1 = .221$ $P_2 = .395$ $P_3 = .167$

 $P_1 = P$ -value of the aberration parameters statistically compared between preoperative and 1 wk postoperative;  $P_2 = P$ -value of the aberration parameters statistically compared between preoperative and 3 m postoperative;  $P_3 = P$ -value of the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_3 = P$ -value of the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_3 = P$ -value of the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_2 = P$ -value of the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_2 = P$ -value of the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_3 = P$ -value of the aberration, the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_3 = P$ -value of the aberration, the aberration parameters statistically compared between 1 wk and 3 mo postoperative;  $P_3 = P$ -value of the aberration, the aberration parameters statistically compared between 1 wk and 3 mo postoperative.

# 3.6. Comparison of corneal endothelial cell density before and after surgery in the EVO-ICL group

Table 6 displays that there was no significant difference in corneal ECD of EVO-ICL group before and 3 months after surgery (P > .05).

#### 4. Discussion

The most common evaluation methods of visual quality after refractive surgery are subjective measurements of light and shade

Table 5						
Scores of	NEI-RQL-42 b	efore and	3mo	after	EVO-ICL	(-10.25
$D \sim -18.0 D$	) implantation.					

	Pre	3 mo post	P value
Total score	58.21 ± 0.05	$84.64 \pm 0.03$	<.0001*
Clarity of vision	60.04 ± 0.04	85.49 ± 0.03	<.0001*
Expectation	$31.25 \pm 0.01$	81.21 ± 0.14	<.0001*
Near vision	80.72±0.30	81.41 ± 0.12	<.0001*
Far vision	80.26±0.10	83.37 ± 0.12	<.0001*
Visual fatigue	73.38±0.11	$79.25 \pm 0.06$	<.0001*
Activity limitations	38.93±0.61	88.14 ± 0.05	<.0001*
Glare	72.14±0.12	71.95 ± 0.07	<.0001*
Symptoms	71.68±0.07	78.41 ± 0.07	<.0001*
Dependence on correction	24.83±0.21	$98.30 \pm 0.03$	<.0001*
Worry	52.93 ± 0.08	$77.30 \pm 0.06$	<.0001*
Suboptimal correction	69.21 ± 0.10	88.24 ± 0.63	<.0001*
Appearance	47.34±0.12	90.31 ± 0.06	<.0001*
Satisfaction with correction	55.17±0.22	90.47 ± 0.11	<.0001*

P=P-value of the scores of NEI-RQL-42 statistically compared between preoperative and 3 mo postoperative. \*P < .05 = the difference was statistically significant. EVO-ICL = Implantable Collamer Lens with center hole, NEI-RQL-42 = National Eye Institute Refractive Error Quality of Life Instrument-42.

perception, environmental, and contrast visual acuity, as well as objective measurements of whole eye wavefront aberration and corneal wavefront aberration.<sup>[15–17]</sup> However, scattering and diffraction are important factors that affect visual quality in humans.

Previous study<sup>[18]</sup> showed that compared with wavefrontguided LASIK, the ICL implantation has significantly fewer ocular higher order aberration not only in patients with high disease status but also in moderate or low disease status.<sup>[19]</sup> Some scholars<sup>[20]</sup> also reported that after implantation based on the Artisan phakic IOL, the higher order aberrations number has increased. The patients in this study had less astigmatism; thus, the postoperative UDVA was less affected. The postoperative UDVA was better than the preoperative BCVA. One and 3 months after EVO-ICL implantation, the visual quality index of OQAS II was significantly better than that before operation, and the good visual quality was consistent with previous studies. Igarashi et al revealed an enhance contrast sensitivity of ICL implantation to modify the high myopia.<sup>[18]</sup> To excellent the ICL implantation visual performance, the parameters such as increased higher order aberrations and decreased retinal magnification might be useful and valuable.[18,19,21-24] In the present study, after ICL implantation, the excellent optical

### Table 6

Comparison of corneal endothelial cell density before and after surgery.

	Preoperative	3 mo postoperative
EVO-ICL	$2871.25 \pm 102.21/mm^2$	2831.42±104.39/mm <sup>2</sup>

Comparisons of ECD before and after surgery was P > .05. ECD = endothelial cell density, EVO-ICL = Implantable Collamer Lens with center hole.

quality was in accordance with previous studies. Previous studies have suggested that the implantation of ICL increases the amount of intraocular refractive medium, which might lead to more intraocular scattering. Nevertheless, we hypothesize that ICL would not produce more intraocular scattering because the thickness of the EVO-ICL loop is 100 to  $200 \,\mu$ m, the optical zone thickness is only 40 to  $50 \,\mu$ m, and the ICL is located in the ciliary sulcus, which rarely tilts or shifts. Even the visual quality of patients with severe myopia and unhealthy fundus was partially improved.

The corneal wound healing response, refractive regression,<sup>[25]</sup> and the security problem make corneal refractive surgery a less attractive choice for patients with high myopia. However, patients with EVO-ICL implantation retained normal corneal morphology to avoid increasing cornea scattering, and the increase in higher-order aberrations was lower. In our study, there was no significant difference in corneal ECD between the patients before and 3 months after surgery. The visual quality at 3 months after surgery was significantly better than that before surgery, and all patients had satisfactory safety, effectiveness postoperative visual quality. At 1 week and 3 months after EVO-ICL implantation, the TA, tLOAs, and defocusing were lower than those before operation, while the tHOAs and spherical aberration were significantly increased at 1 week after operation. The values of TA, tLOAs, tHOAs, defocus, and spherical aberration at 1 week after operation were higher than those at 3 months after operation. We believe that the increase of highorder aberrations at 1 week after operation is due to the incision has not yet healed completely and the inflammatory response has not completely subsided after operation. At 3 months after operation, the incision has healed and the inflammatory response has subsided, so the aberrations at all levels have decreased. All patients might achieve satisfactory safety, efficacy, and postoperative visual quality after surgery. After the posterior chamber IOL implantation in the hypermyopia patients, the imaging of the external object in the retina was almost the same as that of emmetropic eves. The retinal magnification of corneal surgery was 0.97, which was less than that of the posterior chamber IOL, which was close to that of the eye node, with a magnification of 1.0. To a certain extent, this also enables patients after EVO-ICL implantation to have better visual quality.

NEI-RQL-42 scale analysis showed that the glare score was lower than that before operation, and the other indexes were higher than those before operation at 3 months after operation. The edge of the central hole of EVO-ICL may lead to glare to a certain extent, but the edge of the central hole is much thinner than that of the traditional ICL, so we think that the central hole will not cause obvious glare. The increase of glare in patients with EVO-ICL implantation was considered to be caused by early postoperative inadaptability to the central foramen.

We speculated that the visual quality in patients with hypermyopia after EVO-ICL implantation was much better than before surgery. There were some limitations in this study. The number of cases included was small and the short follow-up period was not sufficient to expose all potential risk factors. In the future, we will expand the sample size, extend the observation time, and carry out more in-depth research, in order to better guide the clinical work. When OQAS II was used to measure visual quality before operation, some lenses were added to the machine because of the excessive high degree, which may increase objective scatter index to a certain extent. Additional research is necessary for confirmation of optical quality parameters under natural viewing conditions before and after surgery.

In conclusion, the subjective and objective visual quality of patients with hypermyopia at 3 months after operation is better than that before operation. In terms of corneal integrity, surgical safety, and effectiveness, EVO-ICL implantation should be considered first.

### **Acknowledgments**

The authors thank the following team members for their contributions to the success of this trial. Participating Centers: Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University (Department of Ophthalmology), Jinling Clinical Medical College of Nanjing Medical University (Department of Ophthalmology).

#### **Author contributions**

Conceptualization: Qin Qin, Lianyun Bao, Zhenping Huang.

- Data curation: Qin Qin, Zhengcan Wu, Lianyun Bao, Hui Chen, Liping Yang, Zifang He.
- Formal analysis: Qin Qin, Zhengcan Wu, Zhenping Huang. Funding acquisition: Qin Qin.
- Investigation: Qin Qin, Hui Chen, Liping Yang.
- Methodology: Qin Qin, Lianyun Bao, Zhenping Huang.
- Supervision: Qin Qin, Zhenping Huang.
- Writing original draft: Qin Qin.
- Writing review & editing: Zhenping Huang.

#### References

- Hornbeak DM, Young TL. Myopia genetics: a review of current research and emerging trends. Curr Opin Ophthalmol 2009;20:356–62.
- [2] Morgan IG, Ohno-Matsui K, Saw SM. Myopia. Lancet 2012;379:1739.
- [3] Torky MA, Alzafiri YA. Visual and refractive outcomes of small-incision lenticule extraction in mild, moderate, and high myopia: six-month results. J Cataract Refract Surg 2017;43:459–65.
- [4] Kim JR, Kim BK, Mun SJ, et al. One year outcomes of small incision lenticule extraction: mild to moderate myopia versus high myopia. BMC Ophthalmol 2015;10:59.
- [5] Alfonso JF, Baamonde B, Fernández-Vega L, et al. Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow-up. J Cataract Refract Surg 2011;37:873–80.
- [6] Igarashi A, Shimizu K, Kamiya K. Eight-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. Am J Ophthalmol 2014;157:532–9.
- [7] Bloomenstein MR, Dulaney DD, Barnet RW, et al. Posterior chamber phakic intraocular lens for moderate myopia and hyperopia. Optometry 2002;73:435–46.
- [8] Shimizu K, Kamiya K, Igarashi A, et al. Early clinical outcomes of implantation of posterior chamber phakic intraocular lens with a central hole (Hole ICL) for moderate to high myopia. Br J Ophthalmol 2012;96:409–12.
- [9] Qin Q, Bao L, Yang L, et al. Comparison of visual quality after EVO-ICL implantation and SMILE to select the appropriate surgical method for high myopia. BMC Ophthalmol 2019;19:21.
- [10] Shimizu K, Kamiya K, Igarashi A, et al. Intraindividual comparison of visual performance after posterior chamber phakic intraocular lens with and without a central hole implantation for moderate to high myopia. Am J Ophthalmol 2012;154:486–94.
- [11] Li D, Chen S, Zhang H. Evaluation of accuracy of anterior segment biological measurement by panoramic ultrasound imaging UBM. Chin Ophthalmic Res 2008;26:384–6.
- [12] Saad A, Saab M, Gatinel D. Repeatability of measurements with a double-pass system. J Cataract Refract Surg 2010;36:28–33.
- [13] Vilaseca M, Peris E, Pujol J, et al. Intra- and intersession repeatability of a double-pass instrument. Optom Vis Sci 2010;87:675–81.

- [14] Marcos S. Aberrations and visual performance following standard laser vision correction. J Refract Surg 2001;17:S596–601.
- [15] Neeracher B, Senn P, Schipper I. Glare sensitivity and optical side effects 1 year after photorefractive keratectomy and laser in situ keratomileusis. J Cataract Refract Surg 2004;30:1696–701.
- [16] Dougherty PJ, Bains HS. A retrospective comparison of LASIK outcomes for myopia and myopic astigmatism with conventional NIDEK versus wavefront-guided VISX and Alcon platforms. J Refract Surg 2008; 4:891–6.
- [17] Prieto PM, Vargas-Martín F, Goelz S, et al. Analysis of the performance of the Hartmann–Shack sensor in the human eye. J Opt Soc Am A Opt Image Sci Vis 2000;17:1388–98.
- [18] Igarashi A, Kamiya K, Shimizu K, et al. Visual performance after implantable collamer lens implantation and wavefront-guided laser in situ keratomileusis for high myopia. Am J Ophthalmol 2009;148:164– 70.
- [19] Kamiya K, Igarashi A, Shimizu K, et al. Visual performance after posterior chamber phakic intraocular lens implantation and wavefrontguided laser in situ keratomileusis for low to moderate myopia. Am J Ophthalmol 2012;153:1178–86.

- [20] Sanders DR, Vukich JA, Doney K, et al. Implantable Contact Lens in Treatment of Myopia Study GroupU.S. Food and Drug Administration clinical trial of the Implantable Contact Lens for moderate to high myopia. Ophthalmology 2003;110:255–66.
- [21] Kamiya K, Shimizu K, Kawamorita T, et al. Effects of myopic correction by replacement of spectacles, laser in situ keratomileusis, and phakic intraocular lens implantation on modulation transfer function and retinal magnification. Nippon Ganka Gakkai Zasshi 2008;112:519–24.
- [22] Applegate RA, Howland HC. Magnification and visual acuity in refractive surgery. Arch Ophthalmol 1993;111:1335–42.
- [23] Applegate RA, Chundru U. Experimental verification of computational methods to calculate magnification in refractive surgery. Arch Ophthalmol 1995;113:571–7.
- [24] García M, González C, Pascual I, et al. Magnification and visual acuity in highly myopic phakic eyes corrected with an anterior chamber intraocular lens versus by other methods. J Cataract Refract Surg 1996;22:1416–22.
- [25] Ganesh S, Gupta R. Comparison of visual and refractive outcomes following femtosecond laser-assisted lasik with smile in patients with myopia or myopic astigmatism. J Refract Surg 2014;30:590–6.