

Implantable collamer lens for high myopia: assessment of visual quality after implantation.

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Abstract

Background: Patients with high myopia have higher risk of eye diseases. Currently, Implantable collamer lens (ICL) implantation is one of the widely used refractive intraocular lens surgical intervention methods.

Purpose: To evaluate the effectiveness of implantable collamer lens (ICL) implantation in high myopia patients and the changes in wavefront aberrations after the operation.

Methods: Thirty-two eyes with high myopia were enrolled. The spherical equivalent, visual acuity including near vision, uncorrected distant visual acuity (UDVA) and corrected distant visual acuity (CDVA), and the total aberrations root mean square (Total-RMS) were measured before and after ICL operation. Furthermore, Total-RMS fixating on targets at 2 distances (5 m and 30 cm) was compared.

Results: One month after ICL implantation, UDVA and CDVA were increased ($P < 0.05$). The average spherical equivalent, entire eye Total-RMS and internal optics Total-RMS were decreased ($P < 0.05$). Furthermore, Total-RMS of entire eye and internal optics were lower with fixating on 5m distance target than with 30cm distance target at three postoperative time points. 6-month after ICL operation, total LOA-RMS and total HOA-RMS fixating on targets at 2 distances were different ($P < 0.001$ and $P = 0.026$, respectively). Moreover, compensation effect of internal optics aberrations on corneal aberrations was better with fixating on 5 m distance target than with 30 cm distance target ($P = 0.002$).

Conclusions: After ICL implantation, high myopia patients have significant improvement of visual acuity. Furthermore, wavefront aberrations of distant vision are obviously lower than that of near vision after ICL implantation in high myopia patients.

Keywords: High myopia, Implantable collamer lens, Visual acuity.

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Introduction

Myopia is the most common type of ametropia worldwide [1]. In China, the prevalence of myopia in adults and adolescents reached 22.9% and 70-81%, respectively, in 2005, and up to 90% of teenagers and young adults are short-sighted [2-5]. High myopia is myopia over -6.00D. Patients with high myopia have higher risk of developing eye diseases mainly because of the elongation of the optic axis and the stretching of the retina. Thus, high myopia ranked at the 4th to 7th place in the blindness causing diseases [6-8]. At present, the main therapies for treating high myopia include optical correction (including frame glasses and contact lenses), drug intervention, and surgical intervention (including keratorefractive surgery, posterior scleral reinforcement and refractive intraocular lens implantation) [9-11].

Fyodorov et al. were the first to use refractive intraocular posterior chamber lens to treat high myopia [12,13]. Swiss STAAR company produced a new-type refractive intraocular posterior chamber lens using a material called Collamer, and the lens were named as Implantable Collamer lens (ICL). ICL

was implanted between the iris and the lens to correct high myopia so that the original eye's refractive system was untouched. Due to the advantage, ICL implantation is currently one of the widely used refractive intraocular lens implantation methods. A large number of clinical studies showed that the effects of this operation were predictable, stable and safe [14,15]. The life quality of high myopia patients was improved after the surgery. Kobashi et al. reported that ICL offered significant vision-related quality-of-life advantages over wavefront-guided in situ keratomileusis (LASIK) for myopia in a long term follow-up [16]. In addition, the optical quality and intraocular scattering of eyes undergoing implantation was equivalent to those of healthy eyes [17]. Moreover, patients with ICL implantation retained the ocular accommodation ability and their visual quality was obviously improved [18].

At the ideal state, the wavefront across the human refractive system could be focused into a point on the retina. However, the human eyes are not a perfect refractive system. Therefore, wavefront aberrations were used to reflect the deviation between the actual and ideal state and became prevalent parameters to assess the optical system imaging quality.

Cornea and lens in human refractive system are two intraocular structures which have the greatest influences on the wavefront aberrations. Therefore, the corneal aberrations and internal optics aberrations constituted the major parts of the entire eye aberrations. Additionally, based on the order of zernike polynomial, wavefront aberrations are divided into low-order aberrations (such as defocus and astigmatism) and high-order aberrations (such as spherical aberration and coma).

Wavefront aberrations could be measured by aberrometers such as OPD-Scan, WASCA Analyzer, Mult ispot-1000 and i-Trace visual function analyzer [19]. i-Trace visual function analyzer is the latest aberrometer and has the following advantages. First, it is an open-view aberrometer so it could be used for measuring aberrations when subjects are fixated on targets at different distances. Second, it could separate the corneal aberrations from the entire eye aberrations so that entire eye aberrations, internal optics aberrations and corneal aberrations could be investigated individually. Third, it allows the measurement of RMS value at different pupil diameters. In the present study we utilized the above advantages of i-Trace function analyzer to evaluate the visual quality of high myopia patients after ICL implantation, and examined the visual acuity and diopters of spherical equivalent.

Materials and Methods

Patients and implantation procedure

Seventeen patients (32 eyes) with high myopia who received ICL implantation in our hospital from November 2014 to June 2015 were enrolled. The inclusion criteria were as follows: age 18-50 years; myopic diopter -2D to -18.00D; astigmatism diopter -0.5D to -5D; anterior chamber depth (ACD) \geq 2.8 mm; no ocular diseases except ametropia. The mean age of all subjects was 30.3 ± 7.5 years (range 18 to 45 years). The preoperative equivalent spherical mirror was -6.75 D to -18.00 D (the average was -12.36 ± 5.25 D). Patients received laser peripheral excision (Nd:YAG) at the position of 10 o'clock or 11 o'clock one week before the operation, and the incision diameter was about 1 mm. The operation was performed in strict accordance with the standard operation procedures (ICL implantation surgery). Compound Tropicamide drops were used for mydriasis 30 min before the surgical anesthesia. After the topical anesthesia, ICL was loaded into the special push device under a microscope (Carl Zeiss, Germany). A 3.2 mm transparent corneal incision was made in the temporal side and an auxiliary incision made at 6 o'clock or 12 o'clock. After the injection of sodium hyaluronate into the anterior chamber, ICL was pushed slowly into the iris plane, and then to the middle of the posterior of the ciliary sulcus with hooks. Viscoelastic intraocular material was rushed out after surgery and the corneal incision was sealed with water. No obvious complications were observed during or after the surgery. The fourth generation posterior chamber intraocular lenses were purchased from the STAAR (STAAR Surgical, Nidau, Switzerland ICL V4). The lens degree was calculated by

STAAR software, and the lens diameter was measured by ORBSCAN II Corneal topography.

Measurements

Before and after the operation, distance vision was measured with the international standard visual acuity chart at 5m. Near vision was measured with the Jaeger near visual acuity chart.

Measurements of wavefront aberrations were performed under the same illumination environment, and measurements of each eye were done with the other eye covered. An i-Trace visual function analyzer was used for measurement (4.1.1 version, the Tracey, USA). The aberrations were measured when patients were asked to fixate on a target at 5 m and 30 cm, with the international standard visual acuity chart and the Jaeger near visual acuity chart, respectively. The 5 m distant target fixating by each patient was the smallest clear letter in the international standard visual acuity chart and the 30 cm distant target was the smallest clear one in the Jaeger near visual acuity chart. The wavefront aberrations at 1 month, 3 months and 6 months after the surgery were assessed. The compensation factor (CF) was $CF = 1 - (\text{entire eye aberration group RMS} / \text{corneal aberration group RMS})$. The positive and negative values of CF were counted at 1 month, 3 months and 6 months after surgery.

Statistical analysis

All data were analyzed with SAS9.3 software. The quantitative data were recorded as mean \pm SD. All data were analyzed by ANOVA followed by SNK multiple comparisons test. A paired T test was used to compare the data of fixating on at 5m distance target and 30 cm distance target. The CF data were compared using a chi-squared test. $P < 0.05$ was considered as significant difference.

Results

The average spherical equivalent before and after ICL operation

The average spherical equivalent in all subjects ($n=32$) was -12.36 ± 5.25 D before ICL operation, and significantly decreased to -0.96 ± 0.42 D -0.95 ± 0.39 D and -0.87 ± 0.40 D, at 1 month, 3 and 6 months after the operation, respectively ($P < 0.05$ versus Pre-operation). Furthermore, no significant difference was found in the average spherical equivalents at three post-operation time points.

Changes of visual acuity in high myopia patients after the ICL implantation

Three parameters in visual acuity including near vision, UDVA (uncorrected distant visual acuity) and CDVA (corrected distant visual acuity) were measured. As shown in table 1, no difference was found in near vision before and after ICL operation. However, UDVA was significantly increased in high myopia patients 1 month, 3 months and 6 months after ICL

operation. In addition, CDVA was significantly increased in high myopia patients 1 month, 3 months and 6 months after ICL operation. These data indicated that UDVA and CDVA in high myopia patients were significantly improved by ICL implantation 1 month later and the improvement of UDVA and CDVA stayed stable for at least 6 months.

Table 1. Changes of Visual Acuity in high myopia patients after the ICL implantation

Time	J	UDVA	CDVA
Pre-operation	1.04 ± 0.32	0.06 ± 0.02	0.87 ± 0.19
Post-operation			
1 month	1.09 ± 0.29	1.06 ± 0.22*	1.17 ± 0.25*
3 month	1.06 ± 0.24	1.06 ± 0.19*	1.18 ± 0.21*
6 month	1.04 ± 0.24	1.08 ± 0.18*	1.19 ± 0.19*

J: near vision, UDVA: uncorrected distant visual acuity, CDVA: corrected distant visual acuity. ANOVA followed by SNK multiple comparisons test. * P<0.05 versus Pre-operation (n=32 eyes).

Changes of wavefront aberrations in high myopia patients after ICL implantation

As shown in table 2, entire eye Total-RMS in all subjects was 6.81 ± 2.43 before ICL operation. One month after ICL operation, the entire eye Total-RMS was significant decreased. No further reduction in the entire eye Total-RMS was detected 3 months and 6 months after ICL operation.

Table 2. The changes in the Total-RMS fixating on 30cm distance target.

Time	Entire eye (μm)	Internal optics (μm)	Corneal (μm)
Pre-operation	6.81 ± 2.43	6.19 ± 2.76	0.37 ± 0.25
Post-operation			
1 month	0.86 ± 0.27*	0.81 ± 0.31 *	0.64 ± 0.34*
3 month	0.80 ± 0.25*	0.78 ± 0.27*	0.47 ± 0.23#
6 month	0.73 ± 0.28*	0.71 ± 0.35*	0.35 ± 0.18#,**

ANOVA followed by SNK multiple comparisons test. * P<0.05 versus Pre-operation; # P<0.05 versus 1 month, ** P<0.05 versus 3 month. (n=32 eyes).

Internal optics Total-RMS in all subjects was 6.19 ± 2.76 before ICL operation. One month after ICL operation, the internal optics Total-RMS was significant decreased. No further reduction in the internal optics Total-RMS was detected 3 months and 6 months after ICL operation.

Corneal Total-RMS in all subjects was 0.37 ± 0.25 before ICL operation, and was significant increased one month after ICL operation, but was then significantly reduced 3 months and 6 months after ICL operation.

The changes in the wavefront aberrations with fixating on 5m distance target after the ICL operation

Values of the wave aberrations with fixating on 5m distance target at different time points were shown in table 3. With fixating on 5m distance target, both the entire eye aberrations and internal optics aberrations on 3 and 6 months after ICL operation were significantly lower than the values on 1 month after ICL operation. Corneal aberrations were gradually decreased over time. No wavefront aberrations with fixating on 5m distance target was measured before ICL operation since the poor UDVA of high myopia patients made it difficult to focus on distant targets.

Table 3. The changes in Total-RMS with fixating on 5m distance target.

Postoperative time	Entire eye (μm)	Internal optics (μm)	Corneal (μm)
1 month	0.59 ± 0.24	0.64 ± 0.30	0.64 ± 0.34
3 month	0.44 ± 0.18#	0.46 ± 0.22#	0.47 ± 0.23#
6 month	0.49 ± 0.23#	0.48 ± 0.32#	0.35 ± 0.18#,**

ANOVA followed by SNK multiple comparisons test. # P<0.05 versus 1 month, ** P<0.05 versus 3 month. (n=32 eyes).

Table 4. Changes of Total-RMS of entire eye after ICL operation.

Postoperative time	fixating on 5 m distance target (μm)	fixating on 30 cm distance target (μm)	P
1 Month	0.59 ± 0.24	0.86 ± 0.27	<0.001
3 Month	0.44 ± 0.18	0.80 ± 0.25	<0.001
6 Month	0.49 ± 0.23	0.73 ± 0.28	<0.001

paired T test (n=32 eyes).

Table 5. Changes of Total-RMS of internal optics after ICL operation.

Postoperative time	fixating on 5 m distance target (μm)	fixating on 30 cm distance target (μm)	P
1 Month	0.64 ± 0.30	0.81 ± 0.31	<0.001
3 Month	0.46 ± 0.22	0.78 ± 0.27	<0.001
6 Month	0.48 ± 0.32	0.71 ± 0.35	<0.001

paired T test (n=32 eyes)

Changes in Total-RMS at each time point with fixating on 5m distance target and fixating on 30cm distance target

Changes in wavefront aberrations of the entire eye at three postoperative time points with fixating on 5m distance target and fixating on 30cm distance target were shown in table 4. Entire eye aberrations significantly increased with ocular accommodation.

As shown in table 5, at postoperative 1 month, 3 month, and 6 month, the internal optics aberrations increased with ocular accommodation. The differences at three postoperative time points were all significant.

Differences in Total LOA-RMS and Total HOA-RMS with ocular accommodation between fixating on 5 m distance target and on 30 cm distance target 6 months after ICL operation

Total-RMS was further detected as Total LOA-RMS (Total low-order aberrations) and Total HOA-RMS (Total high-order aberrations). As shown in table 6, both low-order aberrations and high-order aberrations significantly increased when fixating on 30 cm distance target was compared to fixating on 5m distance target 6 months after ICL operation.

Table 6. Total LOA-RMS and Total HOA-RMS with ocular accommodation 6 months after ICL operation.

Total-RMS	fixating on 5m distance target (µm)	fixating on 30cm distance target (µm)	P
total LOA-RMS	0.41 ± 0.19	0.81 ± 0.32	<0.001
total HOA-RMS	0.11 ± 0.05	0.12 ± 0.07	0.026

LOA: low-order aberrations, HOA: high-order aberrations. paired T test (n=32 eyes).

Table 7. Cases in positive and negative CFs at different time points after ICL operation.

Postoperative time		Positive CFs	Negative CFs	P
1 Month	fixating on 5 m distance target	17	15	<0.001
	fixating on 30 cm distance target	2	30	
3 Month	fixating on 5 m distance target	17	15	<0.001
	fixating on 30 cm distance target	4	28	
6 Month	fixating on 5 m distance target	10	22	0.002
	fixating on 30 cm distance target	1	31	

Chi-squared test (n=32 eyes)

Changes in the compensation factor after ICL operation

The compensation factors (CFs) were used to assess compensation of internal optics aberrations on corneal aberrations. A positive CF suggested that internal optics aberrations displayed a compensative effect on corneal aberrations, while a negative CF suggested that internal optics aberrations had an additive effect on corneal aberrations. Cases of positive and negative CFs at each time point with fixating

on 5 m distance target and fixating on 30 cm distance target were shown in table 7. At each time point, the case number of positive CFs with fixating on 5 m distance target was higher than that with fixating on 30 cm distance target, while the case number of negative CFs with fixating on 5 m distance target was lower than that with fixating on 30 cm distance target. These results indicated that the compensation of internal optics aberrations on corneal aberrations was better in high myopia patients with ICL implantation when they were fixating on 5m distance target.

Discussion

In present study, the effects of ICL implantation on 32 eyes in 17 high myopia patients were investigated. Our results showed that after ICL implantation, the mean diopters of spherical equivalent in the patients significantly decreased. The visual acuity was gradually improved based on the measurement of UDVA and CDVA and the wavefront aberrations were partially alleviated detected by i-Trace visual function analyzer.

Previous studies had shown that the implantation of ICL in high myopia patients was effective on the diopters of the spherical equivalent and the visual acuity. A 5-year follow-up of 188 high myopia eyes undergoing ICL implantation showed that the mean spherical equivalent decreased from -11.17 ± 3.40D preoperatively to -0.88 ± 0.72D postoperatively [20]. Similar results were observed in our study. The mean spherical equivalent decreased from -12.36 ± 5.25D to -0.96 ± 0.42 D 1 month after ICL implantation and stayed at -0.95 ± 0.39 D and -0.87 ± 0.40 D, respectively, 3 and 6 months after ICL implantation. Both the mean UDVA and the mean CDVA were improved compared with preoperative values. Visual acuity was a basic indicator of visual quality. Our study showed that high myopia patients undergoing ICL implantation had an improved distance vision during the 6-months observation period after the operation.

In addition to visual acuity the wavefront aberrations determined the visual quality of the patients with myopia. Before the invention of correcting ametropia by intraocular lens, keratorefractive surgery was the major way to correct ametropia, such as PRK (photorefractive keratectomy), LASEK (laser epithelial keratomileusis), LASIK (laser in situ keratomileusis). In the early stage of keratorefractive surgery, the patients had visual symptoms after operation, such as glare and halos, despite the apparent success of surgery [21]. Therefore, wavefront-guided keratorefractive surgery is used currently. Wavefront-guided LASEK might improve the quality of vision and reduce the amount of aberrations after keratorefractive surgery [22]. Therefore, it is necessary to assess the wavefront aberrations after the surgery. In our study i-Trace visual function analyzer was utilized to measure the wavefront aberrations in high myopia patients with ICL implantation. One advantage of i-Trace visual function analyzer is to separate the internal optics aberrations from the entire eye aberrations. Thus we investigated the entire eye aberrations, internal optics aberrations and corneal aberrations individually in the present study. The second advantage of i-

Trace visual function analyzer is that it could be used for measuring aberrations when subjects are fixated on targets at different distances. Although no wavefront aberrations with fixating on 5 m distance target was measured before ICL operation due to poor UDVA of high myopia patients, the result of wavefront aberrations with fixating on 30cm distance target showed that the Total-RMS of the entire eye and internal optics were reduced after the operation and remained in a stable level one month later. The Total-RMS of the cornea was significant increased one month after ICL operation, but significant reduction was detected 3 and 6 months after ICL operation. This temporary increase of corneal aberrations observed 1 month after ICL operation might be due to the following two reasons: First, the tear film was unstable at an early period postoperatively, which led to a rough anterior corneal surface. Second, corneal incisions were made during the surgery before the wound healed completely, and corneal morphology was affected, which increased corneal aberrations.

The human eyes have the ability to achieve distance vision and near vision through ocular accommodation. The wavefront aberrations were changed dynamically during the ocular accommodation [23]. In our study, the changes of entire eye aberrations, internal optics aberrations and corneal aberrations fixating on the 5 m and 30 cm distance target were investigated at different postoperative time points. The results showed that the entire eye aberrations and the internal optics aberrations were significantly increased when fixating the 30 cm distance target was compared to fixating the 5 m distance target at each postoperative time point. However, no changes were found in the corneal aberrations between the 30 cm distance target and the 5 m target distance target. The increases in the entire eye and internal optics aberrations when looking at the 30 cm target were due to the accommodative changes in the intraocular refractive structures when fixating on the near objects.

Wavefront aberrations included low-order aberrations (LOA) and high-order aberrations (HOA). LOA had greater influence on the visual quality. Although clinical significance of HOA is not fully understood, HOA is involved in the degradation of visual quality [24]. In this study, the differences of LOA and HOA when fixating different distant targets were investigated at 6-month postoperatively. Our data showed that both the LOA and the HOA were significantly higher when fixating the target at 5 m than fixating the target at 30 cm. These data indicated that both low-order aberrations and high-order aberrations increased with ocular accommodation in high myopia patients with ICL implantation. Similar results were reported by Yuan et al. who showed that HOAs increased significantly during ocular accommodation in 35 eyes of young healthy subjects [25].

To further assess the relative contribution of optical aberrations of the corneal and the internal optics to entire eye aberrations, we examined CFs proposed by Artal et al. [26]. CFs were applied to assess compensation of internal optics aberrations on the corneal aberrations. A positive CF value indicated that internal optics aberrations compensated for the corneal

aberrations, while a negative CF value indicated that internal optics aberrations had an additive effect on the corneal aberrations. If CF was 0, the entire eye aberrations and corneal aberrations were equal. By counting the case number of positive and negative values of CFs at different time points after the operation, our results showed that at each postoperative time point, the CF positive number with fixating targets at 5 m distance was more than that with fixating targets at 30 cm distance. This difference suggested that the compensation of internal aberration to the corneal aberrations was better when fixating targets at 5 m distance.

In summary, our results showed that during 6-month postoperative period, high myopia patients after ICL implantation have better visual acuity and improved wavefront aberrations. ICL implantation retained the ocular accommodation ability of the refractive system. This advantage helped us to compare the changes of the wavefront aberrations in fixating targets at different distances in high myopia patients after the operation. One minor limitation in our study is that since the wavefront aberrations are closely associated with patient age, tear film, and intraocular pressure, the lack of information on tear film and intraocular pressure in these patients may weaken the conclusion of our study.

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Conflict of interest

None

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