

One-Year Analysis of the Refractive Stability, Axial Elongation and Related Factors in a High Myopia Population after Implantable Collamer Lens Implantation

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Abstract

Purpose: To investigate the refractive stability, axial length changes and their related factors in a high myopia population after Implantable Collamer Lens (ICL) implantation.

Methods: This prospective study included 116 eyes of 116 patients divided into several groups based on the spherical equivalent refractive error (SE)—SE > -6D, $-12 \leq \text{SE} < -6\text{D}$ and SE < -12D groups—and axial length (AL)—AL < 28mm and AL $\geq 28\text{mm}$ groups. The uncorrected and corrected distance visual acuity, refraction, axial length and intraocular pressure were followed for 1 year.

Results: SE changed from $-11.53 \pm 5.25\text{D}$ preoperatively to $-0.33 \pm 0.70\text{D}$ at 1 week, and further changed to $-0.48 \pm 0.77\text{D}$ at 1 year after ICL implantation, with average progression being $-0.15 \pm 0.37\text{D}$ from 1 week to 1 year after surgery. Axial length changed from $27.95 \pm 2.33\text{mm}$ preoperatively to $27.98 \pm 2.36\text{mm}$ 1 year after surgery, with an average axial elongation of $0.03 \pm 0.12\text{mm}$. The mean axial elongation rate was 0.05mm/year in the SE < -12D group, being significantly faster than the other SE groups ($P < 0.05$); it was 0.06mm/year in the AL $\geq 28\text{mm}$ group, being significantly faster than the AL < 28mm group ($P < 0.05$).

Conclusion: Patients with high myopia and long axial length showed a continuous myopic progression and axial elongation at an adult age after ICL surgery, especially those with myopia higher than -12.0D and AL longer than 28.00mm.

Introduction

Myopia is a global public health problem that proposes a great threat to vision. In recent years, myopia prevention has become a public health focus in China. According to a meta-analysis of studies conducted in Chinese population beginning 2013, the prevalence of myopia and high myopia among adolescents aged 16 to 18 years are 84.8% and 19.3%, respectively, being much higher than those in most Western countries.¹ In 2050, the prevalence of myopia in Chinese children and adolescents aged 3 to 19 years is estimated to be approximately 84%.² In addition to bringing a serious economic burden to the country, complications including retinal detachment, macular degeneration, and glaucoma caused by high myopia are important causes of blindness.³

Currently, interventional strategies including increased outdoor activities have shown to decrease myopia incidence in children,^{4,5} and orthokeratology treatment⁶⁻⁹ and low concentration atropine¹⁰⁻¹³ to slow children's myopia progression. In contrast, adults' myopia remains relatively stable and can be permanently corrected by refractive surgeries, which mainly include corneal refractive surgery and intraocular refractive surgery.¹⁴⁻¹⁹ Corneal refractive surgery can correct myopia by corneal ablation to change the refractive power of the cornea. ICL implantation of a phakic posterior chamber intraocular lens (IOL) is the mainstream of intraocular refractive surgery. Unlike corneal ablation, ICL implantation

has the following advantages: a wide range of ametropia correction, not limited by the thickness of the cornea and retains the natural lens and accommodative function.

Numerous studies¹⁴⁻¹⁷ have confirmed that ICL implantation is a safe, effective and predictable procedure. However, myopia progression and axial elongation after ICL implantation were observed in some patients in our clinics. Therefore, this study aimed at evaluating the refractive stability of ICL implantation for correcting myopia and at analysing the risk factors for myopia progression after surgery. The results of this study provide insight into the possibility of myopia progression in adult patients after ICL surgeries and for a wider high myopia adult population in general.

Materials And Methods

Patient and Public Involvement

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Eye and ENT Hospital Review Board of Fudan University. Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

Study Population

A total of 116 eyes of 116 consecutive patients (female:male = 85:31) with a mean preoperative SE of -11.53 ± 5.25 D and a mean AL of 27.95 ± 2.33 mm were enrolled in this prospective study. The mean age was 29.5 ± 8.2 years (range: 18 to 54 years). They were divided into the following groups: $SE \geq -6$ D, $-12 \leq SE < -6$ D and $SE < -12$ D groups, according to preoperative SE; $AL < 28$ mm and $AL \geq 28$ mm groups, according to the preoperative AL. Preoperatively, all the patients underwent routine ophthalmic examinations at the Refractive Surgery Center of the Department of Ophthalmology, Eye and ENT Hospital of Fudan University (Shanghai, People's Republic of China) and met the surgical requirements for ICL V4c (STAAR Surgical Company, Monrovia, California, USA) implantation. Inclusion criteria were age between 18 and 54 years, patients' commitment of less than 0.50 dioptre/year increase 2 years before surgery, anterior chamber depth ≥ 2.8 mm, and endothelial cell density ≥ 2000 cell/mm². Patients were also required to have a reasonable expectation of the surgical outcomes. Exclusion criteria were history of certain ocular diseases (suspicion of keratectasia, corneal or lens opacity, retinal detachment, glaucoma, macular degeneration, or neuro-ophthalmic disease), history of ocular surgery, ocular inflammation or trauma, and systemic disease. The preoperative biometrics were summarized in Table 1.

Table 1
The Preoperative biometrics of the patients

Variables	Mean ± SD (range)
Refractive error (D)	
Spherical equivalent	-11.53 ± 5.25 (-1.63 ~ -25.63)
Spherical	-10.86 ± 4.99 (-1.25 ~ -23.50)
Cylindrical	-1.34 ± 1.01 (0 ~ -5.00)
Axial length (mm)	27.95 ± 2.33 (22.56 ~ 33.92)
UDVA (logMAR)	1.43 ± 0.45 (0.60 ~ 2.00)
CDVA (logMAR)	0.04 ± 0.15 (-0.30 ~ 0.70)
IOP (mm Hg)	15.20 ± 2.96 (8.3 ~ 22.8)
ECD (cells/mm ²)	3162.31 ± 391.47 (2107 ~ 3946)
UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; D = dioptres; IOP = intraocular pressure; ECD = corneal endothelial cell density.	

Surgical procedures

All surgeries were performed by two experienced surgeons (XW and XZ). Both eyes were implanted the ICL and the left eyes of the patients were included in the study. The implantation of ICL and the surgical procedure were the same as our previous studies.^{20,21}

Follow-up visits

The patients were followed-up for 1 year. During this time period, uncorrected (UDVA) and corrected (CDVA) distance visual acuity, manifest refraction, AL (IOL Master, Carl Zeiss, Germany), intraocular pressure (Tonemeterx-10, Canon, Japan) and corneal endothelial cell density (SP. 2000P, Topcon, Japan) were evaluated.

Statistical analysis

All statistical analyses were performed using SPSS version 20.0 (SPSS Inc., IBM, USA), and the results expressed as mean ± SD. A normal distribution was determined using the Kolmogoro–Smirnov test. Independent t-tests were conducted for parameters with continuous variables, paired t-tests were used to compare the preoperative and postoperative data, and one-way analysis of variance with Bonferroni post hoc comparisons were performed to evaluate differences in axial elongation among various groups. Correlation analysis was performed to investigate the correlation between baseline biometrics and axial elongation at 1 year after surgery. The dependent variable was the axial elongation, and the independent

variables included patient age, sex, preoperative refraction, axial length, and intraocular pressure. A p-value less than 0.05 was considered statistically significant.

Results

Safety and Efficacy

All surgeries were uneventful, and no intraoperative and postoperative complication was observed. The safety indexes (postoperative CDVA / preoperative CDVA) of 1 week and 1 year postoperatively were 1.22 ± 0.27 and 1.24 ± 0.30 , respectively. The logMAR CDVA values at baseline, 1 week, and 1 year were 0.02 ± 0.31 , -0.05 ± 0.20 , and -0.05 ± 0.21 , respectively. At 1 year postoperatively, 3.45% of eyes lost one line of CDVA, 43.10% of eyes gained one line, 8.62% of eyes gained two lines, 14.66% of eyes gained two or more lines of CDVA and 30.17% of eyes did not change compared to the baseline (Fig. 1A). The efficacy indexes (postoperative UDVA / preoperative CDVA) of 1 week and 1 year postoperatively were 1.07 ± 0.26 and 1.08 ± 0.26 , respectively. The logMAR UDVA values at baseline, 1 week, and 1 year were 1.24 ± 0.05 , 0.01 ± 0.28 and 0.00 ± 0.30 , respectively (Fig. 1B).

Refractive stability and axial elongation

The SE changed from -11.53 ± 5.25 ($-1.63 \sim 25.63$) D preoperatively to -0.33 ± 0.70 ($-3.25 \sim 1.25$) D at 1 week and -0.48 ± 0.77 ($-3.75 \sim 0.75$) D 1 year after ICL implantation (Fig. 2A). A significant change in the SE of -0.15 ± 0.37 ($-1.63 \sim 0.50$) D was seen from 1 week to 1 year postoperatively, with 88.79% eyes within ± 0.50 D and 51.72% eyes with no change.

The axial length changed from 27.95 ± 2.33 ($22.56 \sim 33.92$) mm preoperatively to 27.98 ± 2.36 ($22.61 \sim 33.88$) mm 1 year after ICL implantation (Fig. 2B). A significant axial elongation of 0.03 ± 0.12 ($-0.35 \sim 0.62$) mm/year was seen from preoperatively to 1 year postoperatively, with 22.42% of eyes exceeding 0.1 mm/year. There was a significant difference between preoperative and postoperative axial length ($P = 0.007$). There was a significant correlation between the SE changes and the axial elongation. (Pearman correlation coefficient: $r = 0.444$, $P < 0.001$) (Fig. 2C)

Related factors of axial elongation

There was a significant correlation between axial elongation and preoperative spherical refractive error and SE (Pearman correlation coefficient: $r = -0.214$, $P = 0.021$; $r = -0.215$, $P = 0.021$, respectively) (Fig. 3A). A significant correlation between axial elongation and preoperative axial length was also observed ($r = 0.210$, $P = 0.024$) (Fig. 3B). No significant correlation was found between any other factors, such as preoperative cylindrical refractive error, intraocular pressure, or age (Pearman correlation coefficient: $r = -0.113$, $P = 0.228$; $r = 0.041$, $P = 0.661$; $r = 0.029$, $P = 0.753$, respectively). In addition, no significant difference was found between female and male groups ($P = 0.786$).

Comparison of axial elongation according to preoperative SE and AL

The mean axial elongation rate was -0.01 mm/year, 0.04 mm/year and 0.05 mm/year in the $SE \geq -6 D$ ($N = 26$), $-12 D \leq SE < -6 D$ ($N = 36$) and $SE < -12 D$ ($N = 54$) groups, respectively (Fig. 4A). A statistically significant difference was observed between $SE \geq -6 D$ and $SE < -12 D$ groups ($P = 0.031$), while no differences were found between $-12D \leq SE < -6D$ and $SE \geq -6D$ groups or $-12D \leq SE < -6 D$ and $SE < -12 D$ groups ($P = 0.081$, $P = 0.745$, respectively). The mean axial elongations were 0.01 mm/year and 0.06 mm/year in the $AL < 28$ mm group ($N = 64$) and $AL \geq 28$ mm group ($N = 52$), respectively (Fig. 4B). A statistically significant difference was observed between the two groups ($P = 0.024$).

Discussion

Myopia progression and axial elongation after refractive surgeries remains a concern for all refractive surgeons, which are contrary to common sense and worthy of attention. However, there are few reports on the progression of adulthood myopia, before or after surgery. In this study, we mainly discussed the refractive stability of ICL implantation for adult myopia correction and the risk factors for myopia progression after surgery, which can provide insight into adulthood myopia progression.

In agreement with previous studies¹⁴⁻¹⁷, the results of this study also showed that ICL implantation is a safe and effective procedure for myopia correction. High myopic and ultra-high myopic patients can obtain superior visual results after ICL implantation, yet post-operative axial elongation and myopia progression is inevitable in some cases. Therefore, it is of clinical interest and significance to understand the refractive stability, axial length changes and their risk factors in the high myopia population undergoing ICL implantation.

In this study, the mean axial elongation rate for all the patients was 0.03 mm/year. Gaurisankar et al's 5-year follow-up study showed that the mean axial elongation rate was 0.04 mm/year, being slightly higher than that of our study.²² When examining the younger adults (20 to 40, mean, 21.6 years) in their study, Lee et al found that the myopic progression rate was -0.24 to -0.28 D/y and the axial elongation rate was 0.06 to 0.07 mm/year.²³ Both myopic progression and axial elongation was faster compared to our study, most likely due to a well-established fact that the refractive state is relatively unstable in younger adult myopia population.

A large number of previous studies²⁴⁻²⁶ have shown that the main environmental factor for myopia progression in children is the competitive lifestyles and heavy schoolwork. It is generally believed that the myopia will tend to stabilize after adulthood, but pathological myopic patients still have the possibility of myopia progression into middle age.^{27,28} Pathological myopia is a kind of disease characterized by persistent axial elongation, asymmetric posterior scleral thinning, and posterior scleral staphyloma. This pathological process will lead to myopia progression, as well as macular splitting, choroidal neovascularisation, retinal atrophy and other fundus complications, resulting in irreversible visual impairment.²⁹⁻³³ Many studies have confirmed that fundus lesions in high myopia are closely related to axial elongation, and axial length is positively correlated with fundus damage. The shorter the axial length, the lower the incidence of fundus damages. With continuous axial elongation, the retina and

choroid gradually become thinner, Bruch's membrane breaks and choroidal neovascularisation may occur.^{28,30} The current study showed that the myopia progression in adults was related to their preoperative ocular biometrics and not related to age and gender. The patients with higher myopia and longer axial length were prone to myopia progression, especially those with myopia higher than -12.0 D and axial length longer than 28.00 mm. For these patients, surgeons should fully communicate with them before surgery, inform them of the possibility of myopia progression and the risk of fundus complications in the long-term after surgery, and follow them up closely after surgery. If necessary, posterior scleral reinforcement can be considered to slow the axial elongation.^{34,35}

Interestingly, we found that the axial length in some of the patients tended to shorten after ICL implantation. The axial length measured by partial coherence interferometry (PCI) represents the optical distance from the anterior surface of the cornea to the retinal pigment epithelium layer along the optic axis, which can be affected by choroidal thickness.³⁶ It has been shown that the choroidal thickness after ICL implantation became significantly thicker than that before surgery, especially in the foveal and nasal areas.^{37,38} Therefore, we speculate that the increase of choroidal blood flow and the thickening of the choroid may have lead to the shortening of the axial length measured by PCI in the current study.

This study has a few limitations. The sample size is relatively small, and the follow-up time is relatively short for studying adulthood myopia. In addition, this study population is the adult myopia patients after ICL implantation rather than the general myopia population. Therefore, the conclusion of this study cannot be readily extrapolated to the overall myopic population.

In conclusion, our study found that ICL implantation is a safe and effective surgical method. Adult patients with higher preoperative myopia and longer axial length have a higher possibility to experience continuous axial elongation and myopia progression after refractive surgery, especially for those with myopia higher than -12.0 D and axial length longer than 28.00 mm.

Declarations

ACKNOWLEDGEMENTS

Contributorship statement

XC and ZC conceived of and designed the experiments. XC and ZC performed the experiments. XC, ZC, MHM and XQW analysed the data. XC and ZC wrote the manuscript. XYW and XTZ revised the manuscript and gave final approval of the version for publication.

Competing interests

None declared.

Patient consent

Obtained.

Ethics approval

The study was approved by the Ethical Committee Review Board of Eye and ENT Hospital of Fudan University.

Data sharing statement

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

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Figures

Figure 1

The percentage of eyes that gained/lost lines of CDVA (A) and the cumulative percentage of UDVA (B) at different time points of follow-up after Implantable Collamer Lens implantation.

Figure 2

The manifest spherical equivalent (A) and axial length (B) during the follow-up after Implantable Collamer Lens implantation. Correlation of spherical equivalent changes and axial length changes (C) (Pearman correlation coefficient: $r = 0.444$, $P < 0.001$, $y = 1.34x - 0.11$)

Figure 3

Correlation between preoperative spherical error (A) and spherical equivalent error (B), axial length (C) and axial elongation after Implantable Collamer Lens implantation (Pearman correlation coefficient: $r = -0.214$, $P = 0.021$, $y = -0.005x - 0.025$; $r = -0.215$, $P = 0.021$, $y = -0.005x - 0.025$; $r = 0.210$, $P = 0.024$, $y = 0.011x - 0.274$, respectively).

Figure 4

The axial elongations among the $SE \geq -6$ D, -12 D $\leq SE < -6$ D and $SE < -12$ D groups (A) and between the $AL < 28$ mm and $AL \geq 28$ mm groups (B).