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 (AL) 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 > −6 D, −12 ≤ SE < −6 D and SE < −12 D groups—and AL—AL < 28 mm and AL ≥ 28 mm groups. The uncorrected and corrected distance visual acuity, refraction, AL and intraocular pressure were followed for 1 year.

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

Conclusion  Patients with high myopia and long AL showed a continuous myopic progression and axial elongation at an adult age one year after ICL surgery, especially in those with myopia higher than −12.00 D and AL longer than 28.00 mm.
Keywords  Implantable Collamer Lens · High myopia · Stability · Axial length · Myopic progression

Introduction

Myopia is a global public health problem that poses 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 treatment [6–9] and low concentration atropine [10–13] 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. Implantable Collamer Lens (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 studies [14–17] 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 analyzing 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 18–54 years). They were divided into the following groups: SE ≥ − 6 D, − 12 ≤ SE < − 6 D and SE < − 12 D groups, according to preoperative SE; AL < 28 mm and AL ≥ 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 D/year increase 2 years before surgery, anterior chamber depth ≥ 2.80 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 are summarized in Table 1.
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 distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), the safety indexes (postoperative CDVA/preoperative CDVA), the efficacy indexes (postoperative UDVA/preoperative CDVA), 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 Kolmogorov–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. Pearson 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, AL, 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 indices 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, 3.5% of eyes lost one line of CDVA, 43.1% of eyes gained one line, 8.6% of eyes gained two lines, 14.7% of eyes gained two or more lines of CDVA and 30.2% of eyes did not change compared to the baseline (Fig. 1a). The efficacy indices 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 to −25.63) D preoperatively to −0.33 ± 0.70 (−3.25 to −1.25) D at 1 week and −0.48 ± 0.77 (−3.75 to −0.75) D 1 year after ICL implantation (Fig. 2a). A significant change in the SE of −0.15 ± 0.37 (−1.63–0.50) D was seen from 1 week to 1 year postoperatively, with 88.8% eyes within ±0.50 D and 51.7% eyes with no change.

The AL changed from 27.95 ± 2.33 (22.56–33.92) mm preoperatively to 27.98 ± 2.36 (22.61–33.88) mm 1 year after ICL implantation (Fig. 2b). A significant axial elongation of 0.03 ± 0.12 (−0.35–0.62) mm/year was seen from preoperatively to 1 year postoperatively, with 22.4% of eyes exceeding 0.10 mm/year. There was a significant difference between preoperative and postoperative AL (P=0.007). There was a significant correlation

### Table 1 The preoperative biometrics of the patients

| Variables                          | Mean ± SD (range) |
|-----------------------------------|-------------------|
| **Refractive error (D)**          |                   |
| Spherical equivalent             | −11.53 ± 5.25 (−1.63 to −25.63) |
| Spherical                         | −10.86 ± 4.99 (−1.25 to −23.50) |
| Cylindrical                       | −1.34 ± 1.01 (0 to −5.00)   |
| Axial length (mm)                 | 27.95 ± 2.33 (22.56 to 33.92) |
| UDVA (logMAR)                     | 1.43 ± 0.45 (0.60 to 2.00)  |
| CDVA (logMAR)                     | 0.04 ± 0.15 (−0.30 to 0.70)  |
| IOP (mmHg)                        | 15.20 ± 2.96 (8.3 to 22.8)   |
| ECD (cells/mm²)                   | 3162.31 ± 391.47 (2107 to 3946) |

*UDVA* uncorrected distance visual acuity, *CDVA* corrected distance visual acuity, *D* dioptres, *IOP* intraocular pressure, *ECD* corneal endothelial cell density
between the SE changes and the axial elongation (Pearson 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 (Pearson 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 AL 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 (Pearson 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, corresponding to myopia progressions of 0.02 D/year, 0.16 D/year and 0.21 D/year, respectively (Fig. 4a). A statistically significant difference was observed between SE $\geq -6$ D and SE $< -12$ D groups.
While no differences were found between $-12 \leq SE < -6$ D and $SE \geq -6$ 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 ($N=52$), corresponding to myopia progressions of 0.09 D/year and 0.22 D/year, 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 studies [14–17], 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 postoperative axial elongation and myopia progression is inevitable in some cases. Therefore, it is of clinical interest and significance to understand the refractive stability, AL changes and their risk factors in the high myopia population undergoing ICL implantation.

In this study, the mean axial elongation rate was 0.03 mm/year for all the studied population. 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/year 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 studies have shown that myopia tends to progress in childhood and juveniles, with the main environmental factors being reduced time outdoors, decreased natural light exposure, and competitive education [24–26]. It is generally believed that myopia will tend to stabilize after adulthood, but patients with pathological myopia still bear the possibility of myopia progression into middle age [27, 28]. Pathological myopia is a type 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 AL is positively correlated with fundus damage. The shorter the AL, 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 myopia progression in adults was related to their preoperative ocular biometrics but not related to age or gender. The patients with higher myopia and longer AL were more prone to experience myopia progression after ICL implantation, especially those with myopia higher than −12.0 D and AL 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, and follow them up regularly after surgery. Posterior scleral reinforcement can be considered to slow the axial elongation if necessary [34, 35].

Interestingly, we found that AL in some of the patients tended to shorten after ICL implantation. The AL 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 optical axis, which can be affected by choroidal thickness [36]. It has been shown that the choroidal thickness after ICL implantation becomes significantly thicker than that before surgery, especially in the foveal and nasal areas [37, 38]. Therefore, we speculate that the increase in choroidal blood flow and the thickening of the choroid may have led to the shortening of the AL measured by PCI in the current study.

This study has a few limitations. First, the sample size is relatively small, and the follow-up time is relatively short for studying adulthood myopia. Second, collection of preoperative history was based on the recall of the patients, rather than previous refraction and AL on the record. Therefore we cannot rule out the possibility that patients’ refractive status was unstable in the first place. Third, this study population is adult myopic patients after ICL implantation rather than general myopic patients. 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 AL have a higher possibility to experience continuous axial elongation and myopia progression one year after refractive surgery, especially for those with myopia higher than −12.0 D and AL longer than 28.00 mm.
Author contributions XC and ZC conceived of and designed the experiments. XC and ZC performed the experiments. XC, ZC, MHM and XQW analyzed the data. XC and ZC wrote the first draft and edited the manuscript. XYW and XTZ revised the manuscript and gave final approval of the version for publication.

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Declarations

Conflict of interest 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.

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