15-month outcomes of Visian ICL implantation for high myopia in patients with shallow anterior chamber depth

CURRENT STATUS: ACCEPTED

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DOI:
10.21203/rs.2.497/v1

SUBJECT AREAS
Internal Medicine Specialties

KEYWORDS
High myopia; ICL V4c; anterior chamber depth
Abstract

Background: High myopia with shallow anterior chamber depth (ACD < 2.8 mm) is not rare. This observational study aims to: evaluate clinical outcomes after implantation of the Visian Implantable Collamer Lens with a central hole (ICL V4c) in these patients. Methods: A prospective cohort of consecutive 51 eyes of 31 patients (20 to 42 years old) was followed for 15.35 ± 4.90 months (12 to 25 months). The preoperative ACD was 2.74 ± 0.04 mm (2.65 to 2.79 mm). Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure (IOP), manifest refraction, vault, and endothelial cell density (ECD) were measured during the follow-ups after the surgery.

Results: All surgeries were performed safely and no complication was observed during the follow-ups. At the last follow-up, the safety index (postoperative CDVA / preoperative CDVA) was 1.33 ± 0.60 and the efficacy index (postoperative UDVA / preoperative CDVA) was 1.14 ± 0.54. After the surgery, no eye had decreased CDVA and 59% (30 eyes) of the eyes gained at least one line. Forty-seven eyes (92%) were within ± 1.0 D and 35 eyes (69%) were within ± 0.5 D of the attempted refraction. The mean postoperative vault was 380.00 ± 152.84 µm (90 to 700µm). The ECD was reduced by 8.38 ± 0.06% compared to the preoperative value (p < 0.001). No significant change was observed in IOP (p = 0.061) at the last follow-up. Ultrasound Biomicroscopy (UBM) showed none of the eyes had trabecular-iris angle closed. Conclusions: In this prospective observational study, ICL V4c implantation in patients with high myopia and shallow ACD achieved satisfying and stable visual outcomes. Its long-term safety and stability require further investigation. Trial Registration: This trial was retrospectively registered on 05/08/2018 under the number (ChiCTR1800017594)

Background
Since approved by the FDA in 2005, implantation of Implantable Collamer Lens (ICL™, STAAR Surgical, Nidau, Switzerland), a posterior chamber phakic intraocular lens, has been demonstrated a safe and effective way to correct high myopia[1, 2]. Advantages of ICL include faster visual recovery, more stable refraction, and better visual quality than corneal refractive surgery [3-5]. However, an anterior chamber depth (ACD) no less than 2.80 mm is usually recommended [6] and patients with shallow ACD may be at a higher risk of implantation failure [7].

The CentraFLOW technology has a 360 μm central hole in the Visian ICL (ICL V4c), which promotes the natural circulation of the aqueous humor, reduces the influence of metabolism on its own crystal, and alleviates the pain and discomfort caused by preoperative laser iridotomy [8, 9], resulting in decreased risks of cataracts, high intraocular pressure (IOP) and endothelial cell loss after ICL implantation [8-10]. However, it remains unknown whether implantation of ICL with a central hole is feasible in patients with shallow ACD (< 2.8mm), which is not rare in East Asian patients [11].

In this study we aimed to investigate the efficacy, safety, predictability and stability of ICL V4c implantation in patients with shallow ACD.

Methods

Subjects

A prospective, observational cohort study was carried out on consecutive patients who underwent ICL V4c implantation in the Department of Eye & ENT Hospital of Fudan University from April 2015 to May 2017. The study is adhered to the Declaration of
Helsinki and was approved by the Ethics Committee of the Eye & ENT Hospital Hospital, Fudan University, China. All patients provided signed informed consent after a detailed explanation of risks and potential outcomes of the implantation and the study.

The baseline characteristics and preoperative biometric values of the patients are shown in Table 1. The study enrolled 51 eyes of 31 patients (4 men and 27 women, 36 ICLs and 15 Toric ICLs) with a mean age of 32.45 ± 6.85 years old. All patients underwent routine preoperative examinations and met the surgical indications of ICL implantation for the correction of high myopia. The inclusion criteria were: age between 20 and 45 years old, spherical refraction of more than −6.00 D, astigmatism of up to −5.00 D, corrected distance visual acuity (CDVA) of 20/200 or better, and ACD of < 2.80 mm. The exclusion criteria includes a history of ocular conditions other than myopia (suspicion of keratectasia, cornea or lens opacity, retinal detachment, glaucoma, macular degeneration, or neuro-ophthalmic disease) with or without astigmatism, a history of ocular surgery, inflammation or trauma, any chronic systemic disease, and an endothelial cell count < 2000 cells/mm².

**ICL V4c**

The ICL V4c (STAAR Surgical, Nidau, Switzerland) corrects −0.50 D to −18.00 D myopic spherical refraction and up to −5.00 D cylindrical refraction. There are 4 sizes: 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm. Power calculation of the ICL V4c was performed as per the manufacturer using a modified vertex formula, according to the provided preoperative refractive parameters. The size of the implanted ICL V4c was determined based on the white-to-white horizontal corneal diameter and ACD. Toric ICL V4c is designed to correct both spherical and cylindrical diopters.
Surgical technique and follow-ups

All implantations were performed by two experienced surgeons (XZ and XW). The surgical technique has been previously described by Chen X et al [12]. Briefly, pupils were dilated before surgery. After injection of 1% sodium hyaluronate into the anterior chamber via a puncture site at the 6 o’clock position of the cornea, an ICL V4c was implanted via a 3.0 mm temporal corneal incision using an injector cartridge and then was placed in the posterior chamber. After that, the viscoelastic surgical agent was completely removed using a balanced salt solution, and a miotic agent was instilled. After the surgery, patients were given 1% tobramycin dexamethasone for 3 days followed by 0.1% fluorometholone (tapered gradually over 2 weeks), 0.5% left ofloxacin for 1 week, non-steroidal anti-inflammatory (NSAID) eye drops for 2 weeks, and artificial tears for 1 month.

All the patients were followed at 1 day, 1 week, 1 month, 6 months – 12 months and 24 months after the surgery. The mean follow-up time was 15.35 ± 4.90 months (ranges from 12 to 25 months). Routine measurements before and after the surgery include: decimal of uncorrected distance visual acuity (UDVA), decimal of corrected distance visual acuity (CDVA), manifest refraction (spherical equivalent, SE), anterior chamber depth (ACD; Pentacam, Oculus, Germany; measured from the corneal endothelium to the anterior lens), endothelial cell density (ECD; noncontact specular microscopy, SP-2000P, Topcon Corporation, Japan), intraocular pressure (IOP; non-contact tonometer, Canon, Japan), axial length (IOL master, Carl Zeiss, Germany), standard slit-lamp biomicroscopic and funduscopic examinations, central corneal thickness (Pentacam), horizontal corneal diameter (white-to-white, WTW; IOL master) and ultrasound biomicroscopy (UBM; Quantel medical, France)
**Statistical analysis**

Refractive outcome graphs were plotted using Microsoft Excel according to the refractive outcomes at 1 month, 6 months, and 12 months and 24 months in the patients. All statistical analyses were performed using the software Statistical Package for the Social Sciences (SPSS) Version 20.0 (SPSS, Chicago, IL, USA). The Kolmogorov–Smirnov test was used to determine if a variable is normally distributed. The results were expressed as the mean ± standard deviation (SD). According to each variable’s distribution, a paired t test or Wilcoxon signed-rank test was chosen to compare the parameters between time points and \( p < 0.05 \) was considered statistically significant. Statistical analysis for visual acuity was based on Decimal units.

**Results**

All procedures were completed successfully and no complication was observed during the follow-up periods. The mean preoperative ACD for all patients was 2.74 ± 0.04 mm (2.65 to 2.79 mm). The preoperative mean CDVA was 0.86 ± 0.31 (0.1 to 1.2) and the mean SE was -14.03 ± 4.46 diopters (D) (-7.50 to -25.75 D). Twelve eyes had preoperative SE over -18.00 D.

**Safety and Efficacy**

The mean postoperative CDVA was 1.00 ± 0.27 (0.4 to 1.5). The safety index (postoperative CDVA / preoperative CDVA) was 1.33 ± 0.60. No CDVA was lost at the final follow-up. Overall, 59% (30 eyes) of the patients had a CDVA increased at least 1 line over the preoperative CDVA. In 16% (8 eyes) of the eyes, CDVA increased by 3 lines or more. (Figure1A)
The mean postoperative UCVA was 0.89 ± 0.30 (0.12 to 1.2), and the efficacy index (postoperative UDVA / preoperative CDVA) was 1.14 ± 0.54. At the final follow-up, the mean SE was -0.67 ± 1.29 D (-6.00 to 0.75D). Thirty-seven eyes (73%) achieved a residual SE within ± 0.5 D, and forty-one eyes (80%) achieved a residual SE within ± 1.0 D (Figure 1B). Among all the patients, 35 eyes (69%) had a postoperative UCVA of 20/20 or better (Figure 1C). All twenty-two eyes with Toric ICL had a postoperative astigmatism of no more than 1.0 D.

_Predictability and Stability_

A scatter plot of the attempted versus achieved spherical equivalent (SE) corrections is shown in Figure 1D. Postoperatively, thirty-five eyes (69%) were within ± 0.5 D of the attempted SE. Forty-seven eyes (92%) had a postoperative SE within ± 1.0 D of the attempted SE. Additionally, all cases with a preoperative SE more than -18.00 D (39 eyes) were within ± 1.0 D of the attempted SE. In the four eyes that the corrected SE exceeded ±1.0 D of the attempted SE at the 2-year follow-up, their refraction changes between 1 month and 24 months after the surgery were over 1.0 D (Figure 1E) and the axial lengths increased by 0.10 - 0.31 mm as compared to the preoperative values.

_Intraocular pressure (IOP)_

The preoperative trabecular-iris angle was 33.22° ± 3.72° (27.9° to 45.2°) and reduced to 19.03° ± 4.24° (11.0° to 27.1°) after the surgery. No eye had a closed trabecular-iris angle as evaluated by UBM examination. At the last follow-up, the average IOP was 15.15 ± 2.57 mmHg, which was not significantly different from the preoperative IOP (p = 0.061).

_Corneal endothelial cell density (ECD)_
The postoperative corneal ECD was 2963.64 ± 396.17 cells/mm², which equals to a 8.38 ± 0.06% reduction to the preoperative ECD (p < 0.001). However, no eye decreased to less than 2000 cells/mm² and no eye had a significant ECD loss (≥ 30%) (Table 2). There was no significant correlation between the preoperative ACD and the change in the ECD at the last follow up (Pearson correlation coefficient $r = 0.169$, $p = 0.286$).

**Vault**

The average vault was 380.00 ± 152.84 µm (90 to 700 µm). Forty eyes (78.4%) had vault within 250 - 750 µm at the last follow-up. In four eyes (7.8%) with vault less than 200 µm, UBM showed that three eyes had haptics located on the ciliary processes (Figure 2A) and one eye had haptic located at the posterior segment of the ciliary processes (Figure 2B). No obvious cataract was observed in these four eyes, and UBM showed no significant enhancement in crystal echo.

**Discussion**

Since 2014, ICL V4c has been implanted in more than 60,000 eyes in the mainland of China, and the outcomes appeared to be satisfying [5, 12-14]. However, a recommended condition of ACD over 2.80 mm may restrict its use in patients with shallow ACD which is not rare in East Asian patients [11]. In this study we presented the short-term (average 15 months) clinical results after the implantation of ICL V4c for high myopia in patients with shallow ACD (< 2.8 mm).

No complication such as cataract was observed during and after the surgery in the studying cohort. Using ICL without a central hole, Lim reported subcapsular cataract in 2 out of 18 eyes with preoperative ACD of 2.71 ± 0.08 mm (range, 2.42 to 2.79 mm) and the
ICL were exchanged for these two eyes [7]. The use of CentraFLOW technology in ICL V4c may improve the dynamic circulation of the aqueous humor and reduces the influence of metabolism on its own crystal [8]. The mean percentage of endothelial cell loss was 8.44%, and no eye had ECD less than 2000 cells/mm² in this study. These results are similar to the FDA-reported endothelial loss of 8.9% at 3 years and 7.7% at 5 years after the surgery in patients with normal ACD [15, 16]. Additionally, we found no significant correlation between the preoperative ACD and the change in the ECD at the last visit. Therefore, the risk of ECD loss may not increase in patients with shallow ACD.

In all 51 eyes, forty-seven eyes (92%) were within ± 1.0 D of the attempted SE, and thirty-five eyes (69%) were within ± 0.5 D at the final follow-up, which is similar to the previous study in normal ACD patients by Sanders et al. showing that 67.5% of the patients were within ± 0.5 D and 88.2% were within ± 1.0 D of attempted correction at 3 years after the surgery [16]. In four eyes the achieved SE were more than ± 1.0 D of the attempted SE and the refractive changes exceeded 1.0 D between 1 month after the surgery and the last follow-up. The preoperative manifest refraction of these eyes were higher than -18.00 D. We found that in these patients, the axial length increased by 0.10 to 0.31 mm, resulting in mild myopia regression at the last follow-up. Kamiya [17] found that axial length had increased more than 0.5 mm at 8 years after surgery in eyes with a preoperative axial length of more than 27.5 mm. Thus the elongation of axial length may affect the predictability and stability of ICL implantation in high myopia.

In our study, four eyes (7.8%) had a vault less than 200 mm at the 2-year follow-up, in which haptics were not placed right in the ciliary sulcus. Although no obvious cataract occurred in these eyes and UBM showed no significant enhancement in crystal echo,
whether low vault may cause complications such as anterior subcapsular opacification in these patients may need further observation [18].

Narrowing of the trabecular-iris angle is another concern in patients with shallow ACD. Fernandez et al. reported that after ICL V4c implantation, the trabecular-iris angle was reduced by 34.5% ~ 42% at 3 months after surgery in patients with normal ACD [19], which is similar to our results (42.7% reduction after the surgery). Alfonso et al. reported that eyes with acute increases in intraocular pressure (IOP) were significantly more myopic and had shallower ACD [20]. However, no postoperative angle closure or abnormal IOP was observed during the follow-ups in this study. The mean IOP was 15.15 ± 2.57 mmHg, which was not significantly different from the baseline. Nevertheless, considering the trabecular-iris angle narrows with increased age and crystalline lens height[21], the trabecular-iris angle and IOP should be closely followed for longer period of time.

This study has several limitations. Firstly, the number of patients was relatively small and the follow-up time was only 15 months. Complications may be revealed in larger population and over longer follow-up period. Therefore, continuous follow-ups of these patients are very important before efficacy and safety of the procedure can be further validated. Secondly, although the clinical data were prospectively collected, the results need to be further verified by randomly controlled studies as compared to patients with higher ACD. Such studies may finally justify the feasibility of ICL V4c in patients with shallow ACD.

Conclusions

In this 15-month prospective study, ICL V4c implantation in patients with ACD less than 2.8 mm was shown to be a safe, effective and stable way to correct high myopia. There
was no significant endothelial loss or increase in IOP. Patients could achieve high, stable operative visual outcomes one year after the surgery.

Declarations

- **Ethics approval and consent to participate:** 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.

- **Consent for publication:** All participants in this study signed written consent forms for the publication of their relevant clinical data.

- **Availability of data and material:** Data and materials are available upon request from the corresponding author at doctzhouxingtao@163.com.

- **Competing interests:** The authors declare that there is no competing interest.

- **Funding:** This work was supported by National Natural Science Foundation of China (Grant No. 81770955 and 81570879), Project of Shanghai Science and Technology (Grant No. 17140902900 and 17411950200) and National Natural Science Foundation of China for Young Scholars (Grant No. 81600762).

- **Authors' contributions:** Literature screening and selection was performed by LN. XW and XZ participated in the design of the study. LN drafted the manuscript. LN and HM carried out the statistical analysis. LD and TH prepare and review of the manuscript. XW and XZ have given final approval of the version to be published. All authors read and approved the final manuscript.

- **Acknowledgements:** The authors thank Lin Wang and Xun Chen of the Eye Department of EENT Hospital for their helpful advice. We would also like to thank all the patients participating in the study.
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Tables

| Characteristics                  | Mean ± SD (N51 eyes) | Range (Minimum, Maximum) |
|----------------------------------|----------------------|--------------------------|
| Age (y)                          | 32.45 ± 6.85         | 20, 42                   |
| Follow-up (moths)                | 15.35 ± 4.90         | 12, 25                   |
| CDVA (Decimal)                   | 0.86 ± 0.31          | 0.1, 1.2                 |
| Spherical refractive error (D)   | -13.31 ± 4.34        | -6.50, -25.50            |
| Cylindrical refractive error (D) | -1.50 ± 1.01         | -4.00, 0                 |
| Spherical equivalent (D)         | -14.03 ± 4.46        | -7.50, -25.75            |
| ACD (mm)                         | 2.74 ± 0.04          | 2.65, 2.79               |
| WTW (mm)                         | 11.67 ± 0.33         | 11.0, 12.9               |
| IOP (mmHg)                       | 15.76 ± 2.68         | 9.7, 20.9                |
| ECD (cells/mm²)                  | 3235.08 ± 478.07     | 2379, 4132               |
| Axial length (mm)                | 28.30 ± 2.01         | 24.18, 32.84             |

CDVA = corrected distance visual acuity; D = diopter; ACD = anterior chamber depth; WTW = white-to-white; IOP = intraocular pressure; ECD = Endothelial cell count. Data are mean ± SD unless otherwise indicated.
| Characteristics                  | Mean ± SD (51 eyes) | Range (Minimum, Maximum) |
|---------------------------------|---------------------|--------------------------|
| UDVA (Decimal)                  | 0.89 ± 0.30         | 0.12, 1.2                |
| CDVA (Decimal)                  | 1.00 ± 0.27         | 0.4, 1.5                 |
| Spherical equivalent (D)        | -0.67 ± 1.29        | -6.00, 0.75              |
| Implanted ICL size (mm)         | 12.58 ± 0.31        | 12.113.7                 |
| IOP (mmHg)                      | 15.15 ± 2.57        | 9.7, 20.4                |
| ECD (cells/mm²)                 | 2963.64 ± 396.17    | 2358, 3651               |
| Axial length (mm)               | 28.33 ± 2.15        | 24.19, 33.15             |
| Vault (mm)                      | 380.00 ± 152.84     | 90, 700                  |

CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity; IOP = intraocular pressure; ECD = endothelial cell density; Data are mean ± SD unless otherwise indicated.
Clinical outcomes of 51 myopia eyes with shallow anterior chamber depth (ACD) after implantation of ICL with a central hole (ICL V4c). Changes of corrected distance visual acuity (CDVA) (A), distribution of postoperative spherical equivalent refraction (B), cumulative percentage of the eyes attaining specified
cumulative levels of uncorrected distance visual acuity (UDVA) (C), attempted spherical equivalent refraction change versus the achieved spherical equivalent refraction change (D) at the last follow-up were plotted. Stability of postoperative spherical equivalent refraction was evaluated over 12 months (E).

Figure 2

Locations of the ICL V4c in the eyes with vaults less than 200 µm at the last follow-ups. Images were captured by ultrasound biomicroscopy (UBM). The haptic of ICL V4c was on the ciliary processes in three eyes (A) and were at the posterior segment of the ciliary process in the forth eye (a representative image shown in B).

Supplementary Files

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