Long Term Assessment of the Quality of Visual-related Daily Activities after ICL (V4C) Implantation for Myopia and Myopic Astigmatism

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Abstract

Background: The purpose of the study was to evaluate long-term quality of visual related daily activities after Central Hole Collamer Lens implantation to treat myopia and myopic astigmatism.

Methods: This retrospective study included 46 eyes (23 patients) receiving an ICL-V4c implantation. The follow up time was at least 24 m. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refraction, eye axis, intraocular pressure, endothelial cell density (ECD), vault, and the patients' satisfaction related to vision related daily activities were recorded at 6 m and 24 m.

Results: The mean spherical equivalents were -0.14 ± 0.21 D and -0.12 ± 0.33 D at 6 m and 24 m after surgery, respectively. UCVA of all eyes were equal to or better than preoperative BCVA. The BCVA at 6 m and 24 m after implantation were -0.03 ± 0.08 LogMAR, and −0.03 ± 0.11 LogMAR, respectively, which was statistically better ($P = 0.031$) than that of pre-operation value of 0.07 ± 0.12 LogMAR. There was no significant differences ($P > 0.05$) between the pre operation and post operation ECD.At 24 m post operation, 10% of the patients complained of difficulty driving at night, but most of patient had satisfactory or very satisfactory vision-related daily activity scores. Some patients, 13%, were worried about the long-term safety and efficacy of the V4c-ICL implantation.

Conclusions: Patients were very satisfied with their vision related daily activities after V4c-ICL implantation. With time, some patients worried about the permanent safety and efficacy.

Background

The Vision Implantable Collamer® Lens (ICL, STAAR Surgical, Minrovia CA, USA) with a central artificial hole is a promising next-generation surgical option for the treatment of moderate to high myopia, with excellent visual performance. Posterior chamber phakic intraocular lens (pIOL) implantation has become an important and inevitable choice for young patients with high myopia[1, 2]. After implantation, the ICL-V4c closes the refractive system nodes, and has less image change and surgical injury, so it has high visual quality and better security compared to the laser refractive surgical[3, 4]. An advantage of posterior chamber IOL implantation is that the integrity of eye is maintained and the surgery is safely reversible, unlike ocular lens extraction surgery in which the

native ocular lens is removed. ICL is made from a collagen copolymer which is highly biocompatibile[5]. The new V4C lens is better than that the older V4 lens because it has a 0.36mm central hole[6, 7]which allows for the circulation of aqueous in a natural manner minimizing iridectomy and reducing the risk of cataract.About the endothelial cell lossing, the U.S. FDA Trial demonstrated that it was 3.3±7.6% at one year postoperatively(90% confidence limits: 2.4% to 4.3%) [8]. Fernandes and colleague[9] reported that the mean endothelial cell loss varied from 9.9% to 3.7% at 2-4 years postoperatively,and that those loss was more prominented within the first 1 to 2 years,but over time ,the ECD was stability or lower progression. Despite the advantages of V4c implantation, complications, such as cataract and elevated IOP levels were observed[10]. Objective and subjective short-term visual quality after ICL implantation has been studied extensively[11] . Some patients complained about halo or glare in dark environments[12]which can cause nighttime driving difficulty, and some patients worried about the safety and the efficacy in the long-term of the implantation.

Long-term visual quality assessment of visual related daily activities in a complex living environment after ICL implantation have not been studied. To ameliorate this gap in knowledge, we assessed the quality of visual related daily activities 24 months after ICL-V4c implantation.

Patients And Methods

The current study included 46 eyes of 23 consecutive patients (mean age 24.04 ± 4.75 years, standard deviation [SD] range 18 - 35 years, including 13 men) who had a posterior chamber phakic collamer (ICL-V4c) implanted at the Affiliated Hospital of Zunyi Medical College. The mean spherical equivalent was -11.25 ±3.23 D (range, -5.25 D to -15.75 D); the average cylinder was -3.27±0.83 D (range, -1.25 D to -4.5 D). Preoperative and postoperative uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) were recorded using the decimal method and converted into the LogMAR (logarithm of the minimal angle of resolution) equivalence. All patients were followed for at least 24 m. The UCVA, BCVA, refraction, eye axis, intraocular pressure, endothelial cell density (ECD), vault, and the patients’ satisfaction related to their quality of vision related daily activities at 6 m and 24 m were recorded.

One senior technician used ultrasound biomicroscopy (UBM) to measure the ICL-V4c central vault and the peripheral vault at 2, 4, 8, and 10 o'clock at 1 m, 6 m and 24 m postoperative. All patients filled out a visual satisfaction questionnaire related to daily vision-related activities. The questionnaire was modified slightly from the questionnaire developed by the Corneal Disease and Excimer Laser Research Unit, University of Dundee, Scotland[13]. This study complied with the Helsinki declaration of the purpose, and all patients gave their informed consent after a comprehensive explanation of the possible risk and complication of V4c-ICL implantation.

Inclusion Criteria. Inclusion criteria was: refraction did not change more than 0.5 D one year after surgery; BCVA was 0.5 or above; contact lenses were not worn for more than two weeks; no obvious eye diseases; a horizontal white-to-white distance between 10.5 and 12.5 mm; the number of corneal endothelial cells had to be greater than 2500mm -2; the central anterior chamber depth had to be more than 2.8mm.

Intraocular Lens. ICL power calculation was performed using the instructions of the manufacturer (STAAR Surgical, Monrovia CA, USA). The emmetropia was the target refraction and the type of the ICL-V4c was chosen following the manufacturer's instructions and based on the anterior chamber depth and the horizontal corneal diameter. The horizontal white-to-white(W-T-W) distance was took by manual measurement.

Surgical Procedure

On the day of surgery, patients were given dilating and cycloplegic agents. Topical anesthesia was performed using 0.4% proparacaine before surgery. If a Toric ICL was implanted, the zero horizontal axis was marked by means of a slit-lamp preoperatively. A 3 mm clear corneal incision and the pre-installed ICL was slowly pushed into the anterior chamber through the incision. A special adjustment hook was used to adjust it into the posterior chamber, and then replaced the viscoelastic agent. All surgeries were performed by one experienced surgeon.

Statistical Analysis

All data were expressed as means ± SD. The preoperative and postoperative axial, IOP and ECD was analyzed using repeated analysis of variance (SPSS 17.0). The Student's T-test was used to test

differences in the central vault, peripheral vaults and postoperative satisfaction score. A value of $P < 0.05$ was considered statistically significant.

Results

Refraction and Visual Parameters. Preoperative SE was - 11.3 ± 3.7 D (-5.25 D to -15.75 D). SE were -0.14 ± 0.21 D (-1.00 to 0.75 D) and -0.12 ± 0.33 D (-1.00 to 0.50 D), postoperative 6 m and 24 m, respectively. Preoperative Log MAR UCVA was 1.4 ± 0.2 LogMAR ,−0.03 ± 0.07 LogMAR and -0.03 ± 0.09 LogMAR postoperative 6 m and 24 m, respectively. All of the 46 eyes had a UCVA equal to or better than the preoperative BCVA(Fig.1). The efficacy indexes were 1.21 and 1.24 (postoperative UCVA/preoperative BCVA). The BCVA at 6m and 24m after operation were -0.03 ± 0.08 LogMAR, −0.03 ± 0.11 LogMAR respectively, which was better than that of pre-operation (0.07 ± 0.12 LogMAR) (P=0.033).The safety index were 1.24 and 1.26(=postoperative BCVA/preoperative BCVA). The average preoperative axial length was 26.9 ± 1.3 mm, and the average postoperative axial length was 27.1 ± 1.3 mm at 24 m ($P > 0.05$).

Fig.1 The change of BCVA after ICL-V4Cimplantation. -2 line□Postoperative BCVA decreased by two line; -1 line: Postoperative BCVA decreased by one line; 0 line: postoperative BCVA equal to preoperative values; 1 line: Postoperative BCVA increased by one line; 2 line: Postoperative BCVA increased by two lines.

Intraocular pressure. There was no significant differences ($P > 0.05$) between the pre operation and post operation IOP (Fig. 2).

Fig.2 The change of IOP after ICL-V4Cimplantation.

Corneal Endothelial Cells Density There was no significant differences ($P > 0.05$) between the pre operation and post operation ECD (Fig. 3).

Fig.3 The ECD before and 1m, 6m and 24m after V4c-ICL

Vault The central vault, 0.46 ± 0.26 mm (0.1 to 0.70 mm) was significantly higher, $P < 0.05$ compared

with the peripheral vault (Fig. 4) at all post operation times. During our follow-up, the central and peripheral vaults were gradually declined with time. At the first 6m after V4c-ICL implantation, the central vault showed a quickly downward trend and then the change of vault was very slowly. In addition, our data showed that the high vault declined more obviously.

Fig.4 The central and peripheral vault after V4c-ICL implantation

Visual Function. All of the 23 patients were required to fill out a questionnaire related to visual functions 6 m and 24 m after surgery. The results of the questionnaire are listed in Table 1. Items one and two were related to near vision, items three through five were related to far distance vision, item six was related to night vision, and items seven through eleven were related to middle-distance vision. Apart from the 10 % of patients that complained of difficulty driving at night 24 m post operation, all of the other items received satisfactory or very satisfactory scores.

We also investigated whether patients had halos after surgery During the early postoperative follow-up period, the halos occurred in 12 patients (52.2%) in a dark environment, while halos were gradually reduced or disappeared over time. Only one patient had a halo that persisted in a dark environment. All of the patients gave satisfactory or very satisfactory scores for all the other items. A few patients, 13%, voluntarily informed us that they worried about the long-term efficacy of V4c-ICL implantation, however after six months post operation, there were no similar complaints. see Table 1

Discussion

UCVA, BCVA and safety index measured in in the current study after V4c-ICL implantation in all eyes were equal or better than preoperative BCVA. No eyes had postoperative BCVA worse than preoperative BCVA. The majority of patients (95.65%) with BCVA improved in a row or more. The safety index at 6 m and 24 m post operation were consistent with a previous study[14] . No significant change was found in the eye axial length . which for patients with high myopia, is realted to refraction[15]. These results indicated that V4c-ICL was a safe and effective treatment for high myopia, and refraction was stable over time.

IOP for all patients was stable and similar to the preoperative level. A high IOP is one of the main problems after ICL implantation. The cause for early postoperative higher IOP levels include: excessive residual viscoelastic agent, an ICL that was too large, or a vault that was too high. The cause for mid-term higher IOP levels include steroid induced higher IOP; long term iris depigmentation, pigmentation blockage or chronic angle synechiae closure. All of the above risks were minimized due to the 0.36 mm central hole .

Maintenance of ECD is important for maintaining corneal transparency. Endothelial cells numbering about 5500 / mm2 lose their proliferation ability after birth and decrease normally by about 0.32% to 0.6% every year[16]. Intraocular surgery, corneal trauma, endophthalmitis and high IOP can the decrease ECD.In this study, we found that the number of corneal endothelial cells at 1m, 6m, and 24m after V4c-ICl implantation decreased by 3.92%, 4.83%, 5.02% respectively. Although not statistically significant, we found a trend towards a decrease in ECD after V4c-ICl implantation. We consider the factors of endothelial cell injury was surgical techniques, artificial lens and change of aqueous humor of physicochemical properties in the early postoperative stage. While from 6m to 24m after V4c-ICL implantation, there had no obvious change about the ECD. Of course, a longer-term observation time and a larger sample size would be advantageous to document ECD changes with time.

Postoperative vault was a determinant of major complications after ICL surgery. Acceptable levels of postoperative vault for the V4C-ICL was defined as 250 to 750 μm[17]. The vault was too low may increase the risk of cataract formation[18]. And the vault was too high will made the iris bulging forward, close to anterior chamber angle, and lead to the elevated IOP and iris dysfunction[19]. In the present study, we used ultrasound biomicroscopy to observe the distance between ICL and natural lens ,we found there were no V4c-ICL contact with lens directly .In the early period of postoperative follow-up, the vault was shown a downward trend, and quickly decreased at first 3m after V4c-ICL implantation, and the higher vault mean more change. And then the change of vault gradually slowed over time. This result was consistent with the previous studies [10, 19]. The peripheral vault was significantly lower than the central vault, which may ensure the optical imaging quality of V4C-

ICL.Because the concave lens has the thin central area (40 um), the outer edge of optical thickness was 500-600um, and the haptic foot plates thickness was less than 100 um. This design allows the V4C-ICL to have the smallest refractive index, and ensure its high order aberration was smaller, to improve the quality of optical imaging.

Evaluation of visual quality after ICL implantation was the focus of many studies[14, 15, 20]. Objective parameters such as contrast sensitivity and high-order aberration after V4c-ICL implantation were measured[21, 22]. There are no studies published regarding long-term vision-related daily activities, so we pursued this aim in the present study. Most of the patients we studied had satisfactory or very satisfactory visual function scores while 10% patients complained of difficulty driving at night. Some patients complained of halos appearing in a dark environment. Haloes may arise from high contrast in a night time environment, and/or the central hole affecting diffraction causing the glare[12]. Our patients with glare complaints were given psychological counseling and with time the glare problems gradually disappeared without any treatment.

Some of the patients, 13%, voluntarily informed us that they worried about the permanent safety and efficacy after V4c-ICL implantation. During the 6 m follow-up, there were no similar complaints. Adequate preoperative communication, regular and long-term follow-up is important to relieve the patients' worries.

Conclusions

In summary, refraction and IOP were stable and there was no change in ECD or vault over a 24 m follow-up time. At 24 m post operation, 10% of the patients complained of difficulty driving at night, but most of patient had satisfactory or very satisfactory vision-related daily activity scores. Some patients, 13%, were worried about the long-term efficacy of the V4c-ICL implantation. V4c-ICL implantation appears to be safe and effective, however a follow up period greater than 24 m and a larger sample size would are necessary to validate the long term safety and efficacy of the implantation.

Declarations

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

Literature screening and selection was performed by SR Linghu and TX Liu. SR Linghu and YL Liao participated in the design of the study. SR Linghu drafted the manuscript.L Pan and R Shi carried out the statistical analysis. SR Linghu and TX Liu prepare and review of the manuscript. TX Liu has given final approval of the version to be published. All authors read and approved the final manuscript.

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 Affiliated Hospital of Zunyi Medical College. Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

Consent for publication

Not applicable.

Competing Interests

The authors declare that there is no conflict of interests regarding the publication of this article.

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Tables

Visual functions	Mean score ±SD 6m / 24m	Very positive %	Positive%	Negative%	Very negative %
Reading in daylight	8.7±0.77 / 8.8±0.8	72.3 / 73.1	27.7/ 26.9	0	0
Reading in artificial light	8.7±0.76 / 8.9±0.7	74.2 / 76.8	25.8/ 23.2	0	0
Watching TV	8.9±0.81 / 9.0±0.78	77.4 / 77.2	22.6/ 22.8	0	0
Watching movie at cinema	8.8±0.72 / 8.8±0.6	80.0 / 81.9	20.0/18.1	0	0
Driving in daylight	8.7±0.82 / 8.7±0.7	77.5 / 76.9	22.5/23.1	0	0
Driving at night	8.0±0.79 / 8.2±0.9	55.2 / 52.6	38.8/37.4	6/10	0
Reading computer screen	8.0±0.69 / 8.3±0.5	55.9 / 55.5	44.1/44.5	0	0
Playing sports	8.8±0.81 / 8.8±0.8	77.2 / 77.6	22.8/22.4	0	0
Swimming	8.5±0.67 / 8.8±0.7	74.5 / 73.6	22.5/23.1	0	0
Shaving/makeup	8.6±0.91 / 8.8±0.7	81.4 / 82.3	18.6/17.7	0	0
Shopping	8.9±0.74 / 9.0 ±0.6	82.9 / 81.2	17.1/18.8	0	0

Table 1: The visual function questionnaire for all 23 patients after ICL implantation

Note: the score is 10 points, which stated that 7.5-10.0 is very satisfied, 5.0-7.5 is satisfied; 2.5-5.0 points is negative; 0-2.5 is very negative.

Figures

Figure 1

The change of BCVA after ICL-V4C implantation

Figure 2

The change of IOP after ICL-V4C implantation

Figure 3

The ECD before and 1m, 6m and 24m after V4c-ICL

Figure 4

The central and peripheral vault after V4c-ICL implantation