

Comparison of Implantable Collamer Lens Visian ICL V4 and ICL V4c for high myopia

A cohort study

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Abstract

The aim of this study was to investigate the visual quality of the 2 kinds of intraocular lens: Visian implantable collamer lens (ICL) V4 and Visian ICL V4c implantations for high myopia.

Twenty cases (20 eyes) with high myopia who received Visian ICL V4 implantation and 18 cases (18 eyes) with high myopia who received Visian ICL V4c implantation in our hospital from April 1, 2014 to November 31, 2016 were enrolled. In 1-month follow-up, near vision, best corrected distant visual acuity (BCVA), uncorrected distant visual acuity (UDVA), and wavefront aberrations were measured, and compensation factor was calculated.

Near vision, UDVA, and BCVA showed no significant difference between ICL V4 implantation and ICL V4c implantation ($P > .05$). However, high-order aberrations and spherical aberrations were higher in ICL V4c implantation than in ICL V4 implantation ($P < .05$). Low-order aberrations (defocus and astigmatism), coma, and subjective visual quality had no significant difference between ICL V4 implantation and ICL V4c implantation ($P > .05$).

The 2 kinds of ICL Visian ICL V4 and Visian ICL V4c had similar efficacy of visual quality for high myopia. The presence of the central hole of Visian ICL V4c has no significant effect on visual quality.

Abbreviations: BCVA = best corrected distant visual acuity, CF = compensation factor, ICL = implantable collamer lenses, IOL = intraocular lens, UCVA = uncorrected distant visual acuity.

Keywords: high myopia, implantable collamer lens, Visian ICL V4, Visian ICL V4c, visual quality

1. Introduction

Myopia is one of the most common ametropic diseases and remains a challenge for ophthalmologists.^[1] The prevalence of myopia was 22.9% in adults and 70% to 80% among adolescents according to a 2015 study in China.^[2,3] A recent study showed that up to 90% adolescents and young people suffered from myopia worldwide.^[4] High myopia is myopia over -6.00 D, which is characterized by progressive damage to the intraocular content and retina, causing multiple visual dysfunction. A number of studies indicate that high myopia is the fourth to seventh disease accounting for blindness.^[5-7] Therefore, prevention and treatment of high myopia is urgent.

Lens refractive surgery becomes the common major operation performed for high myopia, including the extraction of crystalline lens combined with intraocular lens (IOL) implantation and phakic IOL implantation. According to the location of the IOL within the eye, the implantation surgery can be divided into anterior chamber IOL implantation and posterior chamber IOL implantation. In the anterior chamber IOL implantation, the lens is implanted in the phakic anterior chamber, which causes high risk of postoperative complications such as corneal endothelial decompensation.^[8] In recent years, anterior chamber IOL implantation is gradually replaced by posterior chamber IOL implantation. In phakic posterior chamber IOL implantation, the lens are implanted between the iris and the crystalline lens, resulting in good effect to correct myopia.^[9,10] However, there are some complications in the early stage, including corneal endothelial injury, glaucoma, iridocyclitis, and cataract.^[11,12] Currently, implantable collamer lenses (ICL/TICL) produced by Swiss Staar company is the most widely used posterior chamber IOL, and is the only IOL for phakic posterior chamber approved to correct high myopia.

ICL/TICL is made of a collagen called collamer, which is exempted from immune system in the eye.^[13] The first generation of ICL/TICL has many defects such as bad predictability caused by lens design problem. For the second- and third-generation V2 and V3, the incidences of pupil blocking glaucoma and pigment dispersion glaucoma become small. However, studies have shown that 3% to 5% cases have lens opacity under the anterior capsule, which is attributed to the contact between ICL/TICL and crystalline lens.^[14-16] Subsequently, the 4th generation ICL/TICL, Visian ICL V4 is developed to provide more space between ICL/TICL and crystalline lens and prevent cataract formation.^[17]

Editor: Khaled Ahmed Abdelrahman.

The authors have no conflicts of interest to disclose.

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Medicine (2017) 96:25(e7294)

Received: 12 April 2017 / Received in final form: 1 June 2017 / Accepted: 5 June 2017

<http://dx.doi.org/10.1097/MD.0000000000007294>

The latest generation ICL/TICL is Visian ICL V4c, which is based on V4 but has an additional central hole. This “CentraFLOW Technology” design can regulate the compliance of aqueous humor flow between the ICL/TICL and the crystalline lens to eliminate the need of preoperative peripheral iridectomy. When Visian ICL V4c and Visian ICL V4 lens implantations were compared for high myopia therapy, there was no significant difference in the control of intraocular pressure.^[18,19] However, it remains unclear whether “CentraFLOW Technology” affects visual quality. This study aimed to compare visual quality of the 2 kinds of IOL Visian ICL V4 and Visian ICL V4c implantations for high myopia.

2. Methods

2.1. Participants

This study followed the Declaration of Helsinki and was approved by Central South University Xiangya Hospital Medical Ethics Committee, and was registered in China Clinical Trial Registration Center with the registration number: ChiCTR-IOR-14005412. All participants signed the informed consent form, including 20 cases of high myopia patients who underwent Visian ICL V4 implantation (taking the right eye data), and 18 cases of high myopia patients who underwent Visian ICL V4c implantation (taking the right eye data) at Xiangya Hospital between April 1, 2014, and November 31, 2016, and divided into the ICL V4 group and the ICL V4c group, respectively. The inclusion criteria and exclusion criteria were as follows.

Inclusion criteria:

1. 18 to 50 years old, with refractive stability for more than 2 years.
2. The high myopia is generally not suitable for corneal laser surgery.
3. Without any ophthalmic surgery and diseases, such as iritis, glaucoma, cataract, or diabetic retinopathy.
4. The pupil diameter (dim light) ≤ 6 mm.
5. Corneal endothelial cells: $\geq 2000/\text{mm}^2$.
6. Corneal diameter range: 10.6 to 12.5 mm.
7. Anterior chamber depth (exclude central cornea thickness) ≥ 2.8 mm.
8. Myopia diopter -0.5D to -18.00D ; astigmatism -0.5D to -6.00D (Visian ICL V4c: myopia diopter -2D to -18.00D , astigmatism -0.5D to -5.00D).

Exclusion criteria:

1. Younger than 18 years old or older than 50 years old, with refractive instability nearly for 2 years.
2. Pupil diameter (dim light) > 6 mm.
3. Corneal endothelial cells: $< 2000/\text{mm}^2$.
4. Anterior chamber depth (exclude central cornea thickness) < 2.8 mm.
5. Corneal diameter: < 10.6 or > 12.5 mm.
6. Eye diseases: such as the lens diseases (cataract, lens subluxation, etc), corneal degeneration, glaucoma, uveitis, retinal detachment, etc.
7. The patient with systemic disease who is not suitable for intraocular surgery.
8. The patient who cannot understand the risks of the surgery, and has too high expectations and too much anxiety.

2.2. Surgery procedure

Periphery single hole Nd:YAG (LIGHTMED) laser iridectomy was performed 1 week before the surgery, with the location 1:00

or 11:00, and the hole diameter of 1 mm. Visian ICL V4c surgery did not require preoperative periphery Nd:YAG laser iridectomy. The surgery was performed under surface anesthesia using oxybuprocaine and 3 mL equivalent amount of mixed liquor made of 2% lidocaine and 0.5% bupivacaine. At the beginning of surgery, ICL/TICL was loaded into the special syringe. An incision at the location 6:00 (right eye) or 12:00 (left eye) was made by a stab knife (Sharper, Middleboro, MA), DisCoVisc (Alcon) was injected into the anterior chamber, and a transparent corneal incision was made on the temporal side. Next, ICL/TICL was injected slowly into the anterior chamber through transparent corneal incision, pushing to the posterior chamber by the aligning hook. Then the position of ICL/TICL was adjusted to make sure that the optical center must be in the middle. Finally, DisCoVisc was washed out of the anterior chamber from the transparent corneal incision by using Lactated Ringer’s solution. All surgery was completed by the same operator and took about 10 to 15 minutes.

2.3. Data measurement

The follow-up time was 1 month. The distant vision was measured using international standard visual acuity chart (GB11533-89, China), and near vision was measured using Jaeger Chart (ASNT-2224). Wavefront aberrations were measured using the i-Trace visual function analyzer (4.1.1 version, Tracey). Compensation factor (CF) = 1 – entire eye aberrations/corneal aberrations, positive CF indicated that the internal optics aberrations has compensation effect on the corneal aberration, whereas negative CF indicated that the internal optics aberrations has additive effect on the corneal aberrations.^[20]

2.4. Statistical analysis

Statistical analyses were performed using SPSS 19.0 software (SPSS, Chicago, IL). The comparison between 2 groups was analyzed by paired *T*-test. Results of subjective visual quality questionnaire and CF were compared by the χ^2 test. $P < .05$ indicated significant difference.

3. Results

3.1. General data of 2 groups

The preoperative data of ICL V4 and ICL V4c groups are shown in Table 1. The general data showed no significant difference between the 2 groups.

Table 1
Preoperative data of ICL V4 and ICL V4c groups.

	ICL V4 group	ICL V4c group	<i>t</i>	<i>P</i>
Gender	15 females; 5 males	13 females; 5 males	–	–
Age	25.1 \pm 4.2	24.6 \pm 3.9	1.15	.21
UCVA	0.06 \pm 0.02	0.05 \pm 0.03	0.23	.77
BCVA	1.04 \pm 0.27	1.08 \pm 0.25	–0.64	.41
Total-LOA	9.61 \pm 0.19	9.07 \pm 0.13	0.76	.32
Total-HOA	0.64 \pm 0.32	0.61 \pm 0.46	0.34	.67
Spherical, D	–12.15 \pm 6.31	–11.44 \pm 5.18	0.54	.59
Cylinder, D	–1.05 \pm 0.65	–0.95 \pm 0.70	0.61	.45

A χ^2 test was used for gender, $P > .05$.

BCVA = best corrected distant visual acuity, HOA = high-order aberrations, ICL = implantable collamer lenses, LOA = low-order aberrations, UCVA = uncorrected distant visual acuity.

Table 2
Visual acuity of ICL V4 and ICL V4c groups.

	ICL V4 group	ICL V4c group	t	P
UCVA	1.05±0.34	1.07±0.41	-0.57	.57
J	1.02±0.22	1.02±0.19	0.11	.92
BCVA	1.11±0.28	1.14±0.30	-0.13	.89

BCVA=best corrected distant visual acuity, ICL=implantable collamer lenses, J=near vision by Jaeger chart, UCVA=uncorrected distant visual acuity.

Table 3
The wavefront aberrations of ICL V4 and ICL V4c groups.

	ICL V4 group	ICL V4c group	t	P
Total LOA	0.795±0.397	0.883±0.382	-1.67	.12
Defocus	0.725±0.410	0.792±0.375	-0.93	.77
Astigmatism	0.251±0.139	0.203±0.116	0.49	.53
Total HOA	0.223±0.165	0.812±0.347	-9.55	<.05
SA	0.195±0.178	0.573±0.268	-8.16	<.05
CA	0.087±0.073	0.109±0.089	-1.53	.13

CA=coma aberration, HOA=high-order aberrations, ICL=implantable collamer lenses, LOA=low-order aberrations, SA=spherical aberration, unit=μm.

3.2. Visual acuity of 2 groups

Visual acuity was observed at 1 month after the surgery, the results are shown in Table 2. Uncorrected distant visual acuity (UCVA) was 1.05±0.34 (range 0.8–1.5) in the ICL V4 group and 1.07±0.41 (range 0.9–1.5) in the ICL V4c group, the difference had no significance ($t=-0.57, P=.57$); the near vision was 1.02±0.22 (range 2–1) in the ICL V4 group and 1.02±0.19 (range 2–1) in the ICL V4c group, the difference had no significance ($t=0.11, P=.92$). Best corrected distant visual acuity (BCVA) was 1.11±0.28 (range 0.9–1.5) in the ICL V4 group and 1.14±0.30 (range 1.0–1.5) in the ICL V4c group, the difference had no significance ($t=-0.13, P=.89$).

3.3. The wavefront aberrations of 2 groups

The wavefront aberrations of 2 groups were measured at 1 month after the surgery, and the results are shown in Table 3. Total high-order aberrations (HOA) was 0.223±0.165 μm (range 0.134–0.5 μm) in the ICL V4 group and 0.812±0.34 μm (range 0.286–1.193 μm) in the ICL V4c group, the difference was

Table 4
The compensation factor for ICL V4 and ICL V4c groups.

Total RMS	Group	CF (+)	CF (-)
LOA	ICL V4	9	11
	ICL V4c	8	10
HOA	ICL V4	7	13
	ICL V4c	6	12

CF=compensation factor, HOA=high-order aberrations, ICL=implantable collamer lenses, LOA=low-order aberrations, RMS=root mean square.

Table 5
The subjective visual quality questionnaire of ICL V4 and ICL V4c groups.

	ICL V4 group	ICL V4c group
Visual fatigue	5 (near)	4 (near)
Halo	13	10
Glare	0	0

ICL=implantable collamer lenses.

significant ($t=-9.55, P<.05$); the spherical aberration was 0.195±0.178 μm (range 0.087–0.236 μm) in the ICL V4 group and 0.573±0.268 μm (range 0.396–0.891 μm) in the ICL V4c group, the difference was significant ($t=-8.16, P<.05$) (Fig. 1). Total low-order aberrations (LOA) (defocus and astigmatism) and coma aberration showed no significant difference between the 2 groups.

3.4. Compensation factor of 2 groups

One month after the surgery, CF for the LOA and the HOA was measured (Table 4). The results showed no significant difference between the 2 groups.

3.5. The subjective visual quality questionnaire of 2 groups

Visual fatigue and halo occurred in both groups, visual fatigue occurred in the case of near vision, the incidence of visual fatigue was 25% in the ICL V4 group and 22.2% in the ICL V4c group; the incidence of halo was 65% in the ICL V4 group and 55.6% in the ICL V4c group. These incidences showed no significant difference between 2 groups (Table 5).

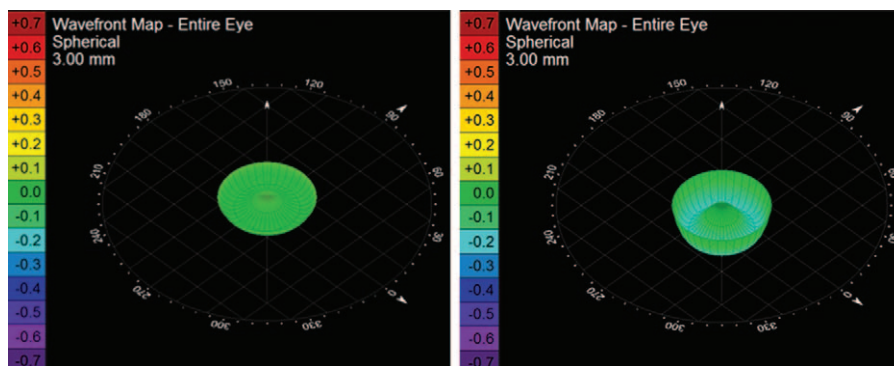


Figure 1. Three-dimensional schematic diagram of spherical aberration. The left was for Visian ICL V4 and the right was for Visian ICL V4c. The spherical aberration was small in the left panel diagram, with relatively flat shape, while the spherical aberration was large in the right panel diagram, with a bowl shape with a convex bottom. ICL=implantable collamer lenses.

4. Discussion

Currently, the efficacy of Visian V4c ICL has already been reported.^[21] However, there are still concerns about the optical performance of the ICL with the central hole because the presence of the central hole may affect the visual quality of high myopia patients.

A retrospective study compared UCVA and BCVA 3 months after the implantation between the new Visian ICL V4c and the conventional Visian ICL V4 and found no statistically significant difference.^[22] Similar to this study, in the present study, we compared BCVA between 2 groups 1 month after the surgery, both groups had no significant differences. In addition, we compared the near vision after the surgery, the results showed that the near vision of both groups 1 month after the surgery had no significant differences. These results indicate that both ICL V4 and ICL V4c implantations could improve the visual acuity significantly and achieve the same efficacy.

A clinical study by Shimizu et al^[23] reported that HOA (spherical aberration and coma aberration) with pupil diameters of 4 and 6 mm showed no significant difference between Visian ICL V4c and Visian ICL V4. However, our study showed that both total HOA and spherical aberration 1 month after the surgery were more in the Visian ICL V4c group than in the Visian ICL V4 group, and their differences were statistically significant although the difference of coma aberration was not statistically significant.

To understand whether the additional central hole in Visian ICL V4c can affect postoperative visual quality and cause inconvenience to the patients, we underwent the subjective visual quality questionnaire. Our results showed that the difference between Visian ICL V4c and Visian ICL V4 groups was not statistically significant, similar to the results of Huseynova et al^[22] Kamiya et al^[24] performed ICL V4 implantation to 1 eye of the patient, and ICL V4c implantation to the other eye of the same patient, then compared the postoperative visual quality of both eyes. The results showed no significant difference. For ICL V4c implantation, there is no need to undergo the iridectomy, so the situations such as visual decline caused by light leakage of the iridectomy hole can be avoided, but the presence of the central hole may cause visual quality problems.

To further analyze visual quality of the eye after the ICL V4c implantation, we introduced the concept “CF” to evaluate the compensation effect of internal optics aberrations to the corneal aberration. This concept has been used in the studies of various refractive surgeries to treat myopia, such as keratorefractive surgery.^[25,26] Previous study demonstrated that the wavefront aberrations had close relationship with visual quality.^[27] When human eye corneal aberrations match the internal optics aberrations, the retinal image will have a good quality.^[28] For most people, the internal optics aberrations have compensation effect on the corneal aberrations.^[20] Any surgery that change corneal aberrations or internal optics aberrations will change CF. The IOL implantation will inevitably lead to changes in corneal aberrations or internal optics aberrations, resulting in CF changes. V4c ICL has 1 more central hole than V4 ICL. In this study, we found that the compensation rate of ICL V4c and ICL V4 groups had no significant difference for either LOA or HOA. Thus, we speculated that after ICL V4c implantation the patients will not notice visual quality problems caused by the central hole, because the hole with a diameter of 0.360 mm is so small that the visual impairments such as glare have no clinical significance.

In summary, ICL implantation to treat high myopia using Visian ICL V4c or Visian ICL V4 achieved similar efficacy, but Visian ICL V4c caused more HOA, especially spherical aberration, but there was no difference in CF and subjective visual quality. Therefore, the presence of the central hole of Visian ICL V4c has no significant effect on visual quality.

Acknowledgments

This study was supported by the Clinical Research Fund of Central South University, Changsha, Hunan, China (No. 2013L07) and National Scientific Foundation of China (No. 81400400).\

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