• Clinical Research •

Early clinical outcome with lens position adjustment following implantable collamer lens surgery

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Abstract

• **AIM:** To observe early clinical outcome with lens position adjustment following the implantable collamer lens (ICL) surgery.

• **METHODS:** Sixty patients were selected for this retrospective study. One eye from each patient received Toric ICL for astigmatism correction, and the other received non-astigmatic ICL surgery using horizontal position. Patients with higher postoperative arch height were selected, and their non-astigmatic eye clinical outcome were observed after ICL surgery at 1wk, 1, and 3mo. The clinical measurements included uncorrected visual acuity (UCVA), intraocular pressure (IOP), refractive state, corneal endothelium cell count, and arch height. Three months later, the ICL in each patient's non-astigmatic eye was adjusted to the vertical from the horizontal position. The results were compared before and 1wk, 1, and 3mo after adjustment.

• **RESULTS:** UCVA and IOP were significantly reduced 1wk after position adjustment compared to 1wk after ICL implantation (P<0.05). The patients demonstrated significantly reduced arch height and corneal endothelium cell count 1wk, 1, and 3mo after adjusting position compared to 1wk, 1, and 3mo after ICL implantation (P<0.05). However, there was no significant difference in refraction between 1wk, 1, and 3mo after ICL implantation and position adjustment (P>0.05).

• **CONCLUSION:** Early positioning adjustment post-phakic ICL implantation can benefit patients with adjusted arch height or higher IOP. Despite the good clinical effects, the doctors should pay attention to the potential for adverse effects on UCVA and corneal endothelium cells following early position adjustment after posterior chamber phakic ICL implantation.

• **KEYWORDS:** implantable collamer lens; myopia; lens positional adjustment; arch height; intraocular pressure

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INTRODUCTION

Surgery is currently a common way to correct myopia. There are two main types of surgery: corneal refractive surgery (CRS) and intraocular lens implantation[1]. CRS is a safe and effective way to correct moderate and low refractive errors with stable and predictable effects[2-3]; however, limitations exist. For instance, patients with high myopia may develop dry eye syndrome, refractive error regression, subepithelial corneal haze, and corneal dilation post-CRS[4-5]. Additionally, CRS is unsuitable for some patients with thin corneas, keratoconus, and dry eye disease[6].

The use of implantable collamer lenses (ICLs) was recently popularized because of its high refractive accuracy and postoperative visual improvement[7-8]. It is an excellent option for patients with high myopia. After ICL surgery, patients have better best-corrected visual acuity (BCVA), predictability of postoperative actual refractive error, and stability of implantation compared to CRS[9].

The arch height is the distance between the anterior and posterior surfaces of the ICL[10]. An appropriate arch height is important for ensuring the success of ICL placement. Too-high or too-low arches will negatively affect intraocular anatomy. An arch that is too low will create friction between the posterior and anterior lens surfaces, potentially inducing cataract formation. Conversely, an arch that is too high may cause narrowing of the anterior chamber angle, disrupting

aqueous humor circulation[11-12]. Most ciliary sulci are vertically elliptical, with a longer vertical than horizontal diameter[13]. The same-sized ICL can achieve different arch heights depending on its implantation direction[14]. Therefore, we can modify the ICL's implantation direction to change the arch height; however, predicting the postoperative arch height under ideal conditions remains challenging due to the many factors affecting arch height.

This study utilized a retrospective analysis to investigate the clinical efficacy of adjusting the ICL position after implantation in patients with slightly higher arch heights.

SUBJECTS AND METHODS

Ethical Approval This study was approved by the Ethics Committee of Aier Eye Hospital, Tianjin University (2020KY(L)-45). Informed consent was waived due to the retrospective nature of the study.

Study Subjects This was a retrospective study comprised 60 patients (30 males and 30 females) admitted to our hospital between 2017 and 2020 with high arch heights after ICL (V4C) implantation. One eye was implanted with a Toric implantable contact lens, and the other with a non-astigmatism ICL implanted horizontally.

The inclusion criteria for the study were: 1) stable refractive state over the past 2y and desire to stop using eyeglasses; 2) completion of regular preoperative exams and conformance with surgical indications and requirements; 3) higher arch height (>800 μm) in the non-astigmatic eye after astigmatism correction, horizontal diameter of cornea ≤11.2 mm and ≥11.1 mm; 4) patients with regular follow-up records.

We excluded patients with 1) surgical history or systemic contraindications; 2) not ICL (V4C) implantation; 3) ocular diseases such as cataracts, keratoconus, and corneal haze that affected vision; 4) incomplete clinical data.

Surgical Method One eye of each enrolled patient was implanted with a non-astigmatic ICL V4C. The STAAR Surgical Online Calculation & Ordering System was utilized to calculate the necessary power and version (ranging from 12.1 to 13.7 mm) of ICL V4C. All surgeries were performed by the same experienced physician who had already completed more than 1000 surgeries. All ICLs were implanted horizontally into the ciliary sulcus through a temporal clear corneal limbus incision. The patients were administered levofloxacin (1–2 drops *q2h*, 8 times daily; Jiangsu Hanchen Pharmaceutical Co., Ltd., China) 3d before surgery. Tropicamide eye drops were used one hour before surgery for full mydriasis. During surgery, proparacaine hydrochloride eye drops were given twice to achieve surface anesthesia. Gentamicin saline was used to rinse the conjunctival sac, and an auxiliary incision was made at 12 o'clock on the upper corneal limbus with a 15-degree knife. An anterior chamber was punctured and appropriately injected with methylcellulose. A 3.0-mm tunnel knife was used to make a tunnel incision at 9 o'clock on the clear corneal limbus. Then, a preloaded ICL V4C (STAAR, Switzerland) was implanted into the anterior chamber through an injector. The ICLs were adjusted horizontally into the ciliary sulcus. After molding the anterior chamber, a watertight suture was placed on the incision. Antibiotics, hormones, intraocular pressure (IOP)-lowering medications, and artificial tears were administered for 1mo postoperatively.

Positional Adjustment of ICL Three months post-ICL implantation, the ICL V4C implants were adjusted from the horizontal to the vertical position in 60 patients with arch heights >800 μm. Antibiotics, hormones, anti-IOP drugs, and artificial tears were administered for 1mo after surgery.

Outcome Measure The uncorrected visual acuity (UCVA), refractive error, IOP, corneal endothelium cell count, and arch height were measured before, 1wk, 1 and 3mo post-ICL implantation, and 1wk, 1 and 3mo after ICL position adjustment. UCVA and BCVA were measured using a standard logarithmic visual acuity chart with decimal notation. The refractive error was determined using an auto-refractometer. The IOP was measured using a noncontact tonometer. Corneal endothelial cells were counted using an endothelial cell counter (TOMEY, Japan). The arch height was measured using a Pentacam anterior segment analyzer (OCULUS, Germany).

Statistical Analysis All data were analyzed using SPSS 26.0. The measurement data was detected with normality test. Standard deviations (SD) were used for normally distributed variables, while medians (M) and interquartile range (IQR) were used for non-normally distributed variables. A two-factor repeated measures analysis of variance tests were performed for between-group comparisons at different time points, followed by an LSD post hoc test for pairwise comparisons. $P<0.05$ indicates a significant difference.

RESULTS

Uncorrected Visual Acuity As shown in Table 1, there were no significant within-group differences in UCVA ($P>0.05$); however, there were significant between-group changes in UCVA over time ($P<0.05$). Pairwise comparisons showed that patients demonstrated decreased UCVA 1wk post-ICL implantation ($P<0.05$).

There was no significant between-group or within group differences in refractive error ($P>0.05$; Table 2). The pairwise comparison also showed no significant difference in the refractive states of patients who received ICL implantation and had their lens position adjusted after 1wk, 1, and 3mo ($P>0.05$).

Arch Height Significant between- and within-group differences in arch height ($P<0.05$) were observed in patients who underwent ICL V4C implantation and position adjustment. The between-group differences in refraction

Table 1 UCVA upon ICL implantation and position adjustment

Items	Adjusting position, M (IQR)		*F*	*P*
	Before	After		
1wk	1.2 (1, 1.2)	1 (1, 1.2)	-2.601	0.009
1mo	1 (1, 1.2)	1 (1, 1.2)	-0.347	0.728
3mo	1 (1, 1.2)	1 (1, 1.2)	-1.147	0.251
Intergroup			0.788	0.377
Time			2.211	0.112
Intergroup×time			4.012	0.019

UCVA: Uncorrected visual acuity; ICL: Implantable collamer lens.

Table 2 Refractive error after ICL implantation and position adjustment

Items	Adjusting position, M (IQR)		*F*	*P*
	Before	After		
1wk	0.25 (-0.25, 0.25)	0.25 (-0.25, 0.5)	-0.485	0.628
1mo	0.25 (-0.25, 0.5)	0.25 (-0.25, 0.5)	-0.042	0.967
3mo	0.25 (-0.25, 0.25)	0.25 (-0.25, 0.5)	-0.45	0.653
Intergroup			0.180	0.672
Time			0.161	0.851
Intergroup×time			0.142	0.868

ICL: Implantable collamer lens.

also changed significantly over time (P<0.05). A pairwise comparison revealed significant differences in patients' arch heights 1wk, 1, and 3mo post-ICL implantation and position adjustment (P<0.05). After position adjustment, the arch height reached an appropriate range of 250–750 μm (Table 3).

Corneal Endothelium Cell Count There were no significant between- or within-group differences in cell counts over time (P>0.05). However, pairwise comparisons revealed significant changes in cell counts 1wk, 1, and 3mo post-ICL lens implantation and position adjustment (P<0.05; Table 4).

Intraocular Pressure There were no significant between-group differences in IOP over time (P>0.05). However, significant within-group differences were noted over time (P<0.05). Further analysis revealed that patients' IOP values were lower 1wk after ICL implantation compared to 1wk after lens position adjustment (P<0.05). Moreover, there was no significant difference in IOP between patients after receiving ICL implantation and adjusting the lens position for 1 and 3mo (P>0.05; Table 5).

DISCUSSION

ICL implantation is used to treat patients with ultrahigh myopia and refractions of 9.5–21.5 D, expanding the number of patients appropriate for surgery. More importantly, ICL implantation preserves the cornea's relative integrity, optical properties, and regulatory functions[15], while producing predictable and (if needed) reversible results to ensure postoperative visual quality[16], while exerting few effects on IOP. Therefore, ICL implantation is an increasingly popular option for patients and doctors.

Table 3 Arch height after ICL implantation and position adjustment

Items	Adjusting position, μm, M (IQR)		*F*	*P*
	Before	After		
1wk	965 (915, 1050.5)	650 (526.5, 752)	-6.736	<0.001
1mo	923 (862, 1004.5)	618 (506.5, 722)	-6.736	<0.001
3mo	936 (852.5, 1006.5)	628 (514, 722)	-6.680	<0.001
Intergroup			307.163	<0.001
Time			207.713	<0.001
Intergroup×time			10.448	0.001

ICL: Implantable collamer lens.

Table 4 Corneal endothelium cell count after ICL implantation and position adjustment

Items	Adjusting position, cell/mm^2, mean±SD		*F*	*P*
	Before	After		
1wk	2891.2±491.97	2774.28±458.5	11.022	<0.001
1mo	2891.56±490.02	2774.18±466.52	9.759	<0.001
3mo	2877.03±489.87	2772.8±465.63	9.325	<0.001
Intergroup			1.597	0.209
Time			2.893	0.057
Intergroup×time			1.938	0.146

ICL: Implantable collamer lens.

Table 5 IOP after ICL implantation and position adjustment

Items	Adjusting position, mm Hg, M (IQR)		*F*	*P*
	Before	After		
1wk	16 (14.5, 16)	15 (13, 17)	-2.855	0.004
1mo	14 (13, 16)	14 (13, 16)	-1.898	0.058
3mo	14 (13, 16)	14 (12, 16)	-1.745	0.081
Intergroup			1.156	0.284
Time			22.108	<0.001
Intergroup×time			0.702	0.496

IOP: Intraocular pressure; ICL: Implantable collamer lens.

ICL implantation is constantly improving in pursuit of safer surgical procedures that produce better outcomes and reduce the likelihood of postoperative complications or the need for rescue or revision surgeries. We retrospectively analyzed the early clinical effects of ICL implantation with subsequent positional adjustments. A shallow arch height cause ICL implants to shift during the post-surgery period, potentially resulting in poor vision quality. Conversely, a too-high arch can cause serious complications such as secondary glaucoma[17]. Arch height is a critical factor that can determine a surgery's success. Research has shown that an optimal arch height is between 250 and 750 μm. We found that adjusting the ICL's position significantly improved patients' IOP and arch height, especially when the arch height was within the appropriate range of 250–750 μm. This adjustment had no negative refractory effects. Therefore, an appropriate and ideal arch height can be obtained by adjusting the position of the ICL, which can help ensure the success of the surgery while minimizing the risk of complications.

Generally, the ICL is placed into the eyes in a horizontal position; however, in some special cases, for instance, when

a horizontally placed ICL induces a slightly high arch height, the lens can be adjusted to the vertical position to reduce the arch height. Affected by the anatomical structure of the ciliary sulcus, the diameter of sulcus to sulcus (STS) in the vertical direction is slightly longer than that of the horizontal direction[18]. Previous studies have claimed that post-ICL implantation arch height gradually decreases with time[19-20]. Some studies found that arch height tends to stabilize 3mo post-ICL implantation[21]; however, others found that arch height continues to decrease until 1y after surgery[20]. We additionally discovered that, patients with early horizontally placed ICL, arch heights (>800 μm) decreased over time, stabilizing by approximately 3mo. Moreover, after ICL adjustment, the IOP tended to decline compared with measures taken pre-adjustment. Briefly speaking, ICL adjustment opens the anterior chamber angle, contributes to the circulation of aqueous humor, and achieves a new balance between the generation and discharge of aqueous humor.

Post-ICL implantation, patients experienced reductions in corneal endothelial cell counts and UCVA, consistent with Faron *et al*'s[22] research. ICL implantation partially inhibited the iris's blocking effect. This caused the lens to approximate the corneal endothelium, but without the protection of sodium hyaluronate, damaging the corneal endothelium cells and affected UCVA. Therefore, the negative impacts of ICL implantation on corneal endothelium cells and UCVA must be considered.

In contrast, Goukon *et al*[23] reported that ICL did not reduce corneal endothelial cells even 2y postoperatively. The ICL V4C implant has a central pore that allows for the free circulation of aqueous humor, reducing corneal endothelial cell loss and cataracts[24]. A Meta-analysis confirmed the safety and better visual quality enjoyed by the ICL group (in comparison to a small incision lenticule extraction group), affirming the procedure's efficacy for correcting high myopia[25]. However, the safety and side effects of ICL still require further large-sample research.

Of course, our results should be carefully considered alongside specific study limitations. The sample size in this study was relatively small, which may have produced bias within the statistical results. Additionally, the follow-up survey was restricted to within 3mo, rather than continued for a longer time. Therefore, high-quality and well-powered clinical trials with extended follow-up periods are required to enhance the accuracy and credibility of these results and provide a more efficient method for further clinical treatment.

In conclusion, patients with high arches and IOP, caused by early horizontal ICL placement, are candidates for vertical positional adjustment. The arch height and IOP decrease significantly within 1wk to 1mo post-adjustment. The arch height will continue to decrease until it stabilizes within approximately 3mo. Therefore, in certain cases where the corneal diameter reaches the critical value, vertical placement of the ICL is more likely to achieve the ideal arch height and IOP. Despite the positive early clinical impact of ICL implantation, methods are needed to minimize the adverse effects on corneal endothelial cells and UCVA.

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