• Clinical Research •

# Posterior chamber phakic intraocular lens adjustment-causes and complications: a retrospective cohort study

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Received: 2024-05-13 Accepted: 2024-11-28

## Abstract

● **AIM:** To evaluate the visual outcomes of implantable collamer lenses (ICLs) and identify the possible risk factors for ICL axis misalignment, and consequently, repositioning, explanting, or exchanging at a specialized eye hospital in Saudi Arabia.

● **METHODS:** The medical records of 813 eyes with different refractive errors corrected with ICL implantation were identified and included in this single-arm retrospective cohort study. The following data were collected: demographic characteristics, primary diagnosis, preoperative refraction, anterior chamber depth (ACD), white-to-white (WTW) measurement, endothelial cell density (ECD), and axial length. Patients' satisfaction and complaints, and their postoperative refraction, vault depth, and axis alignment with the preoperative target, were reviewed during the postoperative period. Collectively, these data were correlated with symptomatic axis rotation and the need for repositioning, explantation, or exchange due to high or low ICL vaults.

● **RESULTS:** Of 813 eyes, 27 (3.32%), 13 (1.59%), and 11 (1.35%) required ICL repositioning, ICL explantation only without exchange, and ICL explantation with the placement of a new ICL, respectively. The mean follow-up period was 37.5mo. The main cause of explanation or exchange was incorrect WTW measurement in seven (29.17%) eyes, followed by high vault in four (16.56%) eyes. ICL repositioning was required in 27 (3.32%) eyes with considerable rotation. Only 2 (0.24%) eyes developed cataracts that required ICL removal, and retinal complications were reported in 7 (0.86%) eyes. Long-term glaucoma and corneal decompensation were not observed in this cohort.

● **CONCLUSION:** With a high safety profile and reversibility, ICL implantation is a good alternative to corneal-based refractive surgery in eyes unsuitable for laser vision correction. The rate of secondary procedures in our study was 6.26%. Old age is a risk factor for secondary surgical interventions in the repositioning group, whereas abnormal vault and toric ICL rotation in the explantation group necessitated subsequent surgical procedures. Overall, ICL implantation demonstrates a good efficacy index and safety profile in patients with diverse refractive errors.

● **KEYWORDS:** lens-based surgery; refractive error correction; complications; myopic correction; hyperopic correction

**DOI:10.18240/ijo.2025.05.14**

**Citation:** Alarfaj G, Helayel HB, AlSubaie M, Hariri J, Alzaher F, Khan O, Al-Jindan M, AlHabash A, Sulaimani NM. Posterior chamber phakic intraocular lens adjustment-causes and complications: a retrospective cohort study. *Int J Ophthalmol* 2025;18(5):883-888

## INTRODUCTION

Refractive errors are the primary cause of correctable visual loss at both global and local levels[1-2]. Although glasses are mainly used to correct refractive errors, many refrain from using them because of discomfort, poor quality of vision, or cosmetic reasons[3]. Contact lenses are another conservative modality with superior visual quality compared to spectacles. However, in some instances, complications, such as dryness, papillary conjunctivitis, and microbial keratitis, can lead to intolerance and discontinuation[4]. Refractive surgeries are of two types: laser vision correction (LVC), such as photorefractive keratectomy (PRK) and laser-*in situ* keratomileusis (LASIK), or lens-based procedures, such as phakic intraocular lens implantation or clear lens extraction

with implantation of a premium intraocular lens[5]. The main indication for phakic intraocular lens implantation includes eyes deemed unsuitable for LVC, such as those in patients with high refractive errors, thin corneas, and off-label keratoconus. In these previously described group of patients, implantable collamer lens (ICL) implantation, being one of the available phakic intraocular lens models, has high efficacy, safety, and patient satisfaction, which is attributed to rapid visual recovery, superior visual outcomes, better visual quality, and fewer dry eye symptoms than LVC[6-8]. However, ICL implantation may be associated with certain complications[9]. Therefore, this study aimed to identify the complications of this particular group of phakic intraocular lenses and estimate the rate and possible causes of their repositioning, explantation, and exchange.

## PARTICIPANTS AND METHODS

**Ethical Approval** This retrospective study was approved by the Institutional Review Board of Dhahran Eye Specialist Hospital (DESH), and conducted in accordance with the tenets of the Declaration of Helsinki. Informed consent taken for all patients before surgical procedure.

Between January 2014 and December 2019, medical records of 813 eyes with myopia, hyperopia, and refractive errors in ectatic disorders and post-keratoplasty treated with ICL implantation at the DESH were reviewed. Demographic, biometric, preoperative, and postoperative data were also collected. The manufacturer (STAAR Surgical) used a modified vertex formula to calculate the ICL implant power. The size was determined by measuring the horizontal corneal diameter (CD) using calipers. Anterior chamber depth (ACD) and corneal thickness were measured using a rotating Scheimpflug camera (Pentacam, Oculus, Inc., Lynnwood, WA). An IOL Master 500 (Carl Zeiss Meditec, Germany) was used to measure both the axial length and white-to-white (WTW). Patients with posterior segment lesions, such as breaks or holes, observed during a routine clinical examination are usually referred to a retina specialist for clearance and barrier laser treatment if needed before the surgery.

**Surgical Technique and Follow-up** All patients with hyperopia underwent neodymium-yttrium aluminum garnet laser peripheral iridotomy 2wk prior to surgery. All surgeons in this cohort used a standard technique for ICL implantation. Pupils were dilated using tropicamide 1%, cyclopentolate 1%, and phenylephrine 2.5% 1h before surgery. In patients requiring toric ICLs, the 0 and 180 axes are usually marked while they are seated in the holding area.

The toric ICL axis is usually identified using a marked Sinsky and Mendaze gauge, according to the manufacturer's instructions. A 3.0 mm clear corneal incision was made after injection of 1% sodium hyaluronate into the anterior chamber (AC) through an initial paracentesis, and the ICL was injected into the AC using an injector cartridge (STAAR Surgical). The ICL haptics were then pushed behind the iris. The ICL manipulator aids in tucking the ICL haptics horizontally. The correct ICL axis was ensured. Finally, the viscoelastic surgical device was washed with a balanced salt solution using an irrigation-aspiration Simcoe cannula. A myotic agent 1:100 acetylcholine chloride intraocular solution (Miochol-E; Novartis Pharma- ceuticals Corporation, Basel, Switzerland) was injected, and the wound was examined for water tightness following stromal hydration. After the surgery, patients were prescribed 0.5% moxifloxacin for 7d and 0.1% prednisolone acetate drops four times daily, tapered gradually over 2wk.

Patients were then examined after 2h and followed up at 1d, 1wk, and at 1, 3, 6, 12, and 24mo postoperatively. The follow-up frequency is determined based on the patient's clinical course. All patients were followed-up for at least 12mo. Routine measurements before and after the surgery include decimal of uncorrected distance visual acuity (UCVA), decimal of corrected distance visual acuity (CDVA), manifest refraction (spherical equivalent, SE), intraocular pressure (IOP; pneumatonometry, Reichert model 30, USA), endothelial cell density (ECD; non-contact specular microscopy, SP-2000P, Topcon Corporation, Japan), and standard slit-lamp biomicroscopic and funduscopic examinations were performed before and after the surgery. In addition, ultrasound biomicroscopy (UBM; Quantel Medical, France) or the Visante anterior segment optical coherence tomography (AS-OCT; Carl Zeiss, Germany) were used to measure the vault height (distance between the anterior surface of the crystalline lens and the posterior surface of the ICL) postoperatively in patients suspected of having either low or high vault on clinical examination[10]. The vault was clinically assessed by comparing corneal thickness to the space between ICL and crystalline lens[11]. Using AS-OCT, the ICL vault is defined as either a low (≤250 μm) or high (≥1000 μm)[12].

**Statistical Analysis** Frequencies and percentages were calculated to describe the categorical variables. Continuous variables were described as means and standard deviations. The Chi-square test and Student's *t*-test were used to correlate outcomes with categorical and continuous data, respectively. A *P*-value of <0.05 indicated statistical significance. All analyses were performed using the SPSS software (version 26.0; SPSS Inc., Chicago, Illinois, USA).

## RESULTS

Between 2014 and 2019, ICL implantation was performed on 813 eyes of 453 patients at our institute. The mean age of the participants at the time of ICL implantation was 28.76±6.67y, and 258 (56.95%) patients were women. Patient demographics and baseline preoperative biometric measurements were

summarized in Table 1. The most common indication for ICL implantation in our cohort was high myopia in 521 (64.08 %) eyes, followed by ectatic corneal disorders in 164 (20.7%) eyes. Indications for ICL implantation were listed in Table 2. Compared to the preoperative CDVA of 0.18±0.21 logMAR, the mean postoperative UCVA was 0.14±0.73 logMAR, indicating improvement. The postoperative clinical examination results were summarized in Table 3.

During the postoperative period, most patients [758 (93.23%)] reported no visual complaints. Blurred or decreased vision was reported by 25 patients (3.07%), and 17 (2.09%) patients complained of glare.

A clinical assessment of the ICL vault was performed at each postoperative visit. The vault was good in 740 (91.02%) eyes, high in 55 (6.77%) eyes, and low in 18 (2.21%) eyes. In addition, the ACD and the ICL vault were not associated. The mean preoperative ACD in the eyes with a normal ICL vault was 3.4±1.8 mm, and 3.1±0.3 mm in the eyes confirmed to have either a low or high vault ($P$=0.2).

Elevated IOP was observed in 24 (2.95%) eyes. The elevation was temporary and controlled with only topical drops in 20 (2.46%) eyes until complete resolution; however, surgical intervention, such as AC washout or ICL explantation, was required in four (0.49%) eyes.

Cataract formation was observed in only 2 (0.24%) eyes, necessitating ICL removal. Posterior segment complications such as retinal detachment (RD) occurred in 7 (0.86%) eyes. The mean time between ICL and RD was 21.67mo, ranging between 1 and 48mo. Corneal decompensation was not reported in any.

Of the 813 eyes included in this study, toric ICL was implanted in 733 (90.0%) eyes, ICL repositioning, removal, and exchange were performed in 27 (3.32%), 13 (1.59%), and 11 (1.35%) eyes, respectively.

Toric ICL rotation is the primary indication for ICL repositioning. The rotation was observed in 37 (4.55%) eyes. The mean degrees of rotation was 20°±8.5° (range 10°–35°). We found that increased age ($t$-test, $P$=0.01) at the time of ICL implantation was associated with the need for ICL repositioning (mean age 31.7±6 *vs* 28.4±7.7), and this correlation was statistically significant. Of the 27 eyes that required ICL repositioning, 24 (88.9%) had a good vault; only three (11.1%) eyes were confirmed to have a low vault.

Incorrect WTW measurements was the primary reason that necessitated ICL explantation in seven (29.17%) eyes. Examination of the vault position among eyes requiring ICL explantation or exchange revealed a normal, high, and low positions in 8 (33.33%), 10 (41.67%), and 6 (25.00%) eyes, respectively. Abnormal vault positions were reported in 16 of 24 eyes, indicating that the association between abnormal vault position and the need for ICL explantation or exchange was statistically significant (Chi-square test, $P$<0.001).

**Table 1 Demographics and refractive data at baseline**

| Characteristics | Value |
|---|---|
| Age, y (mean±SD) | 28.76±6.67 |
| Gender, *n* (%) | |
| Female | 258 (56.95) |
| Male | 195 (43.05) |
| Preoperative UCVA (logMAR) | 1.26±0.54 |
| Preoperative CDVA (logMAR) | 0.18±0.21 |
| Preoperative sphere (D) | -7.5±5.1 (-24 to 8) |
| Preoperative cylinder (D) | -2.3±1.5 (-7 to 4.5) |
| Spherical equivalent manifest refraction (D) | -8.36±5.86 |
| Preoperative ACD (Pentacam), mm | 3.34±1.60 |
| WTW (Caliper), mm | 11.72±0.56 |
| WTW (IOL Master500), mm | 12.188±0.44 |
| Axial length (mm) | 26.2±3.35 |
| Preoperative ECD (cells/mm$^2$) | 2793.86±1482.15 |

SD: Standard deviation; UCVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity D: Diopters; ACD: Anterior chamber depth; WTW: White-to-white; ECD: Endothelial cell density.

**Table 2 Indications for ICL implantation**

| Preoperative diagnosis | Frequency | Percentage, % |
|---|---|---|
| High myopia | 521 | 64.08 |
| Ectatic disorders | 164 | 20.7 |
| High astigmatism | 37 | 4.55 |
| Post keratoplasty | 34 | 4.18 |
| Hyperopia | 24 | 2.95 |
| Not fit for LVC | 23 | 2.83 |
| Mixed astigmatism | 6 | 0.74 |
| Post LVC | 4 | 0.49 |
| Total | 813 | 100.0 |

ICL: Implantable collamer lenses; LVC: Laser vision correction.

**Table 3 Results of postoperative clinical examination**

| Postoperative | Mean | SD |
|---|---|---|
| UCVA, logMAR | 0.14 | 0.73 |
| Refraction sphere | -0.47 | 1.27 |
| Refraction cylinder | 1.15 | 1.07 |

SD: Standard deviation; UCVA: Uncorrected distance visual acuity.

## DISCUSSION

ICL implantation is an alternative procedure to LVC in patients with high refractive errors and suspicious corneas, for whom cornea-based surgeries are relatively challenging. Herein, we aimed to examine our ICL experience in terms of estimating the rate and exploring the risk factors for repositioning, explantation, and exchange.

Several complications have been reported following ICL implantation, including corneal decompensation due to decreased ECD. The normal loss of ECD in a healthy

individual is approximately 0.6% per year[13]. The rate of ECD decline reaches up to 6.4% during the first year following any intraocular surgery, and then declines at a rate of 1.2% annually thereafter. The sustained reduction in ECD can necessitate ICL removal in some patients, especially when the ECD falls below 1500 cells/mm$^2$[12]. ICL implantation has also been associated with an increased risk of open-angle and angle-closure glaucoma in eyes with high myopia and hyperopia[14-15]. Anterior subcapsular cataracts can develop after ICL implantation, particularly in patients with high myopia and in older age groups[12]. RD is a common complication among individuals with high myopia. Even without intraocular surgery, the risk can be three times higher in these eyes than in those with low myopia. The incidence further increases after ICL implantation[16-18].

Owing to the relative simplicity of the implantation technique, the complication rate in our study was minimal and within the reported range. Proper preoperative measurement is essential to reduce complications caused by an abnormal vault depth, such as increased IOP or cataracts[19]. Horizontal WTW in our study was primarily measured using calipers at the slit lamp, as per the STAAR surgical recommendation. However, this technique is subject to inter-observer differences. Nevertheless, no technique is superior to the others in terms of proper ICL sizing. Formulas and nomograms for ICL sizing and devices for sulcus-to-sulcus measurement, such as swept-source AS-OCT (Pentacam, Oculus) and an autorefractor machine, have been previously documented[19-20]. At each postoperative visit, the depth of the vault was measured using a slit lamp by comparing the depth of the vault with the corneal thickness. An AS-OCT device can be used to obtain an accurate measurement of the ICL vault when an abnormal vault, high IOP, or anterior capsular cataract changes are suspected. Based on the clinical examination and AS-OCT findings, most patients (91.02%) in our study had a normal vault depth. The traditional horizontal measurement of WTW is a reliable method for determining the size of an ICL with a high degree of accuracy. Compared to previous studies, our data showed a lower incidence of low ICL vault among our patients (2.21%), whereas high ICL vault was more prevalent (6.77%)[10-12]. Although Lee *et al*[10] reported that several factors influence postoperative ICL vaulting, among which preoperative ACD, preoperative pupil size, and preoperative axial length were considered in their study. However, they included only those patients receiving 12.6-mm V4c ICLs and having optimal vaulting between 250 and 750 μm. Additionally, the vault value is affected by the horizontal WTW measurement, ACD, SE, patient age, and crystalline lens rise (CLR)[6,20-21]. Considering these factors is essential to the development of new ICL-sizing formulas. Complications such as cataracts and glaucoma may develop after ICL implantation in some patients, especially those with abnormal postoperative vault values[3]. The two main underlying mechanisms for cataract formation in patients with ICL are as follows: 1) contact between the ICL and the anterior lens surface, or 2) changes in the flow of intraocular fluid and a decrease in nutritional supply to the crystalline lens[22]. In our cohort, explantation due to cataract formation was reported in only two eyes (0.24%). Because of the wider use of the central port design that restores the physiological flow of aqueous humor, which leads to a decrease in visually significant cataracts, our study findings were consistent with those of the recently published articles[23-25]. Ocular hypertension and long-term glaucoma are major complications after ICL implantation. Our results of 2.95% were within the range of reported data (0.8%–26.2%)[26-27]. RD is another concern in eyes undergoing ICL implantation, particulary in highly myopic globes owing to their predisposition for spontaneous RD. The rate of RD in our study was 0.86%; the rate varies among different studies between 0.32% and 2.07%[16,28-31].

As previously reported, the incidence of ICL repositioning and the rate of ICL exchange were 3.32% and 1.35%, respectively[9,12]. The mean degree of ICL rotation in the literature is 2.68°–6.96°[32-35]. However, the mean was higher (20°±8.5°, range 10°–35°) in 4.55% of patients in our study. This could be explained by the fact that only symptomatic cases were assessed to confirm rotation.

Among patients who underwent ICL repositioning, older patients had a higher risk of ICL rotation, which could be attributed to thickening of the anterior lens capsule with increasing age, thereby predisposing to a lower ICL vault[36]. Furthermore, the lower ICL vault can be related to an undersized ICL and axis rotation[37]. To our knowledge, studies demonstrating a direct association between ICL repositioning and increasing age are lacking. A possible explanation could be racial and ethnic differences that can affect the proper sizing of ICL, such as WTW measurements[38].

Our study findings elucidate that abnormal ICL vault and off-axis toric ICL rotation were the potential risk factors for ICL explantation in our population, especially in patients who complained of postoperative vision reduction. In contrast, glare complaints were not associated with an increased risk for ICL removal in our patients. In two explantation studies, Alió *et al*[39] and Alhamzah *et al*[40] stated other visual complaints such as glare led to explantation in 1.39% and 3%, respectively. The lower rate of ICL explantation among patients with a history of glare could be related to the conservative approach offered to the patients, such as reassurance or topical drops, such as brimonidine, to constrict the pupil.

Our study had several limitations. First, the retrospective study design affected the data acquisition of parameters, such as

postoperative CDVA. Additionally, routine examination of the toric ICL axis and refractive astigmatism was not performed in all patients except those with visual complaints or headache; therefore, we could not estimate the true prevalence and magnitude of ICL rotation and the actual timing of the rotation, whether the axis was placed off-axis intraoperatively or occurred during the postoperative period. In addition, this single-center study included cases planned and performed by multiple surgeons, which might have affected our data, especially the preoperative measurement of the horizontal WTW using a caliper. Nevertheless, the large sample size, long study duration, and long follow-up period contributed to the strengths of our study.

In conclusion, ICL implantation is a reversible procedure and a safe alternative approach for patients in whom corneal-based refractive surgery is not recommended. A proper and accurate preoperative assessment is necessary to reduce the rates of ICL repositioning, exchange, or explantation. Consequently, better assessment tools are imperative to ensure that the ICL size is accurately determined without relying on human error.

**ACKNOWLEDGEMENTS**

**Authors' Contributions:** All authors contributed to the study conception and design. Conceptualization: Alarfaj G, Helayel HB, Alzaher F, Sulaimani NM; Methodology: Hariri J, AlSubaie M, Al-Jindan M, Alzaher F, Alarfaj G; Formal analysis and investigation: Helayel HB, Alarfaj G; Writing—original draft preparation: Khan O, Alarfaj G; Writing—review and editing: Alarfaj G, Helayel HB, AlSubaie M, Al-Jindan M, Sulaimani NM; Resources: Alarfaj G, Helayel HB, Alzaher F. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Conflicts of Interest: Alarfaj G,** None; **Helayel HB,** None; **AlSubaie M,** None; **Hariri J,** None; **Alzaher F,** None; **Khan O,** None; **Al-Jindan M,** None; **AlHabash A,** None; **Sulaimani NM,** None.

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