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## Comparative Outcomes and Indications of Phakic Implantable Collamer Lens (ICL) Exchange or Explantation in Keratoconus versus Non-Ectatic Eyes at a Tertiary Eye Hospital in Iraq

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### Порівняльні результати та показання до заміни або видалення факічної імплантованої коламерної лінзи (ICL) при кератоконусі та на неектатичних очах в офтальмологічній лікарні третього рівня в Іраку

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#### Abstract

**Objective.** This study aimed to compare the indications, timing, and clinical outcomes of phakic implantable collamer lens (ICL) exchange or explantation between eyes with keratoconus and eyes without keratoconus or other corneal ectasia (non-ectatic eyes), and to evaluate factors associated with the need for secondary ICL intervention, at a tertiary eye hospital in Iraq.

**Methods.** This retrospective record review included ICL (V4b) procedures performed between January 2022 and January 2024. Among 200 implanted eyes, 25 eyes (12.5%) underwent secondary surgery and were included for group comparison: keratoconus group (n=10) and non-ectatic group (n=15). Clinical data included visual acuity, refraction, intraocular pressure, endothelial cell density, corneal parameters,

and vault. Comparative analyses were performed between groups, with  $p < 0.05$  considered statistically significant.

**Results.** In the keratoconus group, ICL exchange occurred in 5/10 (50.0%) and explantation in 5/10 (50.0%); in the non-ectatic group, exchange occurred in 8/15 (53.3%) and explantation in 7/15 (46.7%). The primary indications for exchange/explantation differed between groups. In keratoconus eyes, indications were vault-related issues (7/10; 70.0%), residual refractive concerns (2/10; 20.0%), and patient dissatisfaction (1/10; 10.0%). In non-ectatic eyes, indications were vault-related issues (9/15; 60.0%), cataract (2/15; 13.3%), elevated intraocular pressure (2/15; 13.3%), refractive concerns (1/15; 6.7%), and patient dissatisfaction (1/15; 6.7%).

**Conclusion.** ICL exchange or explantation occurred in 12.5% of implanted eyes in this cohort. Vault-related indications were the most common reason for secondary intervention in both groups, while cataract and elevated intraocular pressure were observed only in the non-ectatic group. These findings support careful sizing/vault assessment and structured follow-up in eyes undergoing ICL implantation.

**Keywords:** ICL exchange, lens removal, implantable collamer lens, keratoconus, cornea

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#### Introduction

The implantable collamer lens (ICL), a type of posterior chamber phakic intraocular lens, has become a widely used option in refractive surgery for correcting myopia, hyperopia, and astigmatism [1]. Despite its strong track record for safety and effectiveness, complications can oc-

asionally occur. These include low-grade inflammation or the formation of anterior subcapsular cataracts, often linked to surgical factors such as laser energy exposure or accidental contact with instruments [2]. Among the leading reasons for ICL removal or replacement, incorrect vault size remains the most common, with cataract formation following closely behind [2].

In patients with keratoconus (KC) – a complex, progressive corneal thinning disorder that typically emerges in the second or third decade of life – ICL implantation has proven to be a valuable treatment option. It can notably enhance both visual acuity and overall quality of life [3]. Among the available approaches, toric ICLs have shown promising results in correcting refractive errors in KC patients, offering strong outcomes in terms of safety, effectiveness, and long-term stability. Importantly, these procedures have not been associated with disease progression in the late postoperative period, reinforcing the role of ICLs as a viable and stable surgical option for managing vision in keratoconic eyes [4-6].

Recent developments in implantable collamer lens (ICL) technology – especially when combined with corneal cross-linking (CXL) – have led to better outcomes for patients needing both refractive correction and corneal stabilization. Xiao Zhang et al. (2016) showed that implanting a toric phakic ICL after riboflavin/UVA CXL offered reliable vision correction and long-term visual stability in patients with keratectasia [7]. In a broader review, Angela Y. Zhu et al. (2019) evaluated several treatment protocols that combined CXL with refractive procedures, finding that these methods not only halted the progression of keratoconus but also led to meaningful gains in visual function [8].

This study aimed to compare the indications, timing, and clinical outcomes of phakic implantable collamer lens (ICL) exchange or explantation between eyes with keratoconus and eyes without keratoconus or other corneal ectasia (non-ectatic eyes), and to evaluate factors associated with the need for secondary ICL intervention.

## Patients and methods

**Study Design.** This investigation employed a retrospective review of patient records to evaluate the clinical outcomes associated with the exchange or removal of phakic implantable collamer lenses (ICLs) performed at a tertiary eye care center in Iraq. The review encompassed procedures conducted from January 2022 to January 2024, with data extracted from a hospital-wide electronic medical records system.

**Study Setting.** The study was situated in a high-volume, specialized ophthalmology hospital in Iraq, which provides advanced anterior and posterior segment surgical services, including refractive procedures involving ICL implantation. Meanwhile all the surgeries were done by single surgeon.

**Study Population and Participant Selection.** During the study timeframe, a total of 200 eyes received ICL im-

plants (model V4b). Among these, 25 eyes (12.5%) underwent subsequent surgical intervention, either through lens exchange (n = 13) or explantation (n = 12). All cases involving such interventions were included in the study cohort.

Participants were stratified into two diagnostic subgroups: Keratoconus (KC) group – 10 eyes diagnosed with keratoconus; Non-KC group – 15 eyes without keratoconus or other corneal ectasia (non-ectatic eyes), confirmed by preoperative corneal topography/tomography and absence of clinical ectasia signs.

**Inclusion Criteria.** Individuals who underwent ICL exchange or removal within the defined period (January 2022–January 2024). Availability of comprehensive preoperative and postoperative data.

**Exclusion Criteria.** Incomplete medical documentation. Absence from postoperative follow-up appointments.

**Data Acquisition.** Patient data were meticulously retrieved from the hospital's electronic health record system. Variables collected included:

Demographics: Age, sex, and laterality (left/right eye).

Surgical details: Date and indication for intervention.

Ophthalmic assessments: Uncorrected and best-corrected visual acuity (Snellen chart).

Subjective and cycloplegic refractive error measurements.

Intraocular pressure (IOP).

Endothelial cell density.

White-to-white corneal diameter (WTW).

Vault height (ideal range defined as 250–750  $\mu\text{m}$ ).

ICL sizing data. (ICL sizing protocol: ICL size selection was performed using a standardized institutional protocol based on white-to-white (WTW) and anterior chamber depth (ACD). When available or when sizing was borderline, sulcus-to-sulcus (STS) measurements were obtained using [UBM/AS-OCT] to support final sizing decisions. Final lens size was selected according to the manufacturer's nomogram for ICL V4b and recorded in the electronic medical record.

Corneal curvature values (K1, K2, K-max).

Central corneal thickness.

Anterior chamber depth and angle assessments.

**Surgical Technique for ICL Exchange or Explantation.** All procedures were performed under topical anesthesia in an operating theater following standard aseptic preparation. A clear corneal incision was created, and a viscoelastic agent was injected into the anterior chamber to protect the corneal endothelium and facilitate lens manipulation. The phakic ICL was mobilized and gently removed through the main incision.

For exchange cases, a new phakic ICL (model V4b) of the selected size was implanted into the posterior chamber and positioned behind the iris with appropriate alignment. Complete removal of viscoelastic was performed using irrigation/aspiration, and the incision was hydrated to ensure watertight closure. Postoperative medications in-

cluded topical antibiotic and topical corticosteroid drops according to the institutional protocol.

**Post-intervention Follow-up Schedule.** Patients were evaluated after ICL exchange or explantation according to the institutional follow-up protocol. Postoperative examinations were scheduled at day 1, week 1, month 1, and month 3 (and month 6 when available). At each visit, uncorrected and best-corrected visual acuity, refraction, intraocular pressure, and slit-lamp biomicroscopy were assessed; endothelial cell density and vault were recorded at month 1 (and at later visits when available).

For comparative outcome analyses, postoperative values were extracted from the primary timepoint: month 1 / month 3 / last available follow-up visit. The follow-up duration for each eye was calculated from the date of exchange/explantation to the last documented postoperative visit.

#### Outcome Variables

**Primary Outcomes:** Change in visual acuity following intervention, Incidence and nature of postoperative complications, and Variation in corneal curvature measurements (keratometry) pre- and post-intervention.

**Secondary Outcomes:** Subjective patient satisfaction, particularly in relation to visual function and surgical complications.

**Statistical Methodology.** Data analysis was performed using IBM SPSS Statistics version 23.0. Descriptive statistics (means  $\pm$  standard deviation) summarized continuous variables, while frequencies and percentages described categorical data. Comparative analyses between keratoconus and non-keratoconus groups employed independent-sample t-tests for continuous data and chi-square tests for categorical outcomes. A p-value  $< 0.05$  was considered statistically significant.

#### Results

The sociodemographic data presented in Table 1 compares patients with and without keratoconus across several variables, revealing no statistically significant differences between the two groups (p-values  $> 0.05$  throughout).

The mean ages of the keratoconus ( $29.10 \pm 3.91$  years) and non-keratoconus ( $28.58 \pm 4.84$  years) groups are closely aligned, with a p-value of 0.77, indicating no age-related bias. Similarly, the time until intraocular collamer lens (ICL) change is slightly longer in the keratoconus group (mean = 38.45 months) compared to the non-keratoconus group (mean = 30.55 months), yet this difference is not statistically significant (p = 0.269). Regarding sex distribution, males are predominant in the keratoconus group (70%) while females are more represented in the non-keratoconus group (66.67%), though this difference approaches but does not reach significance (p= 0.12). The type of surgery and the laterality of the affected eye also show no meaningful differences between groups, with exchange and explantation procedures nearly equally distributed (p= 0.067), as well as similar proportions of right and left eyes affected (p= 0.088). Overall, the absence of statistically significant differences suggests that the two groups are comparable in their baseline sociodemographic and clinical characteristics, which strengthens the validity of subsequent analyses by minimizing confounding due to demographic disparities.

Table 2 presents a comparative analysis of clinical features between keratoconus and non-keratoconus patients, highlighting several statistically and clinically significant differences. Endothelial cell count (ECC) before and after lens exchange or removal shows no significant variation between groups (p = 0.712 and 0.364, respectively), suggesting similar corneal endothelial health. Intraocular pressure (IOP) is notably lower in the keratoconus group after exchange/removal (12.54 mm Hg vs. 17.40 mm Hg, p= 0.005), indicating a potentially favorable pressure response post-procedure. Uncorrected and best corrected visual acuity (UCVA and BCVA) metrics did not reach statistical significance at any stage, although a trend toward better post-insertion BCVA in non-keratoconus patients is evident. Notably, spherical and cylindrical refractive values and spherical equivalent showed significant disparities post-insertion and post-removal. The keratoconus group exhibited markedly higher myopia and astigmatism, par-

**Table 1.** Sociodemographic features of the patients

Variables		Keratoconus group (No. 10)	Non-Keratoconus group (No. 15)	P-Value
Age (years)	Mean $\pm$ SD	29.10 $\pm$ 3.91	28.58 $\pm$ 4.84	0.77
	Range	21-35	19-37	
Sex	Male	7 (70.0%)	5 (33.33%)	0.12
	Female	3 (30.0%)	10 (66.67%)	
Time until the ICL changes (months)	Mean $\pm$ SD	38.45 $\pm$ 18.60	30.55 $\pm$ 13.86	0.269
	Range	11-71	12-70	
Type of surgery	Exchange	5 (50.0%)	8 (53.33%)	0.067
	Explantation	5 (50.0%)	7 (46.67%)	
Side of the eye	Right	4 (40.0%)	5 (33.33%)	0.088
	Left	6 (60.0%)	10 (66.67%)	

**Table 2.** Clinical features of the patients

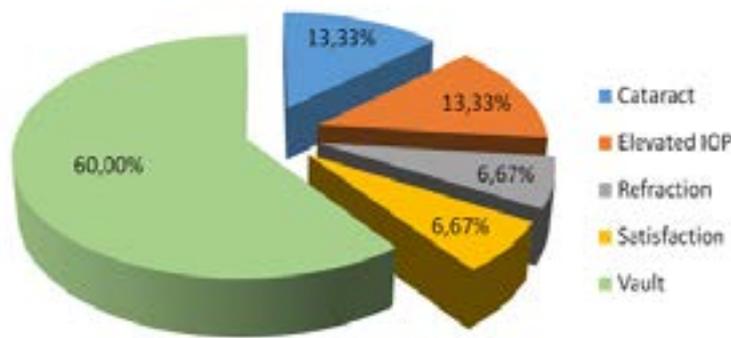
Variables		Keratoconus Group (No. 10)	Non-Keratoconus group (No. 15)	P-Value
ECC (cells/mm <sup>2</sup> )	Before insertion	2720.6	2577	0.712
	After exchange/removal	2485	2267	0.364
IOP (mm Hg)	Before insertion	14.41±1.37 (12.3-17.4)	14.78±3.15 (10.4-22)	0.692
	After insertion	17.85 ±2.13 (13-22)	19.39±6.50 (7-28)	0.406
	After exchange/removal	12.54±0.81 (11.5-14.7)	17.40 ±2.33 (12-25)	0.005
Unconnected visual acuity (UCVA) (logMAR)	Before insertion	0.99±0.03	0.96± 0.1	0.29
	After insertion	0.56±0.35	0.35±0.21	0.112
	After exchange/removal	0.71 ±0.28	0.67±0.28	0.078
Best corrected visual acuity (BCVA) (logMAR)	Before insertion	0.22±0.17	0.22±0.15	0.097
	After insertion	0.47±0.31	0.26±0.17	0.073
	After exchange/removal	0.39±0.27	0.27±0.16	0.062
Spherical value (D)	Before insertion	-7.4	-7.70	0.067
	After insertion	-4.50	-0.66	0.024
	After exchange/removal	-5.50	-2.00	0.367
Cylindrical value (D)	Before insertion	-3.48	-2.12	0.641
	After insertion	-4.00	-1.56	0.024
	After exchange/removal	-4.11	-1.34	0.037
Spherical equivalent (D)	Before insertion	-8.20	-4.74	0.044
	After insertion	-6.25	-0.49	0.002
	After exchange/removal	-4.03	-2.72	0.0037
Corneal thickness		443.5	551.1	0.0081
K1		48	43	0.086
K2		50	43.8	
K-Max		51	44.9	

ticularly after insertion (spherical value:  $p=0.024$ ; cylindrical value:  $p=0.024$ ; spherical equivalent:  $p=0.002$ ) and even after removal ( $p<0.05$  for both cylinder and spherical equivalent), reflecting the more complex refractive profile associated with keratoconus. Corneal thickness was significantly reduced in the keratoconus group ( $443.5\ \mu\text{m}$  vs.  $551.1\ \mu\text{m}$ ,  $p=0.0081$ ), consistent with the hallmark thinning in this condition. Although keratometry values (K1, K2, K-Max) suggest steeper corneas in keratoconus, only K1 is reported with a  $p$ -value ( $0.086$ ), nearing significance. In summary, these findings reinforce the distinct clinical profile of keratoconus patients, particularly in terms of refractive error and corneal structure, which has direct implications for surgical planning and visual outcomes following ICL procedures.

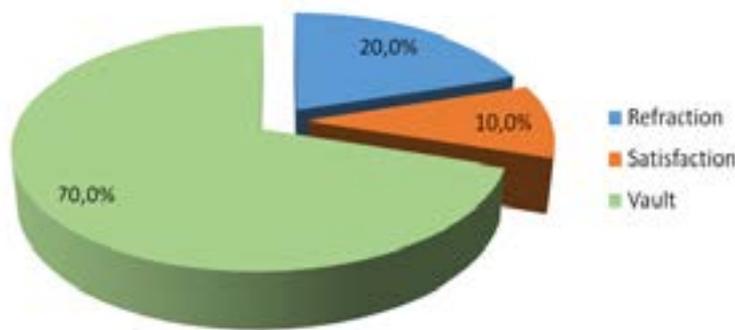
Figure 1 illustrates the distribution of causes for ICL exchange or explantation in the Non-Keratoconus group. The most common cause, accounting for 60% of cases,

is vault-related issues, indicating that suboptimal ICL positioning or sizing played a predominant role in the need for surgical revision. Both cataract formation and elevated IOP contributed equally at 13.33%, reflecting potential long-term complications of ICL implantation. Meanwhile, refractive dissatisfaction and general patient satisfaction issues were less frequent, each representing 6.67% of cases. This distribution highlights that anatomical or physiological complications (vault, IOP, cataract) were more prevalent triggers for ICL revision in this group than subjective or refractive concerns, underscoring the importance of meticulous preoperative assessment and postoperative monitoring in non-keratoconus eyes.

Figure 2 outlines the causes for ICL exchange or explantation in the Keratoconus group, revealing a strong predominance of vault-related complications, which account for 70% of cases. This mirrors the non-keratoconus group, where vault issues were also the leading cause, though



**Figure 1.** Causes for ICL exchange/explanation in Non-Keratoconus group



**Figure 2.** Causes for ICL exchange/explanation in the Keratoconus group

slightly less dominant (60%). In keratoconus patients, refractive issues contributed to 20% of the indications for surgical revision, suggesting difficulties in achieving satisfactory visual correction, likely due to the complex and unstable refractive profiles typical of keratoconus. Patient dissatisfaction, accounting for 10%, remains a minor cause, similar to the non-keratoconus group. Notably, unlike the non-keratoconus cohort, cataract formation and elevated IOP do not appear as reported causes in the keratoconus group. This difference may reflect younger age, less IOP susceptibility, or differing anatomical features in keratoconus eyes.

### Discussion

This study found that the average age of patients in the non-keratoconus (non-KC) group was  $28.58 \pm 4.84$  years, while those in the keratoconus (KC) group had a mean age of  $29.10 \pm 3.91$  years. These findings align with previous literature. For example, AlSabaani et al. (2016) reported a similar average age of  $29.4 \pm 11.1$  years at the time of ICL explantation [2]. In contrast, Chaitanya et al. (2020) observed a younger patient population – mean age  $23.72 \pm 3.23$  years – among individuals undergoing V4c toric ICL implantation for myopic astigmatism, suggesting that this particular intervention may be more commonly pursued at an earlier age [9].

Over the two-year study period at a specialized eye hospital in Iraq, we recorded a 12.5% rate (25 cases) of ICL exchange or explantation. Of these, 40.0% occurred

in patients with keratoconus, while 60.0% involved non-keratoconus cases. This rate is notably higher than those reported in earlier studies. For instance, AlSabaani et al. (2016) documented an ICL exchange/explantation rate of 3.8% [2], while Alhamzah et al. (2021) reported a lower rate of 2.0% in a Saudi Arabian cohort. In their study, the distribution across keratoconus and non-keratoconus groups was 78.57% and 68.57%, respectively [10].

In our study, incorrect vault size was the most common reason for ICL exchange or explantation, observed in 9 cases from the non-keratoconus group and 7 cases from the keratoconus group. This finding is consistent with the results of Alhamzah et al. (2021), who also identified vault miscalculation as a frequent postoperative issue in ICL procedures [10]. Supporting this, Trancón et al. (2020) introduced a multivariable model that accounted for approximately 34% of the variance in postoperative vault height. Their analysis highlighted key contributing factors, including the horizontal size mismatch between the eye and the ICL, the forward protrusion of the crystalline lens, and specific lens parameters such as power and overall size [11].

Cataract formation was the second most common reason for ICL exchange or explantation in our study, accounting for 13.33% of cases in the non-keratoconus group. This finding is in line with the results reported by Alhamzah et al. (2021), who noted cataracts as the second leading cause of ICL removal, comprising 12.5% of cases in their non-keratoconus cohort [10]. However, a mark-

edly lower incidence was observed by AlSabaani et al. (2016), who reported cataract development in only 0.5% of patients following ICL implantation [2]. Supporting these trends, a larger retrospective analysis of 1653 eyes reported a cataract-related ICL explantation rate of 2.78%, further highlighting variability in incidence across different populations and clinical settings [12].

Anterior subcapsular cataract is a known complication following ICL implantation and may result from various intraoperative or postoperative factors. These include subclinical inflammation, disruption of the blood-aqueous barrier, laser-induced trauma, or accidental contact with intraocular devices during surgery [13].

In addition, elevated IOP was identified as another reason for ICL exchange or explantation in our study, accounting for 13.33% of cases in the non-keratoconus group. This is consistent with findings from Alhamzah et al. (2021), who reported elevated IOP as the cause in 9.3% of their explantation cases [10]. Further supporting this, Sánchez-González et al. (2020) found a positive correlation between higher preoperative IOP and increased postoperative vault in patients receiving the ICL V4c model, suggesting that anatomical and pressure-related factors may predispose patients to vault-related complications [14].

Incorrect refractive outcomes were another contributing factor to ICL exchange or explantation in our study, observed in 20.0% of cases within the KC group and 6.67% in the non-keratoconus group. These findings are consistent with those reported by Alhamzah et al. (2021), who noted similar rates of ICL removal due to residual refractive error – 14.28% in the KC group and 6.25% in the non-KC group [10]. Supporting this trend, Fairaq et al. (2021) also documented a case of ICL explantation in a patient with keratoconus, myopia, and myopic astigmatism, due to residual refractive error [15].

Patient dissatisfaction was also a factor influencing explantation in our cohort. One patient from each group (KC and non-KC) requested lens removal due to dissatisfaction with visual outcomes. This aligns with the findings of Alhamzah et al. (2021), where patient dissatisfaction – primarily related to postoperative glare – was cited as a reason for explantation [10]. In contrast, several other studies report generally high satisfaction rates. For instance, Liu and Luo (2013) observed favorable patient satisfaction following toric ICL implantation in keratoconus eyes [16]. While Dougherty and Priver (2017) found that only 1.79% of patients experienced night-time halos, suggesting that visual disturbances, while possible, are relatively uncommon [17].

**Conclusion.** The predominant cause for ICL exchange/explantation among both keratoconus and non-keratoconus patients was inappropriate vault size. Notably, a high vault was more frequently observed in Keratoconus patients.

### Author Contributions

IHS, MHJ, AAF – Conceptualization; Data Curation; Investigation; Methodology; Project administration; Resources; Software; Writing – original draft, review & editing. All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work.

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### Disclaimers

The views expressed in this article are solely those of the authors and do not necessarily represent the official position of their affiliated institution or any funding source.

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### Conflict of Interest

The authors declare that they have no conflicts of interest related to this work.

### Ethical approval

The Medical Ethical Committee of The Department of Surgery, College of Medicine, University of Thi-Qar approved this study.

### Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request. Due to institutional policy and patient confidentiality, raw data are not publicly available.

### Abbreviations

ICL – Implantable Collamer Lens; n – number, KC – keratoconus, CXL – corneal cross-linking, UVA – Ultra violet A, IOP – Intraocular pressure,  $\mu\text{m}$  – Micron, WTW – white-to-white, ACD – anterior chamber depth, STS – sulcus-to-sulcus, SD – standard deviation, ECC – Endothelial cell count, UCVA and BCVA – Uncorrected and best corrected visual acuity.

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