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Research Article

Implantable Collamer Lens Sizing in Eyes with Keratoconus

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Abstract

Aims/Background: The Implantable Collamer Lens (ICL) is an intraocular lens providing refractive correction for a large range of refractive errors. The aim of this study was to investigate the reasons for ICL removal/exchange and to identify cases with excessively high/low vault in patients with keratoconus.

Methods: A real-world chart review was undertaken to assess ICL sizing issues in terms of vault and rotation in patients with keratoconus. Additionally, cases in which the ICL was removed or exchanged were reviewed. The inclusion criteria included eyes with keratoconus that underwent phakic ICL surgery with an internal anterior chamber depth of ≥ 2.8 mm. The STAAR Surgical Online Calculation and Ordering System (OCOS) was reviewed to identify all orders placed between 2017 and 2023. The medical records of these orders were retrieved and reviewed.

Results: Fifty eyes of 39 patients were identified that matched the inclusion and exclusion criteria. Eleven patients had bilateral ICL surgery (on different dates), and 28 patients had unilateral ICL surgery. The mean age of patients was 38.2 (± 7.5) years. Thirteen patients were female and 26 patients were male. In terms of laterality, 27 right eyes and 23 left eyes were included. Two eyes had a low vault (≤ 100 µm), both remain under observation; two eyes had a high vault (≥ 1000 µm), one was removed and one remains under observation; three eyes had rotation/decentration issues, one required rotation and two required exchange for larger diameter ICLs; and one eye had a refractive surprise and the toric ICL was exchanged for a non-toric ICL.

Conclusion: In eyes with keratoconus, it would be prudent to expand pre-operative measurements in an effort to improve sizing issues identified, such as sulcus anatomy and lens rise. It is hypothesised that with additional pre-operative measurements and nomograms, ICL sizing can be improved in eyes with keratoconus.

Keywords: *ICL; Keratoconus; Ectasia; Cornea; Vault; ICL Sizing*

Introduction

The Visian Implantable Collamer Lens (ICL) (STAAR Surgical Inc., CA, USA) is an intraocular lens providing refractive correction for a large range of refractive errors including myopia, hyperopia, and astigmatism [1,2]. It is manufactured from a hydroxyethyl methacrylate/porcine-collagen based biocompatible polymer material and is designed for posterior chamber placement within the ciliary sulcus. It has

been approved for use in Europe since 1997 and in the USA since 2005. More recently, in 2020, CE approval was granted in Europe for use of the ICL in pseudophakic eyes as a piggyback/supplementary lens. The lens has seen a number of modifications over the years. The EVO Visian ICL model for myopia, comprises a 360 µm central port to assist aqueous flow to reduce the risk of cataract formation and eliminate the need to perform a peripheral iridotomy. The EVO+ model includes a larger optical diameter, designed for eyes with larger pupils. The lens is currently available in four sizes: 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm. High levels of safety and effectiveness have been reported for the ICL [3,4].

Despite good visual and refractive outcomes, one of the biggest challenges in ICL surgery is inappropriate sizing resulting in either excessive or insufficient lens vault. The vault is the axial distance between the posterior surface of the ICL and the anterior surface of the crystalline lens. An ideal vault has been suggested to be within the range of 250 to 750 µm [5]. Eyes with excessive vault may develop raised intraocular pressure (and subsequent glaucoma) from angle closure, pupil block, or pigment dispersion and endothelial cell loss (and subsequent corneal decompensation) [6,7]. Eyes with insufficient vault may develop cataract or ICL rotation/dislocation [8-10].

With over 2,000,000 ICLs implanted worldwide [11], the evidence is growing on the efficacy and safety of the lens. However, the outcomes of ICLs in eyes with keratoconus are much less studied. An ICL may be considered in patients with keratoconus in specific situations, such as contact lens intolerance, symptomatic anisometropia, or large refractive errors. However, it is important that patients achieve good spectacle-corrected visual acuity and that the keratoconus is stable.

Purpose of the Study

The purpose of this study was to investigate the reasons for ICL removal or exchange and to identify cases with excessively high or low vault in patients with keratoconus.

Methods

A real-world chart review was undertaken to assess ICL sizing issues in terms of vault and rotation in patients with keratoconus, receiving an ICL. Additionally, cases in which the ICL was removed or exchanged were reviewed. This study was approved by the local institutional review board and adhered to the tenets of the Declaration of Helsinki.

The inclusion criteria included eyes with keratoconus that underwent phakic ICL surgery with an internal anterior chamber depth (ACD) of 2.8 mm or more. The exclusion criteria included eyes with previous corneal transplants (for indications other than keratoconus), post-LASIK ectasia, and ICL surgery for high refractive errors only (without keratoconus). The STAAR Surgical Online Calculation and Ordering System (OCOS) was reviewed to identify all orders placed between 2017 and 2023. The medical records of these orders were retrieved and reviewed.

All patients in this group had at least two manifest refractions to ensure stability of their refractive error. Additionally, stable tomography was a prerequisite for ICL surgery. All patients underwent a full ophthalmic history and examination. Investigations included Pentacam tomography (Oculus, Germany), IOLMaster500 biometry (Zeiss, Germany), and anterior segment optical coherence tomography (OCT). The STAAR OCOS was used to determine the most appropriate ICL power and size. The white-to-white (WTW) measurement entered into the OCOS website was the IOLMaster500 WTW measurement minus 0.4 mm. The internal ACD and central corneal thickness (CCT) measurements entered were taken from the Pentacam scan.

ICL surgery was undertaken by a number of surgeons, including corneal consultant ophthalmologists and corneal fellows. Patients receiving a toric ICL were initially marked at the slit lamp using the surgeon's preferred technique. All patients had pupillary dilation pre-operatively. Surgeries were performed under local anaesthesia with a temporal 3.2 mm limbal corneal incision along with a superior and

inferior paracentesis. After ophthalmic viscoelastic device (OVD) injection, the ICL was implanted into the ciliary sulcus and the OVD was then removed from the anterior chamber. In cases of a toric ICL, the lens was rotated to the appropriate axis. Wounds were hydrated with balanced salt solution followed by an intracameral injection of cefuroxime and acetylcholine chloride. Patients received post-operative eye drops (antibiotics [chloramphenicol] and steroids [dexamethasone]), and typically oral acetazolamide 250 mg twice daily for 3 days. Intraocular pressure was assessed at one hour post-operatively prior to discharge from the hospital. Patients were typically reviewed at 1 week and subsequently depending on the clinical situation. Our general clinical approach was to accept a vault within the range 250 to 750 µm, in line with previous studies [5]. In cases of vault values outside this range, this was explained to patients and the potential implications. Generally, in cases with vault values ≤ 100 µm or ≥ 1000 µm, patients were strongly advised to have the ICL exchanged for a different size. Generally, vault values between 100 - 250 µm and 750 - 1000 µm were closely observed in clinic with patients informed of the potential complications associated with high or low vault.

Results

In total, 50 eyes of 39 patients were identified that matched the inclusion and exclusion criteria. Eleven patients had bilateral ICL surgery (on different dates), and 28 patients had unilateral ICL surgery. The mean (± standard deviation) age of patients was 38.2 (± 7.5) years. Thirteen patients were female and 26 patients were male. In terms of laterality, 27 right eyes and 23 left eyes were included.

Initially, 10 eyes were identified: two eyes developed cataract which required ICL removal and subsequent cataract surgery; two eyes had a low vault (≤ 100 µm), both remain under observation; two eyes had a high vault (≥ 1000 µm), one was removed and one remains under observation; three eyes had rotation/decentration issues, one required rotation and two required exchange for larger diameter ICLs; and one eye had a refractive surprise and the toric ICL was exchanged for a non-toric ICL. Each case will be discussed below.

Case 1: Refractive surprise

A 50-year-old female patient with keratoconus was referred for an ICL to the right eye. She was contact lens intolerant in the right eye, and wore a scleral contact lens in the left eye and achieved a visual acuity of 6/6 in the left eye. The manifest refraction in the right eye was -20.00/-5.00x80 which achieved a visual acuity of $6/9.5^{-3}$ and a toric ICL was planned. The WTW measured by the IOLMaster 500 was 12.3 mm. The K1, K2 and internal ACD, measured with the Pentacam, were 53.6 dioptres (D), 56.4D and 2.93 mm respectively. These values were entered into the OCOS website with the WTW adjusted to 11.9 mm. The toric ICL implanted had a power of -18.00/+4.00x156 with a diameter of 13.2 mm. The ICL was placed at an axis of 10 degrees. Five weeks post-operatively, the unaided visual acuity was 6/19, improving to 6/12 with pinhole. The axis of the ICL was recorded as 10-15 degrees with a vault of 524 µm. Three months post-operatively, the unaided visual acuity was 6/30, and the refraction was -1.50/-5.50x10 with a visual acuity of $6/12^{+1}$ (pinhole $6/7.5^{-2}$). The ICL was at an axis of 14 degrees. The refraction remained stable and the ICL was exchanged eight months later, for a non-toric ICL (-18.00 sphere, diameter 13.2 mm). At 1 month follow-up the unaided visual acuity was 6/24 improving to 6/7.5 with pinhole. Unfortunately, no vault was recorded in the medical notes and no refraction was undertaken. This patient has not been seen back in our hospital as she lives far way and undergoes follow-ups at her local hospital. The cause for the refractive surprise is not clear. It may be related to the extreme refractive correction targeted in addition to the high K-readings and keratoconus status of the eye.

Case 2: Insufficient vault

A 32-year-old male patient with keratoconus who had previous right eye corneal cross-linking and intracorneal ring segments, underwent ICL surgery to the right eye. The K-readings (K1 43.21D and K2 48.42D) were taken from the IOLMaster 500. The WTW was measured as 11.6 mm and 0.4 mm was subtracted and entered into the OCOS website. The internal ACD from the Pentacam (3.16 mm) was also entered. The STAAR recommended ICL was a 12.6 mm diameter and power of -7.00/+5.50x100. The post-operative vault was

measured as 100 µm. The toric axis alignment was correct and no cataract was observed. The patient declined an ICL exchange and remains under close observation.

Case 3: Insufficient vault

A 43-year-old female patient with keratoconus underwent bilateral ICL surgery (8 months apart). A value of 0.4mm was subtracted from the IOLMaster 500 WTW measurement and ICLs of diameter 12.1 mm were implanted. The first eye (right eye) had a post-operative vault of 183 µm and the second eye (left eye) had a vault of 99 µm. The patient was very satisfied with the unaided visual acuity, declined an ICL exchange, and remains under close review.

Case 4: Excessive vault

A 59-year-old male patient with keratoconus underwent left eye ICL surgery. The eye had previous intracorneal ring segments. The pre-operative manifest refraction was -8.50/-4.50x92 achieving a visual acuity of $6/12^{+2}$ (pinhole 6/9.5). The WTW with the IOLMaster 500 was 12.1 mm and 0.4 mm was subtracted from this figure and entered into the OCOS website. An error was made in that the ACD depth (3.14 mm) entered was taken from the IOLMaster 500 scan, not the Pentacam, which is our usual departmental practice. The K-readings (K1 53.57D and K2 58.8D) were taken from the IOLMaster 500 measurements. The recommended ICL from the OCOS website was a 13.2 mm diameter which was implanted at an axis of 173 degrees. Ten days post-operatively, the unaided visual acuity was 6/19 (pinhole 6/9.5) and the axis was aligned. However, the vault was 1420 µm. The patient was reviewed 2 months later and the vault was measured as 1570 µm. Specular microscopy was undertaken at that point which revealed an endothelial cell count of 2307. Due to the excessive vault, the patient had the ICL removed 8 days later. A possible cause for the excessive vault was the use of the AC depth from the IOLMaster rather than the Pentacam. The ACD measured with the IOLMaster was 3.83 mm compared to 3.14 mm with the Pentacam.

Case 5: Excessive vault

A 24-year-old male patient with keratoconus who had previous left eye corneal cross-linking and intracorneal ring segments underwent ICL surgery to the left eye. The K-readings (K1 47.34D and K2 52.41D) were taken from the IOLMaster 500. The WTW was measured as 12.1 mm and 0.4 mm was subtracted from this WTW value and entered into the OCOS website (11.7 mm). The internal ACD from the Pentacam (3.18 mm) was also entered. The STAAR recommended ICL was a 13.2 mm diameter lens. The post-operative vault was measured as 1042 µm and the axis of the ICL was at 170 degrees (target 164 degrees) equating to 6 degrees off-axis. An exchange was not undertaken and the patient remains under close observation.

Case 6: Axis misalignment

A 31-year-old male patient with keratoconus who had previous right eye corneal cross-linking and intracorneal ring segments underwent ICL surgery to the right eye. The IOLMaster was unable to obtain a WTW measurement value, hence manual calipers were used and recorded as > 12.5 mm but < 13.00 mm. A value of 12.7 mm was chosen, and 0.4 mm subtracted to give 12.3 mm which was entered into the OCOS website. The K-readings (K1 39.15D and K2 53.07D) were taken from the IOLMaster 500. The internal ACD (3.15 mm) and corneal thickness (397 µm) from the Pentacam were also entered. At 2 days post-operatively, the axis was 143 degrees (target 159 degrees) equating to 16 degrees off-axis and a vault of 257 µm. Two weeks post-operatively, the axis was 103 degrees (target 159 degrees) equating to 56 degrees off-axis and a vault of 276 µm. An OCOS re-calculation was performed and the WTW increased to 12.4 mm which resulted in a larger recommended ICL size of 13.7 mm. The exchange surgery was subsequently performed 3 months after the initial surgery and the larger diameter, 13.7 mm ICL implanted. Two months following the exchange surgery, the axis of the ICL was at 19 degrees (target 5 degrees) equating to 14 degrees off-axis and a vault of 489 µm. A decision was made with the patient to observe and the patient remains under review.

Case 7: Toric ICL rotation and decentration

A 31-year-old male patient with keratoconus who had previous right eye intracorneal ring segments, underwent ICL surgery to the right eye. The IOLMaster 500 was performed three times with three measurements for the WTW: 11.5 mm, 11.4 mm and 11.3 mm. A value of 11.3 mm was entered into the OCOS website. The K-readings (K1 39.06D and K2 44.35D) were taken from the IOLMaster 500. The internal ACD (3.04 mm) and corneal thickness (441 μm) from the Pentacam were also entered. A 12.6 mm ICL size was recommended and was implanted. Post-operatively, the ICL rotated from the implanted axis of 10 degrees to 59 degrees with nasal decentration. The vault was 392 μm. The patient underwent an ICL exchange with a larger diameter of 13.2 mm used. The post-operative unaided visual acuity was 6/4.8.

Case 8: Toric ICL rotation

A 26-year-old female with keratoconus underwent unilateral, right eye, ICL surgery. The WTW was measured with the IOLMaster 500 and 0.4 mm subtracted from this value, and entered into the OCOS website. One of the K-readings was 61.8D; however the maximum K-reading that is possible on the OCOS website is 60D, hence a K-reading of 60D was used. The recommended ICL diameter was 12.6 mm which was implanted. Intraoperatively, the ICL was inadvertently implanted upside down. This was immediately explanted, re-loaded and re-implanted. The target axis for the ICL was 164 degrees, however, post-operatively the axis was measured to be at 120 degrees with reduced visual acuity. The patient returned to the operating theatre and the ICL was rotated to the intended axis of 164 degrees. At 1 week post-operatively, the axis was at 170 degrees (and has remained at this axis) with a vault of 620 μm. The suspected cause for the rotation was retained OVD as the ICL sizing appeared correct in terms of the lens vault.

Cases 9 and 10: Cataract

A 48-year-old male patient with keratoconus who had a previous deep anterior lamellar keratoplasty (DALK) had an ICL implanted for ametropia. The K-readings were K1 41.4D and K2 46.8D, ACD 3.65 mm and corneal thickness 641 μm. The WTW with the IOLMaster was 12 mm and a value of 11.6 mm was entered to the OCOS website. The post-operative vault was 450 μm. Three years following surgery, the patient developed a nuclear sclerotic cataract. The ICL was subsequently explanted and the patient underwent cataract surgery. In this case, the cataract aetiology was presumed secondary to previous surgery, history of keratoconus, topical steroid use and patient age. It was not felt to be directly related to the ICL, particularly in view of the adequate vault. The second case of cataract involved a 55-year-old male patient with keratoconus who underwent bilateral ICL surgery. The post-operative vault was 745 μm in the right eye and 512 μm in the left eye. The patient developed nuclear sclerotic cataracts 4 years later, and underwent ICL removal and cataract surgery. The presumed aetiology of the cataracts was age-related and not felt to be directly related to the ICL surgery.

Based on our cohort of 50 eyes, 4 eyes (8%) had insufficient (≤ 100 μm) or excessive (≥ 1000 μm) vault, and 3 eyes (6%) had significant rotation or decentration requiring surgical intervention. The two cases of cataract were not felt to be directly caused by the ICL.

Discussion

The Visian ICL has demonstrated high levels of safety and efficacy for refractive error correction. The OCOS website is the company-recommended method to calculate the size of ICL to implant. In eyes with keratoconus, sizing appears to be more of an issue with 8% of eyes having an excessive (≥ 1000 μm) or insufficient (≤ 100 μm) vault. Several groups have proven the relatively weak statistical correlation between WTW and sulcus-to-sulcus diameter (STS) using high-frequency ultrasound [12-14]. Further, a number of additional nomograms have been developed to improve sizing predictions, particularly in terms of post-operative vault. Dougherty., *et al*. published a look-up table to improve sizing outcomes for the high-frequency ultrasound measurement of STS diameter [15]. Kojima., *et al*. introduced the concept of adding crystalline lens rise (CLR), including this as a variable in a multivariate ICL sizing formula together with STS and ACD [16]. Igarashi., *et al*. published a formula using the horizontal angle-to-angle (ATA) diameter using OCT to predict the lens vault [17]. Nakamura., *et al*. published the OCT-based Nakamura-Kojima (NK) formula and updated NK-2 formula using a multivariate model including

AC width measured from scleral spur-to-spur, ACD, and CLR from the ATA plane [18]. An updated version 3 (NK-formula V3), using the partial regression coefficient, has been recently published aiming to improve predictions in ICL sizing [19]. Zhang., *et al*. introduced the ZZ formula based on ultrasound biomicroscopy (UBM) video clips and reported that in comparison to the OCOS formula, 10% required a larger ICL size and 16% required a smaller ICL size [20]. Reinstein., *et al*. introduced the measurement of ciliary body inner diameter (CBID), demonstrating this as the single most important predictor of post-operative ICL vault. Reinstein., *et al*. further demonstrated the most powerful influencers of post-operative vault were ICL size, ICL power, sulcus-to-sulcus lens rise, scotopic pupil diameter, and CBID [21]. The Reinstein calculator is available online and provides a prediction of post-operative vault for each ICL size. Rocamora., *et al*. recently introduced the LASSO formula, which integrates parameters from anterior segment OCT and ocular biometry. Similarly, the LASSO formula predicts the post-operative vault for each ICL size [22]. Kim., *et al*. also developed various vault prediction models using parameters measured using anterior segment OCT [23]. Machine learning/artificial intelligence models have also been developed by Russo., *et al.* [24] and Shen., *et al*. [25]. Moshirfar., *et al*. very recently compared a number of sizing nomograms and investigated which preoperative measurements are predictive of vault [26]. They reported the Kim, Rocamora, Russo, and Reinstein nomograms were the most predictive of vault. In addition, ACD, CBID, and pupil diameter were found to be significantly correlated with vault. It is important to note that these formulas have not been developed in eyes with keratoconus. The performance of these formulas in eyes with keratoconus would be a helpful addition to the literature.

There have been previous publications in the literature on outcomes of ICL surgery in eyes with keratoconus. Emerah., *et al*. undertook a retrospective study investigating toric ICL implantation in 14 eyes of 8 patients with stable keratoconus reporting no intraoperative or postoperative complications. They concluded that toric ICL implantation was effective, predictable and safe to correct refractive error and improve visual acuity in patients with stable keratoconus. Post-operative vault values were not reported [27]. In a larger study involving 60 eyes of 60 patients, Li., *et al*. reported predictable correction of refractive error in eyes with keratoconus, however vault was not reported [28]. Fairaq., *et al*. published a retrospective study involving 32 eyes of 32 patients. Cylinder axis rotation of ≥10 degrees occurred in 3 eyes (9.375%) and required repositioning. One patient (3%) developed nonvisually significant anterior subcapsular cataract. One ICL (3.125%) had to be explanted due to residual refractive error and unsatisfactory vision. The mean ICL vault was 421 ± 232 µm (range: 98 to 926 µm) [29]. Alhamzah., *et al*. investigated the causes of ICL exchange/explantation via a retrospective chart review. Over a 7 years period, 2283 ICL procedures were performed; 46 implants (2%) required exchange (21 implants) or explantation (25 implants), of which 14 cases (30.4%) were patients with keratoconus. The most common indication for ICL exchange/explantation in the keratoconus group was inaccurate vault sizing in 11 patients (78.57%), inaccurate refraction in 2 patients (14.28%), and patient dissatisfaction post-operatively in 1 (7.14%) case [30]. However, the total number of eyes with keratoconus who had ICL surgery was not been reported, hence, one can only infer that a higher proportion of eyes with keratoconus required an exchange/explantation. Alfonso-Bartolozzi., *et al*. reported satisfactory outcomes for ICL surgery in 20 eyes with keratoconus after DALK in terms of effectiveness, safety, and stability during 3 years of follow-up [31]. In terms of vault, no eyes had a vault > 800 µm at any visit, and approximately 20% of eyes had a vault lower than 200 µm throughout the follow-up. Alabbasi., *et al*. reported the results of 32 eyes with keratoconus undergoing ICL surgery; the mean SE before surgery was −7.9 ± 4.1D, improving to −0.7 ± 2.1D post-operatively [32]. Unfortunately, vault was not reported.

In the present study, we found that ICL sizing issues in eyes with keratoconus were more prevalent than those found in eyes without keratoconus. Of 50 eyes with keratoconus that underwent ICL surgery, 4 eyes (8%) had insufficient (≤ 100 µm) or excessive (≥ 1000 µm) vault. Further, 2 eyes (4%) had insufficient (≤ 100 µm) vault and 2 eyes (4%) had excessive (≥ 1000 µm) vault. There were 3 eyes (6%) that had significant rotation or decentration requiring surgical intervention. The two cases of cataract were not felt to be directly related to the ICL. This information is useful during the consent process with patients to inform them that the risks of sizing issues are higher than in cases without keratoconus. Rotation issues are usually suspected to be caused by suboptimal haptic support due to an ICL that is too small. However, in cases with a normal vault and rotation, ciliary body cysts [33], an anteriorly positioned ciliary body, haptic malposition, or a damaged haptic(s) [34] may be the cause. The use of ultrasound biomicroscopy can help assist in the diagnosis in such cases [35]. In

cases of ciliary body cysts, an ICL exchange with an oblique or vertically positioned ICL may avoid rotations. Insufficient vault may also increase the risks of cataract formation [8-10]. Excessive vault may result in raised intraocular pressure (and subsequent glaucoma) from angle closure, pupil block, or pigment dispersion, as well as endothelial cell loss (and subsequent corneal decompensation) [6,7]. The present study has a number of limitations, including the involvement of multiple surgeons and the inclusion of both eyes of some patients in certain cases. Inclusion of data obtained from right and left eyes of a patient is often correlated, whereas many statistical tests assume observations in a sample are independent [36]. However, this is a real-world assessment of the ICL in keratoconus and provides useful information for clinical practice.

Conclusion

In eyes with keratoconus, it would be prudent to expand pre-operative measurements in an effort to improve sizing issues identified, such as those related to sulcus anatomy and lens rise [37]. We plan to implement OCT-based ICL sizing calculators to complement the manufacturer-recommended OCOS website. It is hypothesised that with additional pre-operative measurements and nomograms, ICL sizing can be improved in eyes with keratoconus.

Ethics Approval and Informed Consent

This study was approved by the local institutional review board and adhered to the Declaration of Helsinki.

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Conflict of Interest

No financial and non-financial conflicting interests exists for any author.

Authors Contribution

All authors meet conditions 1-5 of IMCJE authorship guidelines. The manuscript has been read and approved by all the authors.

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No prior publications or presentations of this work.

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