



OPEN Vault of the phakic intraocular lens during vertical and horizontal fixation within patient comparison

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This study aimed to compare the postoperative vault and preoperative predictions between vertical and horizontal fixation of implantable collamer lenses (ICLs). In this prospective case series, 63 patients (126 eyes) who underwent bilateral ICL insertion for myopia were randomly assigned to either horizontal or vertical fixation for each eye. An additional control group consisted of 63 patients receiving bilateral horizontal non-toric ICL fixation. Biometric measurements, including anterior chamber depth (ACD) and vault, were obtained using anterior-segment three-dimensional optical coherence tomography preoperatively and at 2 h, 1 day, 1 week, and 1 month postoperatively. ACD values remained stable and similar between both groups ($P > 0.05$). However, vault values were consistently lower in the vertical group than in the horizontal group at all time points ($P < 0.001$). The vault difference between preoperative predictions and actual measurements was significantly larger in the vertical group compared to the horizontal group ($P < 0.001$). The intergroup vault difference was significantly larger than the left–right eye difference in the control group ($P < 0.001$). Vertical ICL fixation reduced the vault by approximately 150 μm compared to horizontal fixation, a deviation from preoperative predictions, which should be considered when determining ICL size.

According to the FDA Visian ICL Product Information (https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030016c.pdf), as a standard procedure for the posterior chamber phakic implantable collamer lens (ICL), a temporal incision of 3.5 mm or less and horizontal fixation are recommended. And most surgeons perform posterior chamber phakic implantable collamer lens (ICL) surgery by using a temporal incision and horizontal fixation¹, while the toric axes of toric models are also designed with horizontal fixation in mind. However, many ICL surgery cases have with-the-rule (WTR) astigmatism, where superior incision offers advantages in astigmatism correction; thus, the number of surgeries performed using a superior incision is increasing¹. Furthermore, the ciliary sulcus, where the ICL is fixed, is often described as a somewhat vertically elongated oval, and reports suggest that vertical fixation may provide better rotational stability^{2,3}.

Currently, the formulas and software used to determine ICL size preoperatively, including those from Staar Surgical's calculator (<https://evo-ocos.staarag.ch/live/>) and the recently popularized anterior-segment three-dimensional optical coherence tomography (A-OCT) device, the CASIA2 (Tomey Corporation, Nagoya, Japan)^{4,5}, have been designed with the assumption that horizontal fixation will be used. Thus, when performing vertical fixation, the difference in horizontal and vertical dimensions of the sulcus distance (STS) might result in a suboptimal postoperative vault (the distance between the anterior surface of the lens and posterior surface of the ICL)⁶. Additionally, the characteristics of postoperative outcomes when the ICL is vertically fixed should be understood to develop a size determination nomogram for vertical fixation.

Our previous study compared the actual postoperative vault and its preoperatively predicted value in cases with vertical fixation as compared to horizontal fixation;⁷ however, that report was based on a comparison between independent groups. Thus, the influence of anatomical differences between cases may have impacted the results, and the analysis was limited to overall trends.

Therefore, the present study compared left and right eyes, each fixed vertically or horizontally, within each individual patient to examine the differences in vault between horizontal and vertical fixation in a more practical manner.

Results

Baseline information and ICL data

Herein, 129 cases were registered, among which, cases of 51 patients who received a toric ICL in one or both eyes and 15 cases who received ICL sizes that differed between the left and right eyes were excluded. All patients

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	Horizontal group	Vertical group	<i>p</i> -value
Age (years)	32.6 ± 6.2		
Sex (male: female)	23:40		–
Axial length (mm)	26.20 (1.49)	26.04 (1.54)	0.41
Depth of anterior chamber (mm)	3.22 (0.31)	3.19 (0.28)	0.46
Corneal transverse diameter (mm)	11.25 (0.45)	11.25 (0.48)	0.94
Angle to Angle diameter (mm)	11.61 (0.39)	11.61 (0.55)	0.52
Corneal thickness (mm)	0.538 (0.052)	0.540 (0.052)	0.57
Lens thickness (mm)	3.78 (0.28)	3.81 (0.36)	0.23
UDVA (Log MAR)	1.30 (0.30)	1.30 (0.30)	0.55
CDVA (Log MAR)	-0.18 (0.00)	-0.18 (0.00)	0.71
Manifest sphere (D)	-6.50 (3.63)	-6.25 (3.75)	0.44
Manifest cylinder (D)	0.17 (0.41)	0.10 (0.33)	0.28
Objective sphere (D)	-6.50 (3.75)	-6.25 (3.63)	0.92
Objective cylinder (D)	-0.50 (0.50)	-0.50 (0.50)	0.55

Table 1. Preoperative basic information. Wilcoxon signed-ranked test. Data are presented as median (interquartile range). *CDVA* corrected visual acuity, *D* diopters, *UDVA* uncorrected visual acuity.

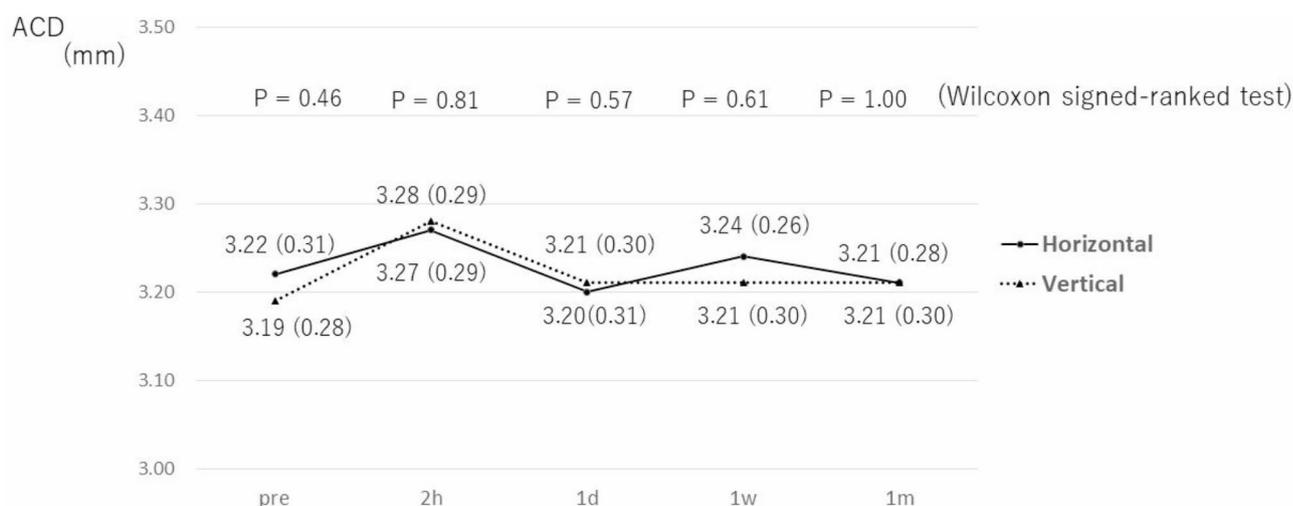


Fig. 1. Temporal changes in anterior chamber depth*. In both eyes with horizontal and those with vertical fixation of the lens, no change in anterior chamber depth is seen from the day after surgery to 1 month postoperatively, as compared to preoperative levels. Additionally, no differences are noted between the horizontal and vertical groups at any observation time point. *Distance from the corneal endothelium to the front of the lens. Pre: Preoperative, 2 h: 2 h postoperatively, 1 d: 1 day after surgery, 1 w: 1 week postoperatively, 1 m: 1 month postoperatively. ACD = anterior chamber depth.

completed the 1 month postoperative examination. The analyzed patients included 23 males and 40 females, with a mean age of 32.6 ± 6.2 years.

The control group consisted of 21 males and 42 females with a mean age of 32.2 ± 6.8 years.

No differences in biometric measurements, such as axial length, ACD, WTW, angle-to-angle distance, corneal thickness, and lens thickness, were found between the horizontal and vertical groups preoperatively. Moreover, no differences in uncorrected or corrected visual acuity, subjective/objective spherical values, and objective cylinder values were noted between the horizontal and vertical groups; only the subjective cylinder differed between these groups (Table 1).

The inserted ICL sizes were as follows: 12.1 mm in 11 (17%) cases, 12.6 mm in 46 (73%) cases, 13.2 mm in 6 (10%) cases, and 13.7 mm in no (0%) cases.

Postoperative biometry

No adverse events or unintended effects were observed in any group during the course of the study. The ACD remained unchanged at all observed time points (2 h, 1 day, 1 week, and 1 month postoperatively) in the horizontal and vertical groups relative to the preoperative values ($P > 0.05$) (Fig. 1). Similarly, the ACD did not differ between these groups at any observed time point ($P > 0.05$) (Fig. 1).

The vault remained constant throughout all observation periods in the vertical group, and similarly, it remained unchanged from 1 day to 1 month postoperatively in the horizontal group. At every observation point, the vault of the horizontal group was significantly higher than that of the vertical group ($P < 0.001$), with the final observation showing vault values of 549.0 (320.0) μm in the horizontal group and 365.0 (189.0) μm in the vertical group. The intergroup vault difference ranged from 144.0 to 209.0 μm during the period from 1 day to 1 month postoperatively; at the final observation, the difference was 150.5 (124.5) μm (Fig. 2), which was significantly larger than the left–right eye difference in the control group [38.5 (22.0) μm] ($P < 0.001$). The percentage of cases where the vault was between 250 and 1000 μm at 1 month postoperatively was 85.7% in the horizontal group and 76.2% in the vertical group, with no cases in either group having a low vault (below 100 μm). Figure 3 shows the vault of horizontally and vertically fixed ICLs in individual cases at 1 month postoperatively. The difference in vault between the right and left eyes showed no significant correlation with the preoperative axial length of the horizontally fixated eye ($r = -0.11$, $p = 0.40$) or the preoperative axial length of the vertically fixated eye ($r = 0.07$, $p = 0.57$). Figure 4 presents a scatter plot of the axial length of the horizontally fixated eye and the vault difference between the right and left eyes one month postoperatively.

The difference between the predicted preoperative vault calculated using the KS formula and the actual measured vault at 1-month postoperatively was -3.0 (206.0) μm for the horizontal group and -154.0 (132.5) μm for the vertical group ($p < 0.001$). The vault dimensions in the horizontal group generally matched the predicted values, while those in the vertical group were lower than the predicted values.

Discussion

The within-patient comparison of the ACD and vault dimensions between horizontal and vertical ICL fixations showed that vertical fixation consistently resulted in a significantly lower vault during the observation period, although no significant changes in the ACD or vault sizes were observed from 1 day to 1 month post-surgery in either group. The vault difference between the two methods of fixation was approximately 150 μm at the final observation; horizontal fixation approximated the preoperatively predicted values, while vertical fixation underestimated the predicted value by more than 100 μm .

ICL surgery involves not only determining the lens power, but also deciding on the optimal lens size to achieve the ideal vault. On the other hand, given the cornea is wider horizontally than vertically, thus a temporal incision and horizontal fixation are typically used as this has less impact on the central cornea. However, some surgeons prefer superior incisions, particularly in younger patients with WTR astigmatism¹, and the lens is inserted and fixed vertically as is. Additionally, some surgeons order toric ICLs that are rotated 90 degrees on the axis by means of preventing rotation and then fix them vertically³. However, considering the ciliary sulcus is reported to be larger vertically in 95% of cases², it is clinically important to examine the postoperative vault when lenses sized for horizontal fixation are fixed vertically. ICLs are available in sizes ranging from 12.1 to 13.7 mm and are selected based on preoperative biometry. Typically, the lens haptics are fixed at four points in an ellipse in the ciliary sulcus; however, measuring the STS preoperatively without special instruments, such as ultrasonic

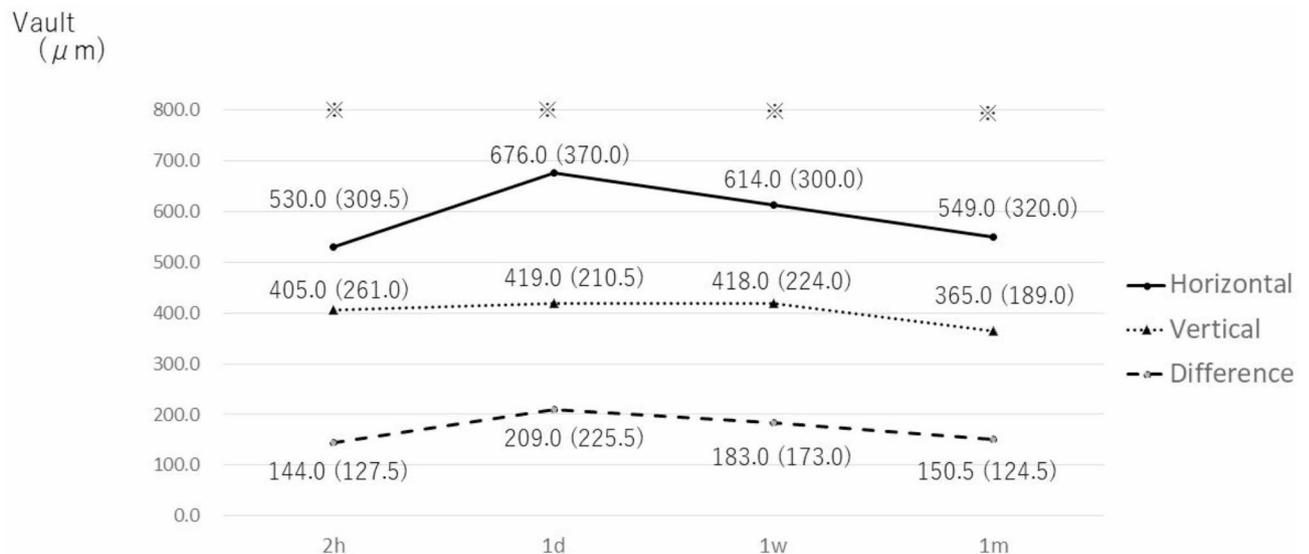


Fig. 2. Temporal changes in postoperative vault. Differences in vault dimensions between vertical and horizontal over time. Throughout this study period, the vault in the vertical group is significantly lower than that in the horizontal group ($\text{※}P < 0.001$; Wilcoxon signed-ranked test).

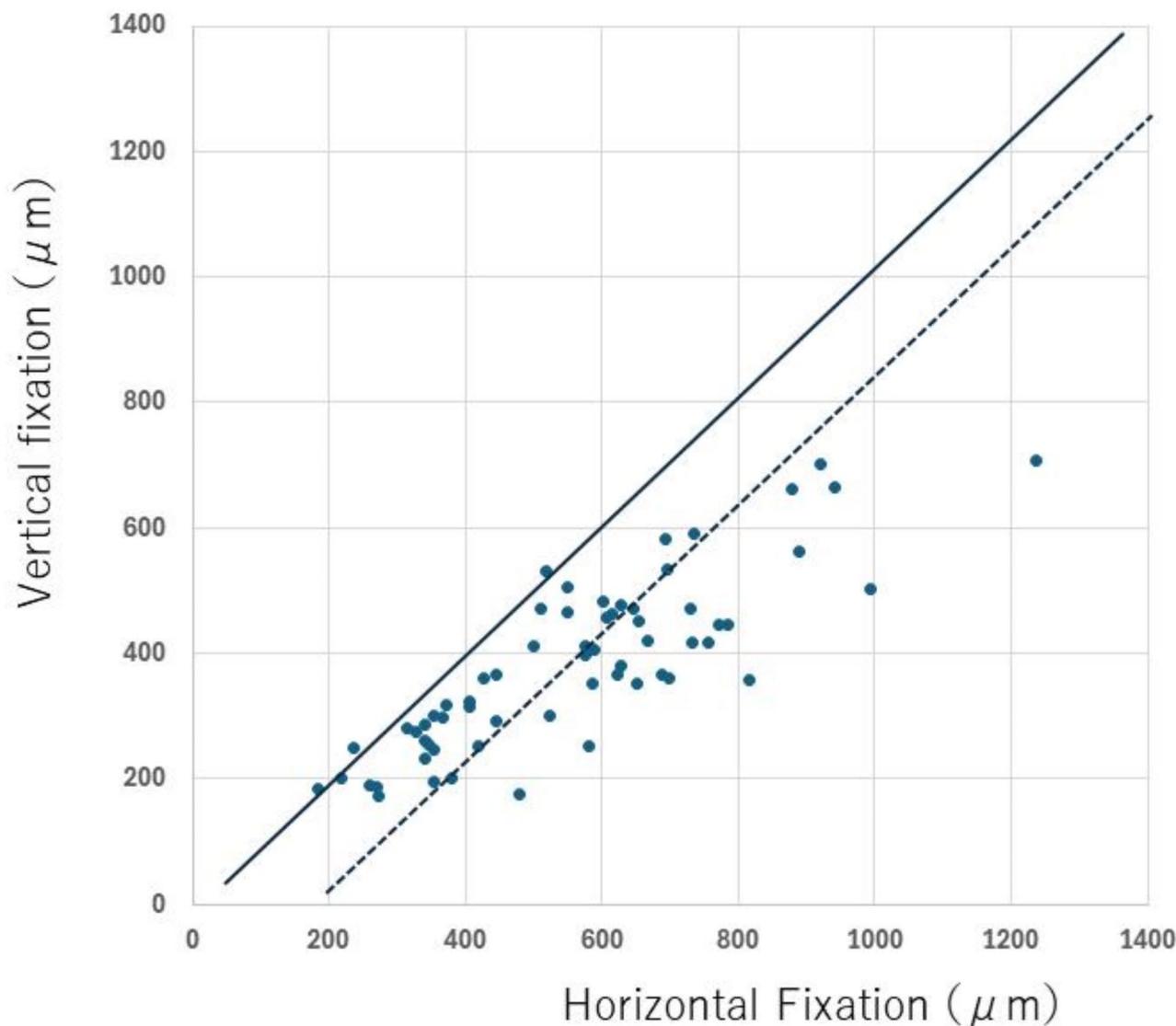


Fig. 3. Distribution of vault dimensions in cases with horizontal vs. vertical fixation of lenses. The solid line is $y = x$; the dotted line is $y = x - 170$. The distribution of points centered around the dotted line are shown; vault in vertical fixation eyes is 170 μm lower than that in horizontal fixation eyes.

biomicroscopy⁸, is challenging, and even Staar Surgical's calculator determines the ICL size based on WTW. While STS and WTW are correlated in emmetropic eyes, this correlation is weak in myopic eyes².

Our previous study found that, in patients receiving vertical fixation of the ICL, the postoperative vault was, on average, 110 μm lower than that of patients receiving horizontal fixation⁷. Although that report measured each fixation method in independent cases, a wide variation in anterior chamber and ciliary sulcus morphology was reported among surgical patients; thus, observing the actual difference in vault between horizontal and vertical fixation within the same patient, as the present study did, provides more convincing results. Moreover, in the present study, by excluding cases with differences in ACD and WTW between the left and right eyes preoperatively and by comparing findings within patients, a more accurate comparison of differences between groups was obtained.

The changes in the ACD and vault dimensions over time showed the same trends as we reported previously⁷. However, the major difference from our previous report⁷, which compared independent groups and could only examine the difference in means, is that the present study, with its within-patient comparisons, allowed examination of the mean of differences. Consequently, the difference in vault dimensions between the two fixation methods was larger than that previously reported, with the mean difference at the final observation period being approximately 150 μm . Additionally, the interquartile range of the difference in the vault dimensions between the left and right eyes was approximately 183.5 μm , which was smaller than that of the control group (222.0 μm),

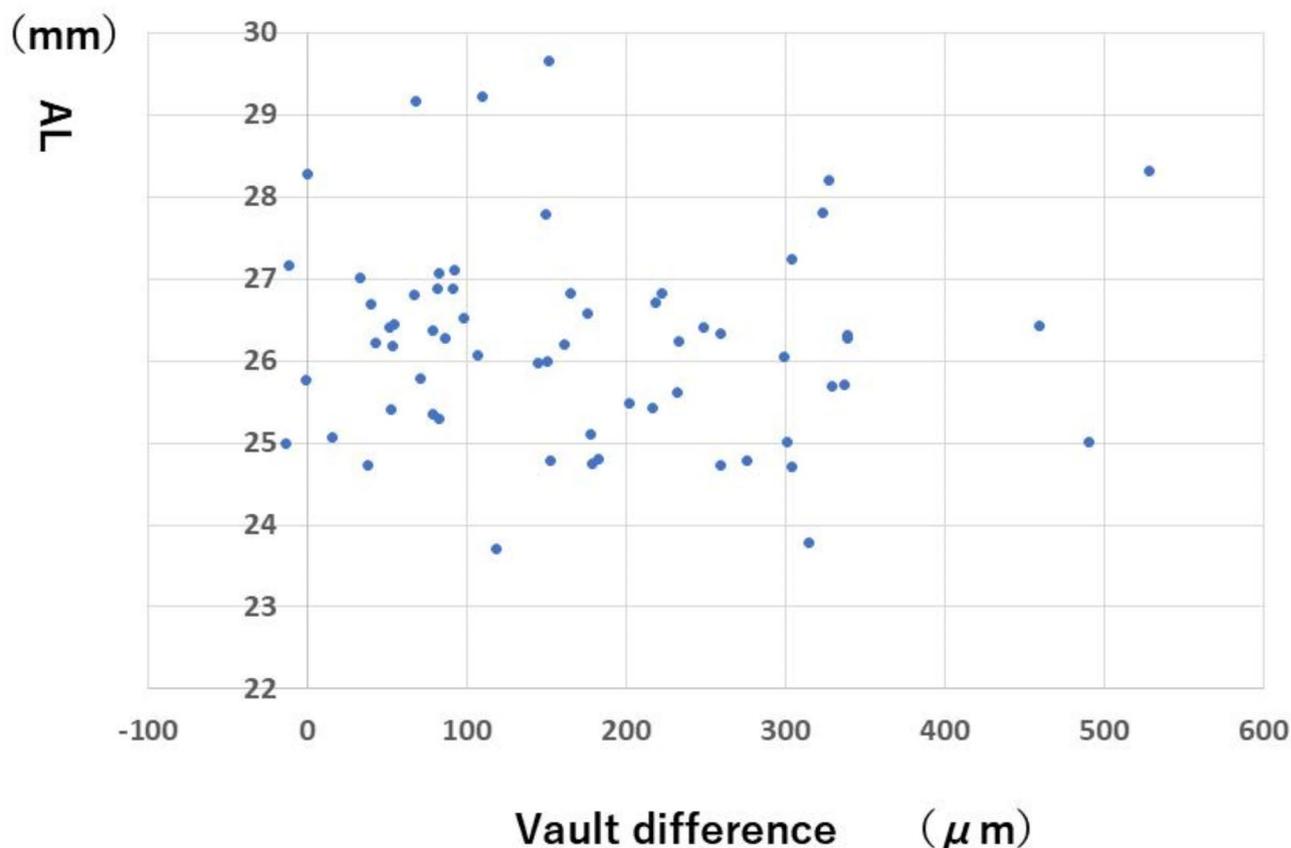


Fig. 4. Relationship between axial length and vault difference. *AL* axial length of the horizontally fixated eye.

in which both eyes were horizontally fixed. This suggests that even within the same individual, some variation in the anatomy of the ciliary sulcus and fixation state of the ICL occurs. Considering this, the results of the current study could be considered to be within an acceptable range of variability in terms of understanding the differences in postoperative vault size between the two fixation methods.

Furthermore, because none of the cases in the present study had a low vault (below 100 μm), even in the vertical fixation group, safety was not compromised. In cases where the postoperative vault is not optimal, the results of this study can be used to predict how much the vault will change by adjusting the rotation of the ICL. However, because the percentage of cases where the vault was within the generally optimal range of 250 to 1000 μm was 85.7% in the horizontal group and 76.2% in the vertical group. Therefore, estimating the postoperative vault to be lower than the preoperative prediction may result in a more appropriate postoperative vault when selecting the size for vertical fixation.

In addition to the direction of fixation, factors that affect the postoperative vault include the anatomical variation in the position where the ICL haptics settle⁹, the anterior–posterior movement of the lens due to accommodation^{10,11}, and push-back on the ICL by the iris during pupil miosis¹², all of which result in a lower vault. Furthermore, regarding temporal changes, reports have suggested that the vault is slightly higher at 2 h postoperatively, significantly declines by the next day, and then gradually returns to its original height over the period of a week to a month¹³. In our study, similar to that in previous reports⁵, the immediate postoperative period (while still dilated) showed the lowest vault, which differed from the findings of Kato et al.¹² and Zhu et al.¹³. However, the effects of residual viscoelastic materials may have had a greater impact immediately after surgery than the interference caused by the movement of the iris.

Thus, while the problem of anatomical variation between cases can be addressed to some extent by comparing findings within patients, differences in surgical techniques, particularly in terms of the removal of viscoelastic substances, cannot be avoided, which is a limitation of the present study. However, since no significant change in the vault was seen from 1 week to 1 month postoperatively, and as it has been reported that the vault is already stable during this period¹⁴, the current study provided clinically relevant information regarding the vault in the final observation period. Further confirmation of the long-term changes in vault over a year postoperatively is warranted. Additionally, if the STS, which is considered most involved in the fixation of the ICL, could be

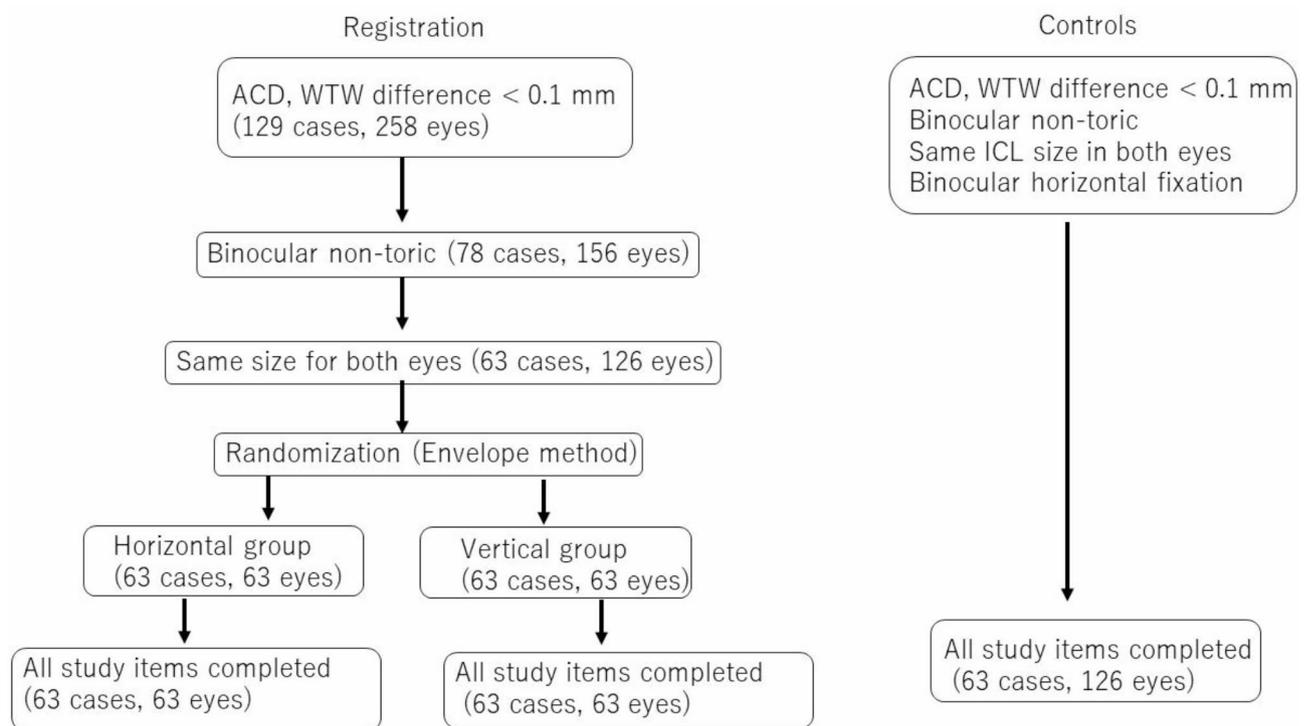


Fig. 5. Flowchart for case selection. ACD = anterior chamber depth; ICL = implantable collamer lens; WTW = white-to-white diameter.

measured directly with A-OCT in future, it could provide more beneficial information. Furthermore, a method to measure the vertical corneal diameter and vertical angle-to-angle distance with high reproducibility needs to be developed, and the relationship between these vertical biometrics and the vault during vertical fixation needs to be clarified in future studies.

In conclusion, when fixing the ICL vertically, the postoperative temporal changes are similar to those seen with horizontal fixation; nonetheless, considering the vault is generally approximately 150 μm lower, the ICL size should be selected with this in mind. Ultimately, refinement of various biometric methods and the construction of calculation formulas for vertical fixation are required.

Patients and methods

The cases were patients who had an EVO + ICL model (Staar Surgical, Monrovia, CA, USA) implanted for myopia at Masayuki Ouchi Eye Clinic and had been observed for more than 1 month postoperatively. Registration criteria were the following: age 20–45 years, subjective spherical value of -3.0 diopters (D) or less, and a difference in the anterior chamber (from the endothelium of the cornea to the anterior surface of the crystalline lens) depth (ACD) and limbal distance (white-to-white, WTW) of no more than 0.1 mm between the left and right eyes.

Case inclusion

Prior to registration, patients' consent was obtained in writing, and after preoperative examinations, cases where either eye had a toric model implanted or where the ICL sizes differed between the left and right eyes were excluded. Left and right eyes of each patient were randomly assigned to either vertical (vertical group) or horizontal (horizontal group) fixation, using the envelope method which was manually generated by preparing slips of paper, prior to surgery.

Furthermore, patients who preferred horizontal fixation in both eyes but consented to the use of their data as controls were considered as candidates for the control group. From these candidates, cases meeting the same inclusion criteria as the previous groups and with non-toric models of the same size fixed horizontally in both eyes were recruited until the number matched that of the horizontal and vertical groups combined (Fig. 5).

ICL specifics determination

The spherical specifications of the ICL were determined using Staar Surgical's web-based calculator (<https://ev-o-ocos.staarag.ch/live/>; Staar Surgical, Monrovia, CA, USA). The lens size was chosen based on the size most frequently recommended by the calculation formula (KS formula) mounted on the CASIA2, based on data obtained from A-OCT measurements (three continuous images taken at each of two preoperative visits). The recommended size was the one in which the predicted postoperative vault, calculated using the KS formula, was closest to 500 μm .

Main items considered

All surgeries were performed by single surgeon (MO), and using a 3.2 mm superior corneal incision, and the ICL was inserted into the anterior chamber under the injection of viscoelastic material (Opegan, Santen Pharmaceutical). Preoperative and 1 day, 1 week, and 1 month post-surgery visual acuity, subjective and objective refraction, and intraocular pressure were measured.

ACD and vault dimensions were measured using A-OCT preoperatively and at 2 h, 1 day, 1 week, and 1 month postoperatively. The aim of this study is to understand the postoperative outcomes of vertical fixation using data obtained through conventional methods, without being influenced by the eyelids or the examiner's skill level, therefore, the scans were standardized horizontally both before and after surgery. The preoperative and postoperative ACD was measured by manually tracing from the corneal endothelium to the anterior surface of the lens. Changes in the ACD and vault over time were compared for each eye, and the differences in the vault dimensions between the left and right eyes at 1 month postoperatively were also compared with those of the control group. The difference between the preoperatively predicted vault and the measured vault at 1 month postoperatively was compared between the horizontal and vertical groups. The preoperatively predicted vault was calculated using the KS formula ver. 4, which was installed on the CASIA2 and based on parameters obtained from horizontal A-OCT scans.

Statistical analysis

Data are presented as the median (interquartile range), and statistical analyses were conducted using R statistical software (<https://www.r-project.org/>: R Foundation for Statistical Computing, Vienna, Austria). First, data normality was confirmed with the F-test. Considering none of the data groups were normally distributed, comparisons between two groups were made using the Wilcoxon signed-ranked test, differences in vault size between the left and right eyes of both groups were compared to those in the control group using the Mann–Whitney U test, and the difference in the ACD from preoperative to each postoperative observation time point was compared between the horizontal and vertical groups using the Steel method. The statistical significance level was set at 5% ($p < 0.05$).

Sample size

The required sample size was estimated assuming an α -level of 0.05 and power of 80%. In our previous research on vertical fixation of ICLs, the mean \pm standard deviation of the postoperative vault for horizontal and vertical fixation was 481.5 ± 203.3 and 350.1 ± 139.2 μm , respectively. Based on these assumptions and accounting for a dropout rate of 5%, a minimum of 40 cases were required for this study.

Ethics and clarity

This study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of Masayuki Ouchi Eye Clinic before being registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR), Japan (registration number and date: UMIN000052884, 24/11/2023), also with the CONSORT 2010 guidelines for reporting randomized controlled trials.

Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author contributions

Masayuki Ouchi is a solo author of this manuscript and designed the study and performed the surgical procedures. Masayuki Ouchi collected and analyzed the data and prepared the manuscript. Masayuki Ouchi created all figures and tables. Masayuki Ouchi reviewed and approved the final manuscript.

Declarations

Competing interests

The authors declare no competing interests.

Patient consent

All participants provided written informed consent.

Additional information

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