Relative position of the central hole after EVO-ICL implantation for moderate to high myopia

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DOI:
10.21203/rs.2.13159/v1

SUBJECT AREAS
Ophthalmology
Abstract
Background: This study aimed to evaluate the relative position of the central hole (CH) of Evolution Visian Implantable Collamer Lens (EVO-ICL), the pupil center (CP), and the corneal center (CC) after implantation of EVO-ICLs for moderate to high myopia. Methods: Eighty-nine eyes of forty-nine patients with moderate to high myopia were evaluated. The mean preoperative spherical equivalent (SE) was -12.58 ± 4.13D. A routine postoperative follow-up was performed within 1-12 months. Positions of the CH of EVO-ICLs, the CP and the CC were recorded using a slit lamp anterior segment photography system, and their relative distances were calculated with the Visio image analysis software. Results: All surgeries were performed safely, and no complications were observed in follow-ups after a mean 4.3 ± 4.82 months. At the last follow-up, the safety index (postoperative CDVA/preoperative CDVA) was 1.23 ± 0.48, and the efficacy index (postoperative UDVA/preoperative CDVA) was 1.08 ± 0.31. The CH in 85 eyes (95.51%) was superior to the CC, with 47.19% (42/89) on the temporal side and 48.31% (43/89) on the nasal side. The CH in 84 eyes (94.38%) was located on the temporal side of the CP, with 56.18% (50/89) superior and 38.2% (34/89) inferior to the CP. The CP of eighty-five eyes (95.51%) was superior on the nasal side of the CC. On the defined x-axis, the average distance from the CH to CC was significantly shorter than the average distance from the CP to CC (p < 0.001). Conclusions: An imperfect mismatch between the central hole of EVO-ICLs and the pupil center does not necessarily indicate ICL dislocation. Compared to the pupil center, the position of the central hole of EVO-ICL is closer to the corneal center.

Background
Implantation of a posterior chamber phakic implantable collamer lens (ICL™, STAAR Surgical, Nidau, Switzerland) has proved to be safe and effective to correct moderate to high myopia [1, 2]. There is no limit to the corneal thickness of the ICL implantation, which preserves the integrity of the cornea and the accommodation function of the lens after surgery. More importantly, the implantation of ICL is reversible.

In refractive surgery, accurate centration helps to maximize visual outcomes and is considered to be
of great importance [3]. Ideally, the position of the corrected center should be aligned to the optical axis or to the intersection point between the optical axis and the anterior corneal surface [4]. However, it is not possible to directly observe the central position of ICL. CentraFLOW technology has recently been applied to the Evolution Visian Implantable Collamer Lens (EVO-ICL), which is characterized by a 360 μm central hole that can facilitate natural flow of the aqueous humor. This reduces the influence of metabolism on the lens and forgoes the necessity for preoperative laser iridotomy [5, 6], resulting in a decreased risk of high intraocular pressure (IOP), cataracts, and endothelial cell loss after ICL implantation. Moreover, it provides an opportunity to directly observe the central position of the EVO-ICL in the posterior chamber. However, it is a common occurrence that the location of the central hole (Cₜ) of the EVO-ICL is not perfectly aligned with the pupil center (Cₚ).

As the structure of the anterior segment of the eye changes as a result of ICL implantation, ultrasound biomicroscopy (UBM) [7], optical coherence tomography (OCT) [8], and rotating Scheimpflug imaging (Pentacam) [9] are used to evaluate the position and the vault of the posterior chamber phakic ICL, as well as relationships between the ICL and its adjacent structures. However, the position of the ICL relative to the corneal center (Cₜ) has not yet been reported. In this study, we therefore aimed to measure the position of the central hole of the EVO-ICL relative to the corneal center and the pupil center, which may be of potential clinical benefit.

Methods

Subjects

This was observational study conducted on patients who underwent EVO-ICL implantation in the Department of Eye & ENT Hospital of Fudan University from January 2016 to October 2016. In accordance with the Declaration of Helsinki, all patients provided written informed consent after receiving detailed explanation of the risks and potential outcomes of the implantation and the study. The study was approved by the Ethics Committee of the Eye & ENT Hospital (EENT) Fudan University.

The study was conducted on 89 eyes from 49 patients (19 males and 28 females, mean age 29.6 ± 7.42 years) who were recruited. All patients underwent routine preoperative examinations, and it was
confirmed that they met the surgical indications for ICL implantation, which are as follows: age between 20 and 45 years, spherical refraction of over −3.00 D, astigmatism of up to −5.00 D, anterior chamber depth (ACD) ≥ 2.80 mm, no contact lens use for 2 weeks, and stable refractive error (refractive error change of ≤0.50 D in the past 2 years). Exclusion criteria were an endothelial cell density (ECD) ≥ 2000 cells/mm², a history of ocular surgery, any chronic systemic disease, inflammation or trauma, and a history of ocular conditions other than myopia with or without astigmatism (suspicion of cornea or lens opacity, keratectasia, glaucoma, macular degeneration, retinal detachment, or neuro-ophthalmic disease).

**EVO-ICL**

The EVO-ICL is made from collamer, a biocompatible hydrophilic copolymer, and hydroxyethyl methacrylate with an ultraviolet light-filtering chromophore [2]. EVO-ICL corrects −0.50 D to −18.00 D myopic spherical refraction and up to −5.00 D cylindrical refraction. There are 4 available sizes: 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm, which are individually selected based on the horizontal white-to-white (WTW) distance and the ACD as per the manufacturer's recommendations. Power calculation of the EVO-ICL was performed by the manufacturer (STAAR Surgical) using a modified vertex formula.

**Surgical procedure and follow-ups**

All implantations were performed by two experienced surgeons (XZ and XW). Chen X et al. have previously described the surgical procedure [9]. Briefly, before surgery, the pupils were dilated. The anterior chamber was filled with sodium hyaluronate (ProVisc, Alcon), and an EVO-ICL was inserted through a 3.0 mm incision in the temporal corneal limbus using an injector cartridge (STAAR Surgical Co), then positioned in the posterior chamber. The remaining viscoelastic surgical agent was removed using balanced salt solution, before a miotic agent was instilled into the anterior chamber. After the surgery, 1% tobramycin and dexamethasone eye drops were prescribed for 3 days, then 0.1% fluorometholone eye drops were prescribed six times per day, decreasing one dose every 3 days until withdrawal. And patients received 0.5% ofloxacin for 1 week, non-steroidal anti-inflammatory (NSAID)
eye drops for 2 weeks, and artificial tears for 1 month after the surgery.

Perioperative examinations included: (1) manifest refraction (spherical equivalent, SE), uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), standard slit-lamp biomicroscopic and funduscopic examinations; (2) anterior chamber depth (ACD) was measured from the corneal endothelium to the anterior lens using a Pentacam camera system (Oculus, Germany); (3) measurements of axial length using an IOLMaster optical biometer (Carl Zeiss, Germany); (4) intraocular pressure (IOP) was measured with a non-contact tonometer (Canon, Japan); (5) measurements of endothelial cell density (ECD) using noncontact specular microscopy (SP-2000P, Topcon Corporation, Japan); (6) central corneal thickness (Pentacam); (7) horizontal corneal diameter (white-to-white, WTW; IOLMaster); (8) ultrasound biomicroscopy (UBM; Quantel medical, France). Patients follow-ups were performed at 1 day, 1 week, 1 month, 6 months, and 12 months after surgery. The mean follow-up time was 4.3 ± 4.82 months (range: 1-12 months).

Image analysis

Under the same illumination conditions, all images were collected in the same room at a 10x magnification using a slit lamp anterior segment photographic system (YZ5FI Slit Lamp + SLICPS 2). Patients sat comfortably with their eyes facing straight ahead. The diffused light from the slit lamp was illuminated 60° from the temporal side. Using Visio image analysis software, the size of the center hole was fixed to 360 μm (7.5 pixels) in both the horizontal (X-axis) and vertical axis (Y-axis), and the image size was then adjusted accordingly. The average horizontal and vertical relative corneal diameters were 214.23 ± 14.66 pixels and 201.78 ± 12.39 pixels, respectively, and the average horizontal and vertical pupil diameters were 52.87 ± 11.95 pixels and 50.58 ± 11.65 pixels, respectively. Images confirmed that both the cornea and the pupil were elliptical (Fig. 1). The actual magnification of the image was calculated according to the following equation: WTW (mm)/relative horizontal diameter of the cornea (mm). Similar to the method reported by Hoang et al. [10], the central hole of EVO-ICL (C_h), the corneal center (C_c), and the pupil center (C_p) were defined as the
intersection between the longest horizontal and vertical diameters of the respective ellipse.

In this study, we set the \( C_c \) of the fitted corneal image as the reference point \((0,0)\) and the position of \( C_h \) and \( C_p \) as \((X, Y)\) using the following formula: \( D = (X^2 + Y^2)^{1/2} \) and calculated the relative distances from the center hole to the corneal center, \( D(H-C) \); the pupil center to the corneal center, \( D(P-C) \); and the center hole to the pupil center \( D(H-P) \) (Fig. 2). According to the equation: actual distance \( D = \) relative distance \( D \times WTW \) (mm)/relative horizontal diameter of the cornea (mm), the actual distances, \( D(H-C) \), \( D(P-C) \) and \( D(H-P) \) were calculated respectively. In all images, the X-axis value of the left eye was converted to a negative value, which was converted to the same nasal and temporal direction as the right eye. The X-axis (\( D_{Hx} \) and \( D_{Px} \)) and the Y-axis (\( D_{Hy} \) and \( D_{Py} \)) on \( D(H-C) \) and \( D(P-C) \) are shown in Fig. 2.

Statistical analysis

All statistical analyses were performed using Stata statistical software, version 14.1 (Stata Corporation, College Station, TX, USA). The Wilcoxon Signed-rank test was used for statistical analysis to compare \( D(H-C) \) and \( D(P-C) \), \( D_{Hx} \) and \( D_{Px} \), \( D_{Hy} \), and \( D_{Py} \). Spearman’s correlation analysis was used to assess the correlation between \( D(H-C) \) and \( D(P-C) \), \( D_{Hx} \) and \( D_{Px} \), and \( D_{Hy} \) and \( D_{Py} \). Results are expressed as mean ± standard deviation (SD), and statistical significance was set at \( p < 0.05 \).

Results

Safety and Efficacy

All surgical procedures were completed successfully and no complications occurred throughout the entire follow-up period. The median follow-up period was 4.3 ± 4.82 months (range: 1-12 months). No postoperative complications were observed, and no loss of corrected distance visual acuity (CDVA) was recorded throughout the entire follow-up period. The mean preoperative spherical equivalent (SE) was -12.58 ± 4.13 D (range: -5.75 to -22.75D). The safety index (postoperative CDVA/preoperative CDVA) was 1.23 ± 0.48. No patient had CDVA loss at any follow-up. The efficacy index (postoperative UDVA /preoperative CDVA) was 1.08 ± 0.31, and the mean vault was 525.93 ± 228.43 \( \mu m \) (range:
100-1070 μm). No eye decreased to [2000 cells/mm² throughout the entire follow-up period.

Relative position of $C_H$ to the $C_C$ and the $C_P$

Relative to the $C_C$, the $C_H$ of EVO-ICL was superior to the $C_C$ in 85/89 eyes (95.51%), with 42/89 (47.19%) superior on the temporal side, 43/89 (48.31%) superior on the nasal side, 3/89 (3.37%) inferior on the temporal side, and 1/89 (1.12%) inferior on the inferior nasal side (Fig. 3A). Relative to the $C_P$, the $C_H$ was located on the temporal side in 84/89 eyes (94.38%), with 50/89 (56.18%) superior on the temporal side, 34/89 (38.2%) inferior on the temporal side, 2/89 (2.25%) superior on the nasal side, and 3/89 (3.37%) inferior on the nasal side (Fig. 3B).

Relative position of the $C_P$ to the $C_C$

$C_P$ was superior on the nasal side of the $C_C$ in 85/89 eyes (95.51%), with 3/89 (3.37%) superior on the temporal side, and 1/89 (1.12%) inferior on the nasal side in (Fig. 4).

Distance between the $C_H$, the $C_C$ and the $C_P$

The average $D(H-C)$ and $D(P-C)$ were $0.37 \pm 0.18$ mm and $0.42 \pm 0.18$ mm respectively, and were approaching a statistically significant difference ($p = 0.058$). The average $D(Hx)$ and $D(Px)$ were $0.16 \pm 0.12$ mm and $0.28 \pm 0.19$ mm respectively, and were statistically different ($p < 0.001$). The average $D(Hy)$ and $D(Py)$ were $0.30 \pm 0.19$ mm and $0.27 \pm 0.14$ mm respectively, and the difference was not statistically significant ($p = 0.624$). The average $D(H-P)$ was $0.35 \pm 0.18$ mm (range: 0.05-1.01 mm). Though there was no significant correlation between $D(H-C)$ and $D(P-C)$ ($r = 0.20, p = 0.062$), $D(Hx)$ was positively correlated with $D(Px)$ ($r = 0.57, p < 0.001$) and $D(Hy)$ with $D(Py)$ ($r = 0.42, p < 0.001$).

Discussion

The new EVO-ICL has reduced risk of high intraocular pressure (IOP), cataracts, and endothelial cell loss after ICL implantation and is more effective and safer than conventional ICLs due to natural flow through a central whole [5, 6, 11]. The position of the intraocular lens is critical during follow-up since
it may be of consequence to corrected visual acuity as well as post-operative complications such as cataracts and glaucoma [5, 11]. However, the position of conventional ICLs, such as the V4, are difficult to evaluate without the use of UBM or a Pentacam [12, 13]. In this study, we were able to evaluate the relative position of the EVO-ICL in the posterior chamber directly based on the position of the center hole in a slit lamp image, without the need for additional inspection.

Here, we described the relative position of the central hole, the corneal center and the pupil center, and found that 95.5% (85/89) of central holes of EVO-ICLs were superior to the corneal center and 94.38% (84/89) of central holes were on the temporal side of the pupil center. Although the difference between $\Delta(H-C)$ and $\Delta(P-C)$ did not reach statistical significance difference ($p = 0.058$), $\Delta(H-C)$ was significantly shorter than $\Delta(P-C)$ on the X-axis ($p < 0.001$) but not on the Y-axis ($p = 0.624$). The selection of ICL diameter depends mainly on the preoperative horizontal corneal diameter (WTW) and anterior chamber depth [14]. ICLs are usually positioned horizontally in the ciliary sulcus with a rotation of $5^\circ$ even implantations of toric intraocular collamer lenses (TICLs) [15, 16]. Hence, the horizontal position of the central hole should be aligned to the horizontal center of the sulcus to sulcus (STS) line. Seo et al. [17] reported that the WTW diameter matched with the distance of the STS on the horizontal direction as measured by UBM, indicating that the center of the ICL should be positioned relative to the corneal center, which is consistent with our observation. Therefore, it is more reasonable to evaluate the position of the EVO-ICL according to the relative position of the central hole to the corneal center.

Moreover, we also found that the central hole and the pupil center both shifted upwards relative to the corneal center during follow-ups. Most pupil centers (95.51%) were located at superior on the nasal side of the corneal center, which is consistent with previous reports [10, 18]. The mean distance between the pupil center and the corneal center in our study was $0.42 \pm 0.18$ mm, which was shorter than that reported by Wilson et al. [19], but longer than the $0.11 \pm 0.07$ reported by Medby et al. [20]. This discrepancy could possibly have resulted from the different imaging methods or due the
different ethnic groups in these studies. Spearman’s correlation analysis showed that DHx was positively correlated with DPx ($r = 0.57$, $p < 0.001$), and DHy was positively correlated with DPy ($r = 0.42$, $p < 0.001$), suggesting that shifts of both the central hole of the EVO-ICL and the pupil center relative to the corneal center were concordant in the horizontal and vertical directions. However, there was no direct correlation between DH(C) and DP(C) ($r = 0.20$, $p = 0.062$). It has been reported that the location of the pupil center may change under various illumination conditions [21-23]. Yang et al. [21] reported that the pupil center moved temporally towards the corneal center under mesopic or pharmacologically dilated conditions. Other studies using UBM have showed that ICLs were in contact with the posterior surface of iris [7, 24], suggesting that the mechanical friction between the iris and the ICL could be responsible for the concordant movement of the implanted lens following the shift of the pupil.

In this study, the position of the center hole, which was mostly superior on the temporal side of the corneal center, was closer to the corneal center than the pupil center, and may move concordantly with the pupil after surgery. It may be more reasonable to evaluate the appropriate position of the ICL according to the corneal center. In this study, we used the slit lamp anterior segment photographic system and objective image analysis to evaluate the relationship between the central hole and the corneal center. This has the benefits of being easy to use, non-invasive, and not requiring any additional equipment, which means that it has certain feasible advantages over other methods for clinical observation.

The current study is limited by a relatively short follow-up time and small sample size. Accordingly, prospective studies with a longer follow-up time and a larger sample size are required to determine the value of this method. These studies should also investigate the relationships between the distance of the central hole to the corneal center and clinical outcomes, such as visual quality, after ICL implantation.

Conclusions
Although the central hole of the EVO-ICL does not perfectly match the pupil center, it is not necessarily indicative of an ICL dislocation. Compared to the pupil center, the position of the central hole of the EVO-ICL is closer to the corneal center.

Abbreviations
EVO-ICL, Evolution Visian Implantable Collamer Lens; SE, spherical equivalent; D, Diopter; Central hole of EVO-ICL, CH; Corneal center, CC; Pupil center, CP; IOP, Intraocular pressure; UBM, Ultrasound Biomicroscopy; OCT, Optical coherence tomography; ACD, Anterior chamber depth; ECD, Endothelial cell density; WTW, White-to-white; NSAID, Non-steroidal anti-inflammatory drugs; UDVA, Uncorrected distance visual acuity; CDVA, Corrected distance visual acuity; SD, Standard deviation; STS, Sulcus to sulcus.

Declarations
- **Ethics approval and consent to participate:** This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Eye and ENT Hospital Review Board of Fudan University. Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

- **Consent for publication:** All participants in this study signed written consent forms for the publication of their relevant clinical data.

- **Availability of data and material:** Data and materials are available upon request from the corresponding author at doctzhouxingtao@163.com.

- **Competing interests:** The authors declare that there is no competing interest.

- **Funding:** This work was supported by National Natural Science Foundation of China (Grant No. 81770955 and 81570879), Project of Shanghai Science and Technology (Grant No. 17140902900 and 17411950200) and National Natural Science Foundation of China for Young Scholars (Grant No. 81600762). The funding agencies had no role in study design, data collection and analysis, interpretation of data, or writing the manuscript.

- **Authors’ contributions:** Literature screening and selection was performed by XH and LN. XZ participated in the design of the study. LN drafted the manuscript. XH carried out the statistical
analysis. HM and FZ prepare and review of the manuscript. XZ has given final approval of the version to be published. All authors read and approved the final manuscript.

- Acknowledgements: The authors thank Lin Wang and Tian Han of the Eye Department of EENT Hospital for their helpful advice. We would also like to thank all the patients participating in the study.

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Figures
The red line and circle is shown for the central hole of the EVO-ICL, the purple line and circle is shown for the pupil center, and the blue line and circle is the corneal center of the right eye. Visio image analysis software was used for image analysis.
Relative position of the central hole of EVO-ICL, the corneal center and the pupil center.

3A: Scatter plot of the central hole relative to the corneal center. (0, 0) represents the corneal center. 3B: Scatter plot of the central hole relative to the pupil center. (0, 0) represents the pupil center.
Figure 4

Scatter plot of the pupil center relative to the corneal center. (0, 0) represents the corneal center.

Supplementary Files
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