

Aligning the Axis of Toric Intraocular Lens with the Corneal Steep Meridian by Setting SIA at 0 Diopter: A Prospective Randomized Controlled Trial

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Purpose: This study aims to investigate the clinical efficacy of aligning the axis of toric intraocular lens (IOL) with the corneal steep meridian in cataract patients.

Methods: This is a prospective randomized controlled trial involving seventy cataract patients who underwent implantation of a Tecnis Toric IOL. Patients were randomly divided into two groups. In the control group, the incision-induced surgically induced astigmatism (SIA) was set at 0.5 D, and the alignment axis was determined using the Tecnis Toric Aspheric IOL Calculator. In the experimental group, incision SIA was set as 0 D and the alignment axis was aligned with the steep meridian of corneal astigmatism. Primary outcome measures, including astigmatism vector analysis, incision SIA and error of refractive astigmatism (ERA) were analyzed. Visual acuity, predicted residual astigmatism (PRA) and residual astigmatism were evaluated at 3 months.

Results: Measurements of postoperative uncorrected and corrected distance visual acuity (UDVA and CDVA), degrees of lens dislocation ($^{\circ}$), incision-induced SIA, target induced astigmatism vector and actual surgically induced astigmatism showed no differences between the two groups ($P > 0.05$). The ERA of the experimental group (0.15 ± 0.32 D) was significantly smaller than the control group (0.58 ± 0.48 D) ($P < 0.001$). Vector analysis of total error vector (EV) was smaller in the experimental group (0.30 ± 0.24 D) than the control group (0.60 ± 0.46 D) ($P = 0.001$). The experimental group showed lower postoperative cylinder (0.49 ± 0.23 D) than the control group (0.71 ± 0.49 D) ($P = 0.055$).

Conclusion: This study suggests that aligning the toric IOL axis with the corneal steep meridian showed by setting SIA as 0 D might be an available method to reduce the error of refractive astigmatism.

Keywords: toric intraocular lens, corneal steep axis, astigmatism correction, cataract surgery

Introduction

Numerous strategies are currently available for the management of preoperative astigmatism during cataract surgery, including clear corneal incisions, limbal relaxing incisions, arcuate keratotomy, and toric intraocular lens (IOLs) implantation—each of which has been validated for clinical efficacy.¹ Among these approaches, toric IOLs implantation has been subjected to in-depth research and is widely used in clinical practice for astigmatism correction.² Recent evidence has further indicated that TIOL implantation yields superior outcomes compared to other incision-based correction techniques.^{2,3}

Residual refractive astigmatism is mainly influenced by the following factors: the magnitude and directional variability of SIA from corneal incisions, as well as the rotational stability of toric IOLs.^{3,4} Incisions of different types, lengths, and directions may affect the value of surgically induced astigmatism (SIA).^{5,6} At present, the most widely used calculation method involves inputting the surgeon's measured SIA value and incision direction into a dedicated calculator to determine the optimal implantation axis of a toric intraocular lens (IOL). However, two key limitations cast doubt on whether the intended astigmatism correction outcome can be reliably achieved. For one thing, SIA values are highly variable due to multiple confounding factors.⁷ For another, a rotational discrepancy of 3–5 degrees often exists between the calculated and the actually

achieved IOL axis.⁸ We proposed a simplified approach in this study where SIA was set at 0 diopters (D), with the toric IOL alignment axis precisely matched to the steep meridian of corneal astigmatism. This method is functionally equivalent to fully correcting all corneal astigmatism with the toric IOL in the first instance, such that any residual postoperative astigmatism can be directly attributed to the SIA induced by the corneal incision.

Given that astigmatism analyses are multi-dimensional, subtle nuances cannot be fully captured by a single graphical display.⁹ The Alpins Method offers a straightforward approach: it employs four distinct graphs to address specific questions, thereby facilitating the identification of factors underlying inaccurate astigmatic correction and the evaluation of astigmatic treatment effectiveness.^{10,11}

Therefore, the purpose of this prospective study is to evaluate the clinical outcomes and the predictability of aligning astigmatic lens axis with corneal steep meridian by setting SIA as 0 D.

Materials and Methods

Patients

Institutional review board approval (Ethics committee of Qingdao Eye hospital, 2022[08]) was obtained for this study following the tenets of the Declaration of Helsinki. Written informed consent for participation was obtained from each patient prior to enrollment. The study recruited patients aged from 35 to 80 undergoing phacoemulsification and toric IOLs implantation at Qingdao Eye Hospital (Qingdao, Shandong, China) from January, 2023 to October, 2023. Patients were required to have between 1.0 D and 3.5 D of preoperative keratometric astigmatism and randomly divided into two groups. The experiment was conducted in a single-blind way. This study was designed as a single-blind trial, with blinding implemented for the patients. Patients were excluded with any ocular diseases such as severe unstable tear film, pterygium, irregular corneal astigmatism, uveitis, retinal detachment, maculopathy, glaucoma, amblyopia, history of eye trauma and serious intraoperative complications.

Preoperative Assessment

All patients had detailed preoperative ocular examinations including subjective refraction, uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) measurements, slit-lamp examination and fundus examination for mydriasis. Ocular biometry was performed using a partial coherence interferometry device (IOL Master 500, Carl Zeiss AG, Oberkochen, Germany). Corneal topography was measured using the Oculus Pentacam (Optikgeräte GmbH, Wetzlar, Germany) and iTrace System (Tracey Technologies, Houston, TX, USA).

Intraocular Lens Calculation

The toric IOL plans were determined based on the Tecnis Toric Aspheric IOL Calculator. The Tecnis Calculator incorporates the anterior chamber depth based on the axial length and keratometry values, and the Holladay formula incorporates the effective lens position in its calculations.^{9,12} For the control group, the corneal incision SIA was set as 0.5 D (the surgeon's personalized SIA, which was calculated using a standard astigmatism vector analysis) using the Tecnis Calculator to select the most appropriate toric IOLs model, alignment axis and incision direction. For the experimental group, the corneal incision SIA was set as 0 D, the alignment axis was same to the steep-axis of cornea astigmatism.

Tecnis Toric IOLs (Abbott Medical Optics, Inc., Santa Ana, CA, USA) were implanted. A monofocal or multifocal toric IOL might be selected based on patient's preference and preoperative assessment. The optic is measured to be 6.0 mm. The lens is available in 0.5 D increments from +6.0 D to +30.0 D. The cylindrical power of the toric IOL can correct corneal astigmatism ranging from 0.5 D to 3.62 D.

Surgical Technique

Preoperatively, markings should be performed at the corneal epithelium inside the limbus with the patient in an upright position. All surgeries were performed by the same experienced surgeon (Yunhai Dai). A 2.5 mm primary 2-plane clear corneal incision was created at surgeon's accustomed direction. A well-centered continuous 360-degree capsulorhexis about 5.5 mm in diameter was created. Phacoemulsification was performed using the cataract ultrasonic emulsification

(Stellaris, Bausch & Lomb incorporated, USA). The folded toric IOLs were implanted into the capsular bag then aligned with the marked axis combined with the image-guided systems (CALLISTO Eye, Carl Zeiss AG, Oberkochen, Germany). The CALLISTO eye aid in preoperative planning of the surgical incisions location and toric IOLs positioning.

Postoperative Assessment

Postoperative examinations were performed at 3 months and included UDVA and CDVA, subjective and objective (auto refractometry) refractions, slit-lamp evaluation, keratometry (IOL Master 500) and toric IOLs direction (The IOL direction was assessed with iTrace). Wavefront aberrometers such as the iTrace system determine the orientation of the toric IOL based on the internal ocular aberrations. The toric IOL enhancement software of iTrace also provides the magnitude and direction of the required rotation to achieve accurate alignment with minimal residual astigmatism.

Astigmatism Vector Analysis

The characteristic results of astigmatism are described using the standard graphs based on the Alpíns Method.¹³ *Target Induced Astigmatism Vector (TIA)*. The astigmatic change (in terms of magnitude and axis) that the surgery is intended to induce. *Surgically Induced Astigmatism Vector (SIA)*. The magnitude and axis of the astigmatic change that the surgery actually induced. *Correction Index (CI)*. The index is calculated as the ratio of the SIA to the TIA, by dividing the SIA by the TIA. A CI value of 1.0 is considered optimal. A value greater than 1.0 indicates overcorrection, while a value less than 1.0 indicates undercorrection. *Difference Vector (DV)*. This refers to the induced astigmatic change (in terms of magnitude and axis) required for the initial surgery to achieve its intended target. The DV serves as an absolute measure of surgical success, with a value of zero being optimal.

Corneal astigmatism was decomposed to vertical/horizontal (X) and oblique changes (Y) using the vector analyses created by Eydelman MB.¹⁴ The vector analyses of the corneal incision SIA was calculated as follows.

$$X = \cos(2 \times A); Y = \sin(2 \times A)$$

$$|SIA| = \sqrt{(X_{preop} - X_{postop})^2 + (Y_{preop} - Y_{postop})^2}$$

$$X_{SIA} = X_{preop} - X_{postop}; Y_{SIA} = Y_{preop} - Y_{postop}$$

C means cylinder (steep axis minus flat axis), A means axis (direction of steep axis), preop means preoperative, postop means postoperative.

The difference between the predicted residual astigmatism (PRA) and the residual astigmatism (RA) obtained by postoperative optometry is the error of refractive astigmatism (ERA). The vector analysis of SIA and ERA instead of simple algebraic addition and subtraction should be carried out. The vector analysis of ERA was represented by the error of vector (EV).

The vector analyses of ERA was calculated as follows.^{15,16}

$$X_{RA} = C_{RA} \times \cos(2 \times A_{RA}); Y_{RA} = C_{RA} \times \sin(2 \times A_{RA})$$

$$X_{PRA} = C_{PRA} \times \cos(2 \times A_{PRA}); Y_{PRA} = C_{PRA} \times \sin(2 \times A_{PRA})$$

$$X_{EV} = X_{RA} - X_{PRA}; Y_{EV} = Y_{RA} - Y_{PRA}$$

$$EV = [(X_{RA} - X_{PRA})^2 + (Y_{RA} - Y_{PRA})^2]^{1/2}$$

RA means residual astigmatism, PRA means expected residual astigmatism, EV means error of vector, ERA means error of refractive astigmatism.

The centroid corneal incision SIA and ERA were assessed by vector analysis. The displays of individual distributions were assessed by the astigmatism double angle plot tool available on the American Society of Cataract and Refractive Surgery website (<https://ascrs.org/tools/astigmatism-double-angle-plottool>).

Statistical Analysis

Statistical analyses were performed with SPSS for Windows (version 26, IBM, Armonk, NY, USA). All data in this study conformed to a normal distribution and were expressed as mean \pm standard deviation. In this study, statistical analysis was performed using the generalized estimating equations (GEE) method. Potential confounding factors, including the type of intraocular lens (monofocal vs multifocal) and the inclusion of both eyes from the same individual, were controlled for in the analysis. A P -value < 0.05 was considered significant.

Results

Visual and Refractive Outcomes

There were 55 patients (70 eyes) aged from 36 to 79 who finished the follow-up in the study. Containing 26 males and 29 females. Data were shown in Table 1. Preoperative corneal astigmatism was 2.22 ± 0.94 D in the control group, and 2.38 ± 0.83 D in the experimental group ($P = 0.363$). Degrees of toric lens dislocation were 4.97 ± 3.54 D in the control group and 4.51 ± 3.06 D in the experimental group ($P = 0.768$). The postoperative cylinder was detected by objective refraction. The experimental group showed lower postoperative cylinder (0.49 ± 0.23 D) than the control group (0.71 ± 0.49 D), although had no significant differences ($P = 0.055$). The PRA was lower in the control group (0.12 ± 0.11 D) than the experimental group (0.32 ± 0.20 D) ($P < 0.001$).

The surgery refractive outcomes were reported (shown in Figure 1) according to the basic standard for reporting cataract surgery refractive outcomes raised by Dan Z. Reinstein.¹⁷ Postoperative UDVA and CDVA showed no differences between two groups (shown in Figure 1A and B). There were 48.6% patients with UDVA same or better than CDVA in which SIA set as 0.5 D. There were 45.7% patients with UDVA same or better than CDVA in which SIA set as 0 D (shown in Figure 1C). The percentage of patients of accuracy of spherical equivalent less than 0.5 D was 60%, and less than 1.0 D was 91.4%, in which SIA set as 0.5 D. The percentage of patients of accuracy of spherical equivalent less than 0.5 D was 71.5%, and less than 1.0 D was 88.6%, in which SIA set as 0 D (shown in Figure 1D). The percentage of patients of postoperative refractive cylinder less than 0.5 D was 54.3%, and less than 1.0 D was 82.9%, in which SIA set as 0.5 D. The percentage of patients of postoperative refractive cylinder less than 0.5 D was 65.7%, and less than 1.0 D was 97.1%, in which SIA set as 0 D (shown in Figure 1E).

Vector Analysis

The astigmatism vector diagram was used to analyze the distribution characteristics of astigmatism indicators, and the distributions of TIA and SIA were roughly consistent in each group. At 3 months postoperatively, in the control group (shown in Figure 2), the arithmetical TIA was 2.06 D, the SIA was 1.91 D, and the DV was 0.71 D; in the experimental

Table 1 Visual and Refractive Outcomes

	Control Group	Experimental Group	P Value
Number	35	35	
Age	64.83 ± 10.22	62.09 ± 11.85	
Preop Corneal astigmatism (D)	2.22 ± 0.94	2.38 ± 0.83	0.363
PRA (D)	0.12 ± 0.11	0.32 ± 0.20	0.000
Postop Cylinder (D)	0.71 ± 0.49	0.49 ± 0.23	0.055
Degrees of lens dislocation (°)	4.97 ± 3.54	4.51 ± 3.06	0.768

Notes: Values are presented as the mean \pm standard deviation.

Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; Preop, preoperation; Postop, postoperation; PRA, expected residual astigmatism.

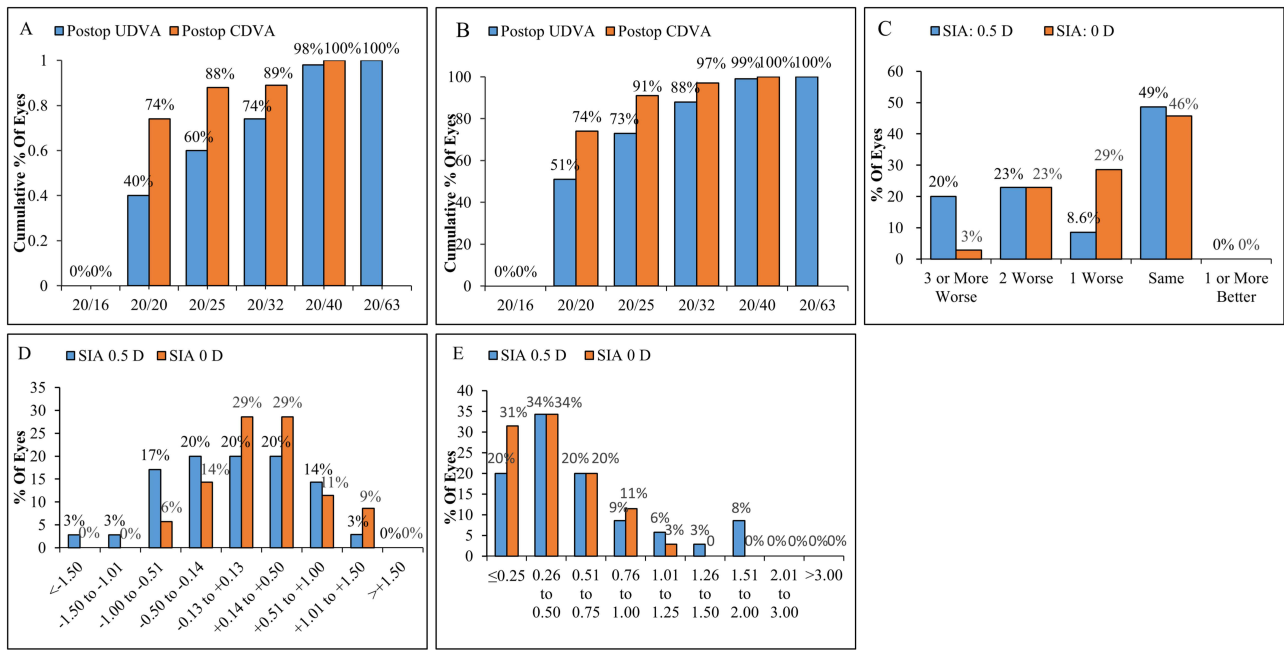


Figure 1 Standard graphs for reporting refractive outcomes for intraocular lens-based procedures at 3 months after the operation. (A) The proportion of uncorrected distant visual acuity greater than 20/x (expressed by Snellen visual acuity) in the control group. (B) The proportion of uncorrected distant visual acuity greater than 20/x (expressed by Snellen visual acuity) in the experimental group. (C) Uncorrected distance visual acuity versus corrected distance visual acuity in two groups (expressed by Snellen visual acuity). Spherical equivalent refraction accuracy (D) and postoperative refractive cylinder (E) in two groups.

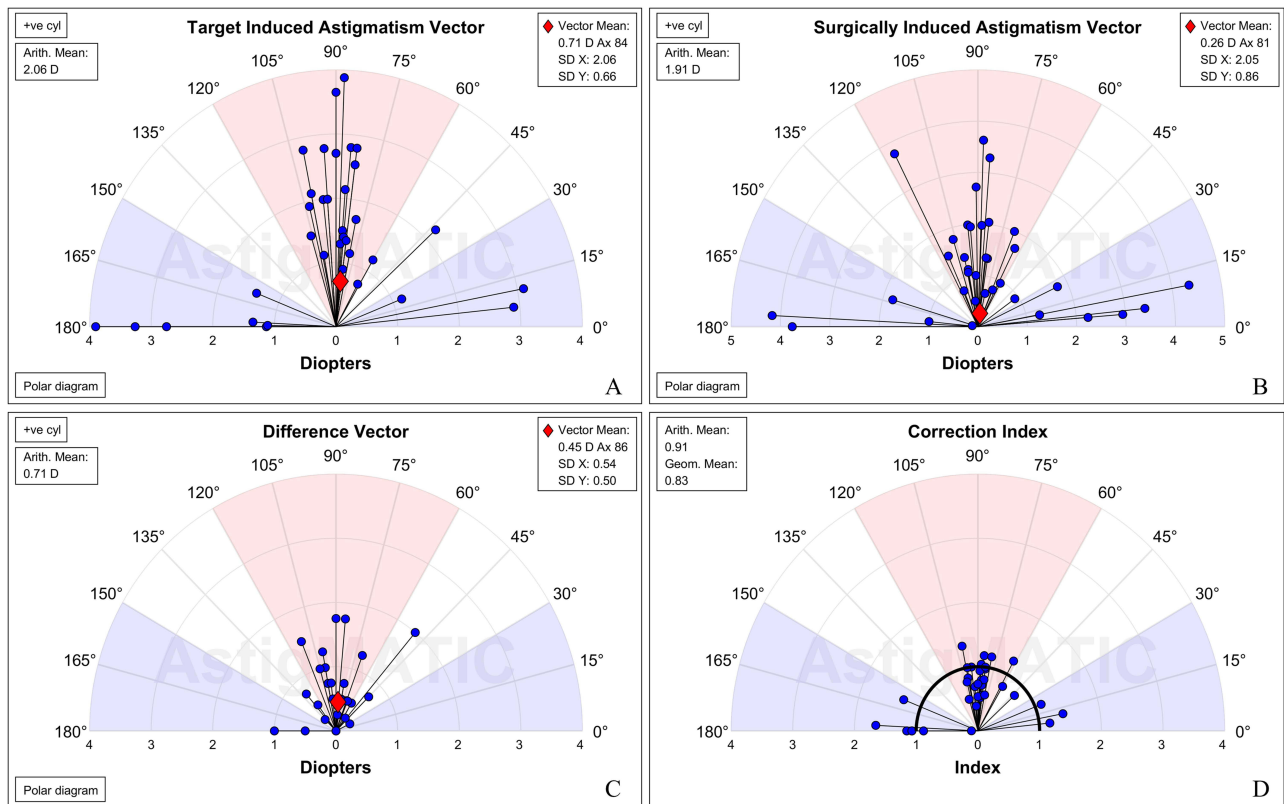


Figure 2 Standard Graphs for Reporting Astigmatism Correction Outcomes of the control group. (A) The vector graph of the target-induced astigmatism vector (TIA), (B) the vector graph of the surgically induced astigmatism vector (SIA), (C) graph of the difference vector (DV), (D) the vector graph of correction index (CI). Vector means—calculated in the double-angle vector space—are plotted as red diamonds, with the standard deviations for the X and Y directions displayed in call-out boxes.

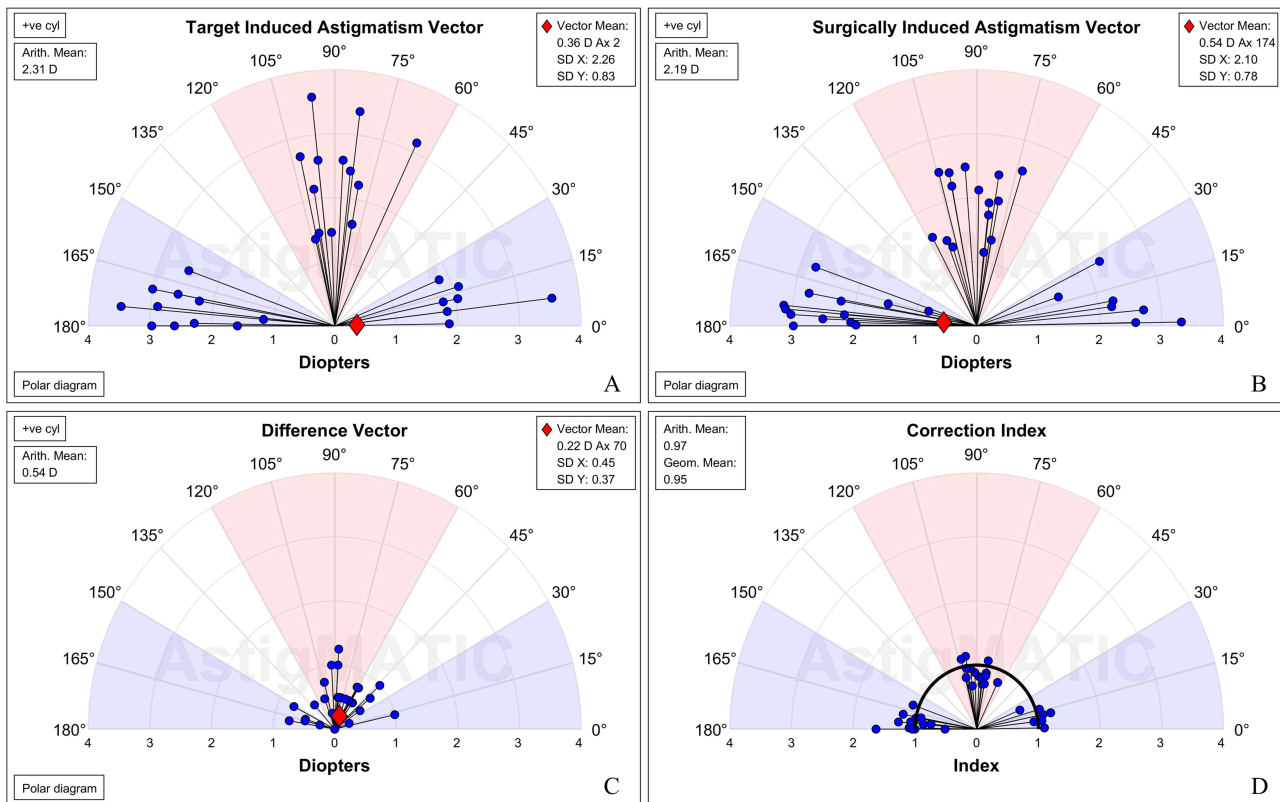


Figure 3 Standard Graphs for Reporting Astigmatism Correction Outcomes of the experimental group. (A) The vector graph of the target-induced astigmatism vector (TIA), (B) the vector graph of the surgically induced astigmatism vector (SIA), (C) graph of the difference vector (DV), (D) the vector graph of correction index (CI). Vector means—calculated in the double-angle vector space—are plotted as red diamonds, with the standard deviations for the X and Y directions displayed in call-out boxes.

group (shown in Figure 3), the arithmetical TIA was 2.31 D, the SIA was 2.19 D, and the DV was 0.54 D. The CI values were 0.91 and 0.97 in the control group and the experimental group, respectively, both indicating an undercorrection status.

Vector analysis of SIA was performed at the 3-month follow-up examination (shown in Table 2). The average arithmetic for X_{SIA} was 0.15 ± 0.09 D in the control group and 0.11 ± 0.43 D in the experimental group ($P = 0.719$). The average for Y_{SIA} was 0.05 ± 0.35 D in the control group and 0.06 ± 0.48 D in the experimental group ($P = 0.690$). The total SIA ($|SIA|$) was 0.52 ± 0.37 D in the control group and 0.56 ± 0.36 D in the experimental group ($P = 0.643$). There was no significant difference of X_{SIA} , Y_{SIA} , and total SIA between the two groups.

The centroid is the arithmetic mean of the position of all points within a two-dimensional region. The centroid SIA analyzed by double angle plot in two groups was 0.04 D @ $86^\circ \pm 0.66$ D (shown in Figure 4A) and 0.14 D @ $102^\circ \pm 0.65$ D (shown in Figure 4B), respectively. Points of SIA in double angle plot had high dispersion of distribution in each group.

Table 2 Statistical Analysis of SIA

	Control Group	Experimental Group	P Value
X_{SIA}	0.11 ± 0.43	0.15 ± 0.09	0.719
Y_{SIA}	0.06 ± 0.48	0.05 ± 0.35	0.690
$ SIA $	0.52 ± 0.37	0.56 ± 0.36	0.643

Notes: Values are presented as the mean \pm standard deviation.
Abbreviations: SIA, surgically induced astigmatism; X_{SIA} , SIA in vertical/horizontal direction; Y_{SIA} , SIA in oblique direction; $|SIA|$, absolute value of SIA.

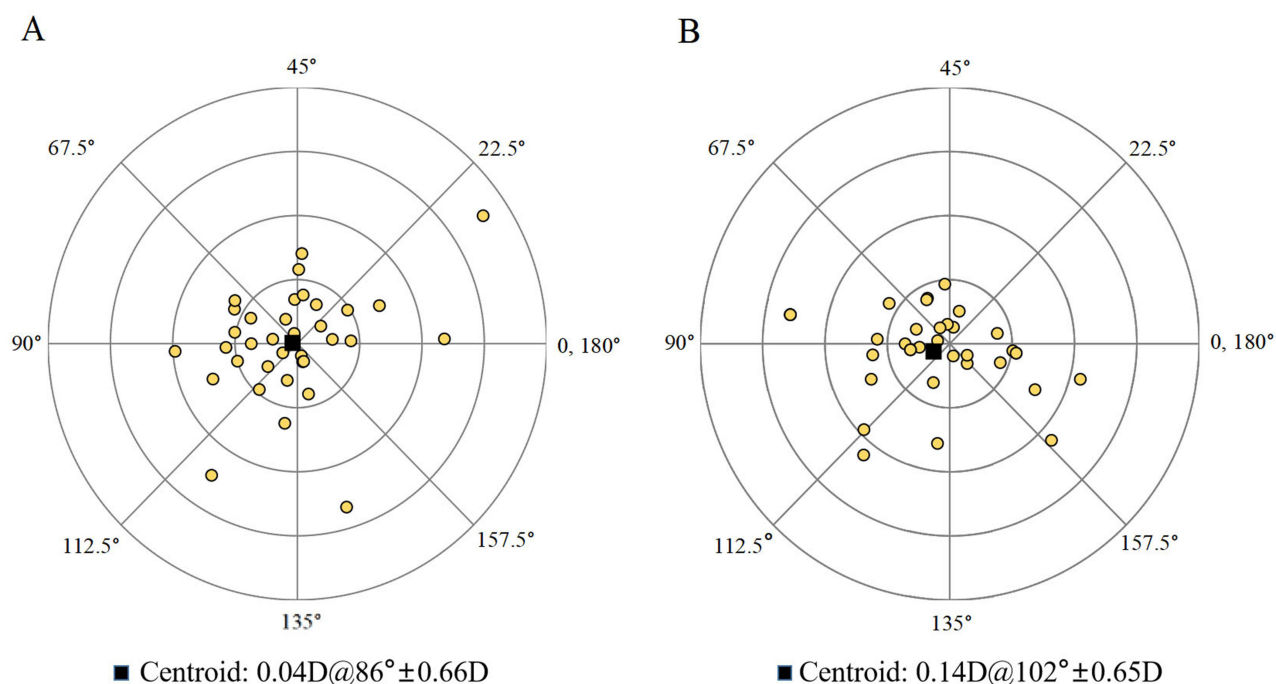


Figure 4 Double-angle vector plot of the corneal incision SIA for each case in the control group (A) and the experimental group (B) at the 3-month postoperative. The yellow dot means the vector coordinate of SIA in each case. The black square means the centroid. Each ring = 0.5 D.

Vectors Analysis of ERA

The magnitude error is the algebraic difference of ERA. ERA was important to evaluate the predictability of corneal astigmatism correction and the effect of postoperative outcomes.¹⁴ The absolute value of ERA in the group SIA set as 0 D (0.15 ± 0.32 D) was obviously smaller than the group SIA set as 0.5 D (0.58 ± 0.48 D) (shown in Table 3). The difference in the two groups was statistically significant (shown in Figure 5, $P < 0.001$).

EV is a vector difference of ERA. Vector analysis of ERA was performed at the 3-month follow-up examination (shown in Table 3). The average arithmetic for X_{EV} was 0.24 ± 0.66 D in the group SIA set as 0.5 D and 0.0 ± 0.26 in the group SIA set as 0 D ($P = 0.049$). The average for Y_{EV} was -0.08 ± 0.30 D in the control group and 0.0 ± 0.20 D in the experimental group ($P = 0.545$). The total error vector in the experimental group (0.30 ± 0.24 D) was significantly smaller than the control group (0.60 ± 0.46 D) ($P = 0.001$).

The centroid ERA analyzed by double angle plot in the group SIA set as 0.5 D (0.41 D @ $174^{\circ} \pm 0.75$ D, shown in Figure 6A) was closer to the original point than the group SIA set as 0 D (0.21 D @ $163^{\circ} \pm 0.68$ D, shown in Figure 6B), which demonstrated a lower error vector of ERA in the experimental group. The distribution of ERA in the experimental group was more concentrated and mostly less than 1.0 D. The closer the centroid is to the origin, the closer the magnitude and axial of the residual astigmatism are to the preoperative prediction.

Table 3 Statistical Analysis of ERA

	Control Group	Experimental Group	P Value
ERA	0.58 ± 0.48	0.15 ± 0.32	0.000
X_{EV}	0.24 ± 0.66	0.0 ± 0.26	0.049
Y_{EV}	-0.08 ± 0.30	0.0 ± 0.20	0.545
$ EV $	0.60 ± 0.46	0.30 ± 0.24	0.001

Notes: Values are presented as the mean \pm standard deviation.

Abbreviations: ERA, error of refractive astigmatism; EV, error vector; X_{EV} , EV in vertical/horizontal direction; Y_{EV} , EV in oblique direction; $|EV|$, absolute value of total EV.

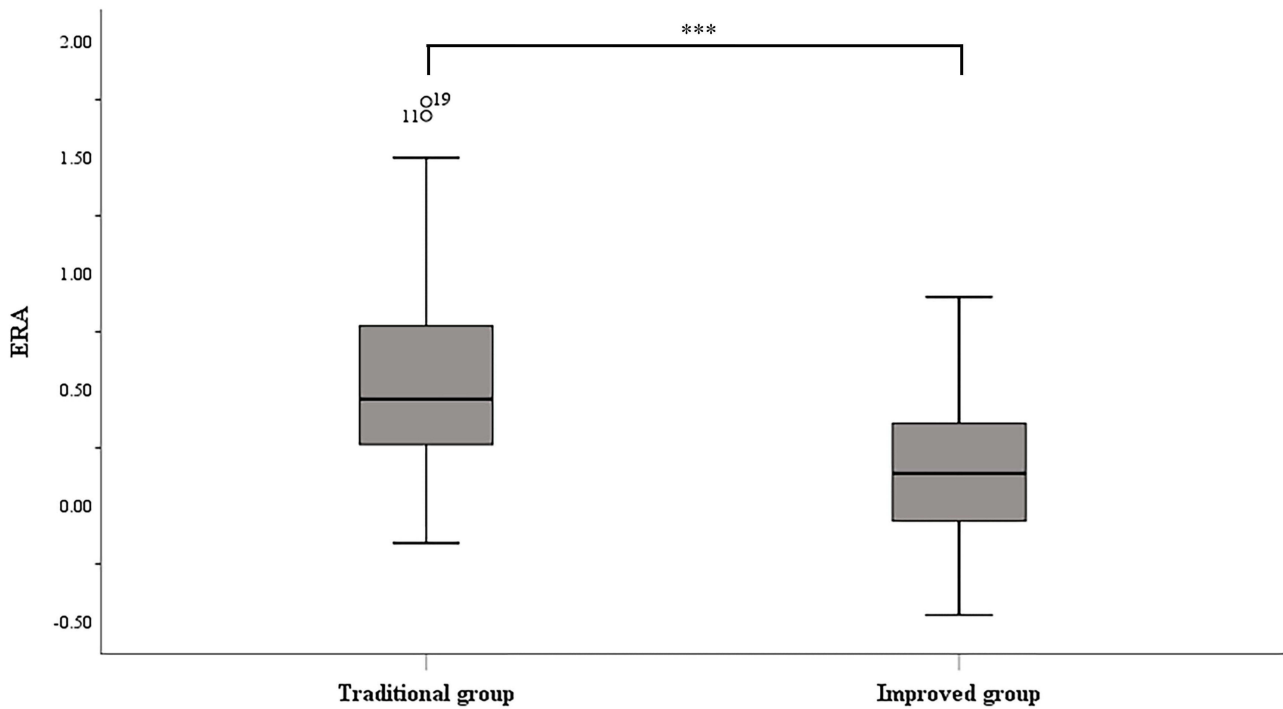


Figure 5 Absolute value of ERA in the control group and the experimental group at the 3-month postoperative. (***) means $P < 0.001$.

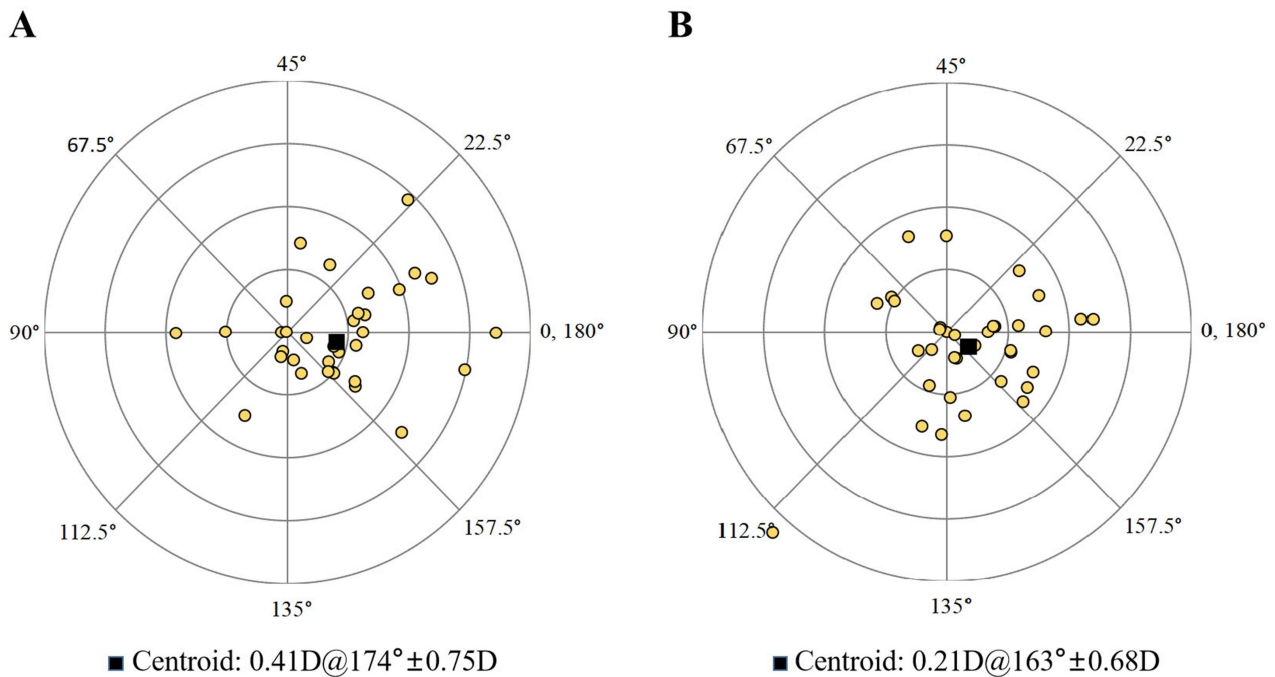


Figure 6 Double-angle vector plot of EV for each case in the control group (A) and the experimental group (B) at the 3-month postoperative. The yellow dot means the vector coordinate of SIA in each case. The black square means the centroid. Each ring = 0.5 D.

Discussion

Toric IOLs are the procedure of choice to correct corneal astigmatism in cases undergoing cataract surgery. Toric IOLs have been proved to have perfect astigmatism correction effect. However, its efficacy is being affected by many factors, such as the value of SIA and postoperative toric IOLs misalignment.

The expected amount of SIA must be incorporated into the toric IOLs power calculation to select the most appropriate toric IOLs models and alignment axis. However, the amount of SIA is difficult to predict and affected by several factors (incision location, incision size, preoperative corneal astigmatism, patients age, etc).^{18,19} In the present study, although all operations were performed by the same experienced doctor, the vector analysis of SIA still had a high dispersion of distribution (shown in [Figure 4A](#) and [B](#)), which prompt the instability of SIA. Even though the percentage of patients of accuracy of spherical equivalent and the value of postoperative refractive cylinder had significant differences in two groups (shown in [Figure 1D](#) and [E](#)), the postoperative UDVA, CDVA, and postoperative cylinder had no significant differences. The reason might be the incisions nowadays are small or even micro in cataract surgery. The Alpins terminology has been in use for more than 20 years, with 13 years of its application preceding the publication of the ANSI article.¹⁴ In the experimental group, the CI (0.97) was closer to 1, indicating that the astigmatism correction effect of this method was more consistent with the predicted value.

The location of the incision is an important factor that influences SIA because corneal incisions lead to flattening of the incised meridian and steepening of the orthogonal meridian as a result of the coupling (flattening/steepening) effect.²⁰ Previous studies have suggested that steep-meridian incision could reduce the cylinder power of toric IOL and induce less irregular astigmatism, which brings about better postoperative visual quality.¹⁸ However, the astigmatism correction effect of the incision was not as stable as the implantation of an appropriate toric IOLs. And making an incision at the location which surgeons were unaccustomed might increase the technical difficulty and cause the error of SIA. Therefore, the steep-meridian incision may not be a surgeon's first option. Postoperative toric IOLs misalignment is also the major factor responsible for suboptimal visual outcomes after toric IOLs implantation.²¹ Every degree of misalignment reduces the effectiveness of a toric IOL by 3%.²² Misalignment of the toric IOLs direction can cause reduction of the cylinder power along the desired meridian and induction of the cylinder in a new meridian.²³ In the group SIA set as 0.5 D, the IOLs direction was differed from the steep axis of the cornea for the reason of considering SIA. As the value and location of SIA changed, the expected toric IOLs direction changed in the traditional calculation method. With the addition rotation of toric IOLs occurred postoperatively, more vector error occurred between the toric IOLs direction and the cornea steep meridian. The method employed in this study, which sets the corneal incision SIA to 0 D, can reduce the vector error between the toric IOLs and the steep meridian of the cornea.

Our study found that the PRA of traditional methods was significantly smaller (shown in [Table 1](#)). Probably because we adjust the incision position and IOLs direction in the toric IOLs calculation to obtain the minimum expected astigmatism value. However, due to the toric IOLs rotation and the instability of SIA, the actual residual astigmatism was much higher than predicted. ERA and EV were significantly smaller in the group SIA set as 0 D, especially in the vertical and horizontal direction (shown in [Table 3](#)). Reasons for why SIA set as 0 D could decrease the vertical and horizontal vector error need further studies. All the results above showed the better predictability of astigmatism correction in the group SIA set as 0 D.

The proposed method of setting SIA as 0 D and implanting the toric IOL alignment axis same to the steep-meridian of cornea astigmatism in this study is equivalent to correcting the corneal astigmatism first, to make it a low astigmatism eye. And then making the main incision in the surgeon's accustomed direction to minimize the incision induced SIA, thus eliminating the influence of unstable SIA and IOLs misalignment. There were some limitation in this paper. The cylinder of Toric IOLs in this study were not increasing by 0.5 D (TECNIS Toric ZCT100, 150, 225, 300 and 400). Differences in incision site locations, variations in intraocular lens (IOL) types, and the involvement of a single surgeon may lead to unavoidable bias. Due to limitations of the testing device (IOL Master 500 and Pentacam), this study only measured the curvature of the anterior corneal surface and did not assess the total and posterior corneal astigmatism. The sample size needs to be expanded in subsequent studies. Moreover, this method needs to be verified in studies involving larger sample sizes, different types of intraocular lenses, and different surgeons.

Conclusion

Our study shows that setting the SIA to 0 D and thereby aligning the axis of the toric intraocular lens with the steep corneal meridian is an available method to reduce the error of refractive astigmatism.

Data Sharing Statement

Data was collected from patients' medical records, which was available from the corresponding author.

Statement of Ethics

The study was approved by Ethics committee of Qingdao Eye hospital, 2022[08], followed the tenets of the Declaration of Helsinki. Informed consent was obtained from each patient prior to enrollment. The study has been registered through the Chinese Clinical Trial Registry (ChiCTR2200066006).

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Disclosure

The authors report that there are no competing interests to declare for this work.

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