



## Full Length Article

## Impact of tear film stability on corneal refractive power measurement and surgical planning for cataract



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## ABSTRACT

**Purpose:** This prospective cohort study aimed to assess the influence of tear film stability on corneal refractive power measurement and surgical planning in cataract patients.

**Methods:** Participants were divided into tear film instability (tear film stability level 2) and control (level 0–1) groups based on Keratograph 5M results. Using IOL Master 700, two consecutive measurements were obtained with a 10-min interval. Parameters including standard keratometry (Kf, Ks and K), keratometric corneal astigmatism (KCA), total keratometry (TKf, TKs and TK) and total corneal astigmatism (TCA) were recorded. IOL power was calculated using SRK-T, SRK-T TK, Haigis, Haigis TK, Barrett Universal II, and Barrett Universal II TK formulas.

**Results:** The results showed significantly higher differences between two measurements in Kf, K, KCA, TKf, TK, and TCA, as well as the vector variability of corneal astigmatism in the tear film instability group (all  $P < 0.05$ ). Of all formulas, only the SRK-T formula displayed significantly higher variability in IOL power calculations in the tear film instability group compared to the control group ( $P < 0.05$ ).

**Conclusions:** This study highlights that tear film instability can lead to deviations in corneal refractive power and astigmatism measurements, contributing to increased prediction errors in IOL power calculation, particularly with the SRK-T formula.

## 1. Introduction

With the increase of the economic development, educational status and longevity of life, the expectation of the cataract patients is not only good visual acuity with spectacle correction but also full range vision without spectacle aids. To meet the demands for better visual function, precise intraocular lens (IOL) calculation is crucial to ensure optimal postoperative visual acuity and function.<sup>1,2</sup> The measurement of corneal refractive power is one of the most important biometric values for IOL calculation in cataract surgical planning.<sup>1</sup>

IOL Master 700 equipped with swept-source optical coherence tomography system provides reliable measurement, which has been regarded as the gold standard for preoperative biometry.<sup>3</sup> Since the keratometry of IOL Master 700 is relied on the reflection of the anterior corneal surface, which is the interface of air and the tear film, the

repeatability and accuracy could be affected in patients associated with poor tear film stability.

Theoretically, the tear film provides a relatively smooth refractive surface for the cornea.<sup>4</sup> However, during transients, the establishment and stabilization of the tear film until its rupture is actually a dynamic process, which prevents the ocular surface microenvironment from maintaining a constant state.<sup>5</sup> An unstable tear film may reduce the quality of corneal mapping image, thus resulting in a less reliant corneal refractive power assessment.<sup>6</sup>

Although it has been previously reported that optical biometry devices provide fairly reliable measurements of corneal refractive power in normal eyes, the clinical evidence regarding their tolerance level for tear film instability is still insufficient.<sup>3,7</sup> Additionally, given the fact that the prevalence of tear film instability increases with age and previous reports showed that more than 50% of age-related cataract patients suffering

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from some degree of tear film instability,<sup>8,9</sup> it is of clinical value to clarify the relationship between the variability of keratometry measurements and the tear film stability.

The present study seeks to understand the correlation of tear film stability with preoperative corneal optical biometric parameters and its impact on IOL calculation by observing the variability of measurements.

## 2. Methods

This prospective observational study was conducted at a tertiary eye hospital after receiving approval from the institution's research and ethics committee [(2020KY(L)-46)], and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all eligible patients after explanation of the study.

The sample size calculation was according to the Consolidated Standards of Reporting Trials (CONSORT) statement and the PICO design guidelines. Assuming a type I error probability of 0.01 and a power of 90%, with an overall standard deviation of 0.40D for IOL power calculations<sup>10</sup> and a meaningful difference of 0.50D between the two groups, the calculation based on formula (1) determined that 19 subjects were required in each group. Considering a dropout rate of 10%, it was necessary to recruit 21 subjects per group, resulting in a total of 42 subjects across both groups.

$$\frac{2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2}{(\mu_1 - \mu_2)^2} \quad (1)$$

Inclusion criteria included a diagnosis of age-related cataract and preparation for preoperative evaluation. Exclude patients with a history of ocular surgery, trauma or diseases that may affect the ocular surface microenvironment such as conjunctivitis, keratitis, blepharitis and allergic rhinitis. Those with a history of corneal contact lens wear within 30 days or recent use of medications such as atropine, neostigmine and artificial tears (that may affect ocular surface function) were also excluded.

All participants underwent routine preoperative examinations without mydriasis. Keratograph 5M (K5M) (Oculus, Wetzlar, Germany) and IOL Master 700 (Carl Zeiss Meditec, Jena, Germany) examinations were performed by a single experienced technician following the standard instrument procedures. After successful focus, each subject was instructed to take two to three full transients and to look at the central gaze point for more than 15s with eyes open. The system automatically captured the scanned images and displayed the measurement results. Only scans of acceptable quality were included in this study.

In order to obtain the original state of the patient's tear film, each subject was first examined by K5M. The first noninvasive break-up time (NIBUTf) and average noninvasive break-up time (NIBUTav) were recorded. The tear film stability was then classified into three levels based on the results of NIBUTf and NIBUTav (Level 0: stable, NIBUTf ≥ 10s or NIBUTav ≥ 14s; Level 1: critical, NIBUTf 6–9s or NIBUTav 8–13s; Level 2: unstable, NIBUTf ≤ 5s or NIBUTav ≤ 7s) based on previous report.<sup>11</sup> Patients in Level 0–1 were assigned to the control group, while those in Level 2 were assigned to the tear film instability group.

After 30 min, two consecutive IOL Master 700 examinations were performed with a break of at least 10 min in between. Optical biometry including the flat, steep, mean standard keratometric values (Kf, Ks, K) and keratometric corneal astigmatism (KCA) and flat, steep, mean total keratometric values (TKf, TKs, TK) and total corneal astigmatism (TCA) were recorded. The absolute value of the difference between two measurements was defined as the variability, which was expressed by the symbol "Δ". In addition, the vector difference between the astigmatism results measured twice in each eye was calculated using the Alpins method recommended by American National Standards Institute (ANSI). The magnitude of the vector difference was considered as the vector variability of corneal astigmatism. IOL power targeting emmetropia was calculated with the built-in Barrett Universal II, Barrett Universal II TK,

Haigis, Haigis T, SRK/T and SRK/T TK formulas. The differences in measurement and IOL power calculation variability between the control group and the tear film instability group were compared.

Data were analysed using NCSS software (v11, Kaysville, UT, USA). Skewness and kurtosis values were calculated to evaluate distribution normality. Variability differences between the two groups were compared using Aspin-Welch Unequal-Variance T-Test or Mann-Whitney Rank Sum Test. Bland-Altman plots were used to estimate the agreement of two measurements. Spearman Rank Correlation Test was used to assess the correlation between the variability of each parameter and the tear film stability level, NIBUTf and NIBUTav. A P-value less than 0.05 is considered statistically significant.

## 3. Result

A total of 45 eyes from 45 subjects were included in this study. There were no differences in gender, age, or type of astigmatism between the control group and the dry-eye group (all  $P > 0.05$ , Table 1). The mean NIBUTf and NIBUTav were significantly shorter in the tear film instability group than in the control group (both  $P < 0.001$ ).

### 3.1. The variability of IOL master 700 measurements between the control and tear film instability groups

The variabilities of measurements in the tear film instability group, including ΔKf, ΔK, ΔKCA, ΔTKf, ΔTK, and ΔTCA, were significantly higher than that in the control group (all  $P < 0.05$ , Table 2). There was no significant difference in the variability of ΔKs, Δsteep meridian and ΔTKs (all  $P > 0.05$ ).

### 3.2. Consistency analysis of the two measurement results obtained from IOL master 700

Bland-Altman analysis showed that when measuring K, TK, KCA, and TCA using IOL Master 700, the average differences between the two measurements in the control group (0.02D, 0.04D, −0.07D, and −0.02D) were all smaller than those in the tear film instability group (0.04D, 0.05D, 0.11D, and 0.11D) (Fig. 1). The 95% limits of agreement in the control group (0.15D to −0.11D, 0.15D to −0.08D, 0.24D to −0.39D, and 0.27D to −0.31D) were also narrower than those in the tear film instability group (0.29D to −0.21D, 0.33D to −0.24D, 0.76D to −0.54D, and 0.75D to −0.53D).

### 3.3. Vector variability of two astigmatism measurements

The mean magnitude of vector difference (i.e., vector variability) between the two measurements of both KCA and TCA in the control group ( $0.25 \pm 0.27$ D and  $0.21 \pm 0.14$ D) was significantly smaller than

**Table 1**  
Demographic data.

	Control (23)	Tear film instability (22)	$T/\chi^2$ - Value	P
Sex, f/m (n)	15/8	15/7	0.044	0.833 <sup>a</sup>
Age (ys)	65.35 ± 9.54	66.73 ± 7.35	−0.542	0.591 <sup>b</sup>
WTR/ATR/ oblique (n)	9/14/0	8/12/2	2.192	0.334 <sup>a</sup>
NIBUTf (s)	12.14 ± 4.81	3.70 ± 1.29	8.126	<0.001 <sup>b</sup>
NIBUTav (s)	14.64 ± 4.52	5.25 ± 3.36	7.879	<0.001 <sup>b</sup>

WTR = with-the-rule astigmatism. ATR = against-the-rule astigmatism.

<sup>a</sup> The Fisher's exact test was used.

<sup>b</sup> The Two sample t-test was used.

**Table 2**

Comparison of the variability of IOL master 700 measurements between the control group and the dry-eye group.

Parameters	Control	Tear film instability	T/Z value	P
K	(n = 23)	(n = 22)		
ΔKf, D	0.09 ± 0.07	0.19 ± 0.16	−2.7851	0.009*
ΔKs, D	0.08 ± 0.07	0.13 ± 0.12	−1.666	0.105
Δsteep meridian, °	13.21 ± 23.78	16.18 ± 25.05	0.16#	0.873
ΔK, D	0.06 ± 0.04	0.10 ± 0.09	−2.1252	0.042*
ΔKCA, D	0.13 ± 0.12	0.27 ± 0.22	−2.707	0.011*
TK	(n = 18)	(n = 20)		
ΔTKf, D	0.08 ± 0.06	0.21 ± 0.18	−2.959	0.007*
ΔTKs, D	0.07 ± 0.07	0.13 ± 0.12	−1.645	0.109
Δsteep meridian, °	14.17 ± 25.65	18.95 ± 27.85	−0.411#	0.681
ΔTK, D	0.05 ± 0.05	0.12 ± 0.10	−2.56	0.016*
ΔTCA, D	0.13 ± 0.17	0.25 ± 0.23	−2.311	0.030*

#, the steep meridians showed non-normal distribution and the *Mann-Whitney Rank Sum Test* were used, while other parameters followed normal distribution with unequal variances and the *Aspin-Welch Unequal-Variance T-Test* were used. K = standard keratometry. KCA = keratometric corneal astigmatism. TK = total keratometry. TCA = total corneal astigmatism. Δ, absolute difference between repeated measurements of the same parameter within the same subject. \*, *P* < 0.05.

that of the tear film instability group ( $0.37 \pm 0.24\text{D}$  and  $0.37 \pm 0.22\text{D}$ ) ( $Z = 2.022$  and  $-2.369$ ,  $P = 0.043$  and  $0.018$ ). The 95% confidence ellipse of the data set was larger in the tear film instability group than that in the control group for both KCA and TCA (Fig. 2).

**3.4. Variability of IOL calculations**

The use of SRK-T formula for IOL calculation resulted in significantly higher median variability in the tear film instability group ( $0.09\text{D}$ ) compared to the control group ( $0.04\text{D}$ ) ( $Z = 2.014$ ,  $P = 0.044$ ) (Table 3). Nevertheless, there were no statistically significant differences between the two groups when the Barrett Universal II formula, Barrett Universal II TK formula, HAIGIS formula, HAIGIS TK formula, and SRK-T TK formula were used for the calculation. (all  $P > 0.05$ ). In the variability box plot, the

interquartile range of the tear film instability group is larger, indicating that tear film instability leads to greater calculation variability. The maximum variability in the tear film instability group is  $0.51\text{D}$ , which occurs with the HAIGIS formula. In the control group, the maximum variability is  $0.68\text{D}$ , also occurring with the HAIGIS formula (Fig. 3).

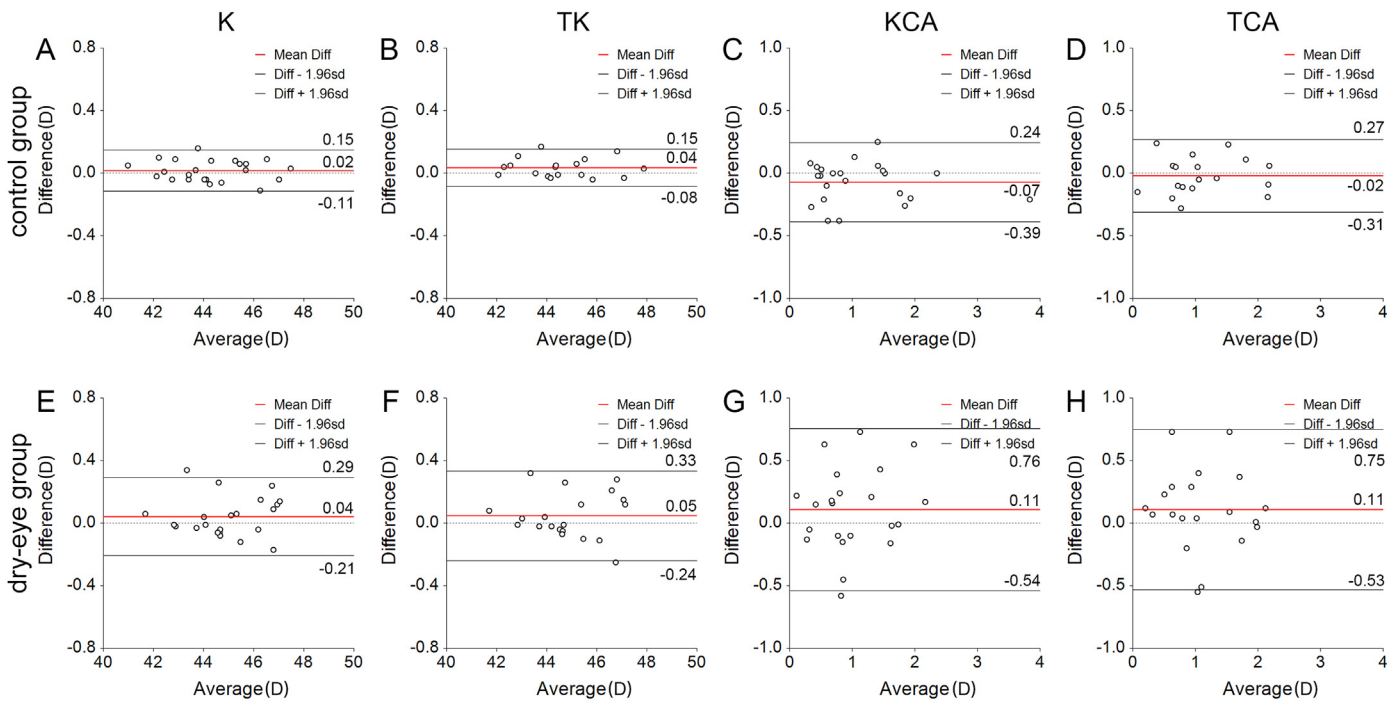
Further analysis was conducted by selecting IOL powers in  $0.50\text{D}$  intervals, targeting emmetropia, and incorporating the next-generation Kane Formula ([iolformula.com](http://iolformula.com)) and Hill-RBF Calculator Version 3.0 ([rbfcalculator.com](http://rbfcalculator.com)). Statistical analysis revealed no significant difference in the proportion of changes in IOL power selection between the two groups across all formulas (all  $P > 0.05$ ) (supplementary table).

**3.5. Correlation between each measured and calculated parameter and NIBUT**

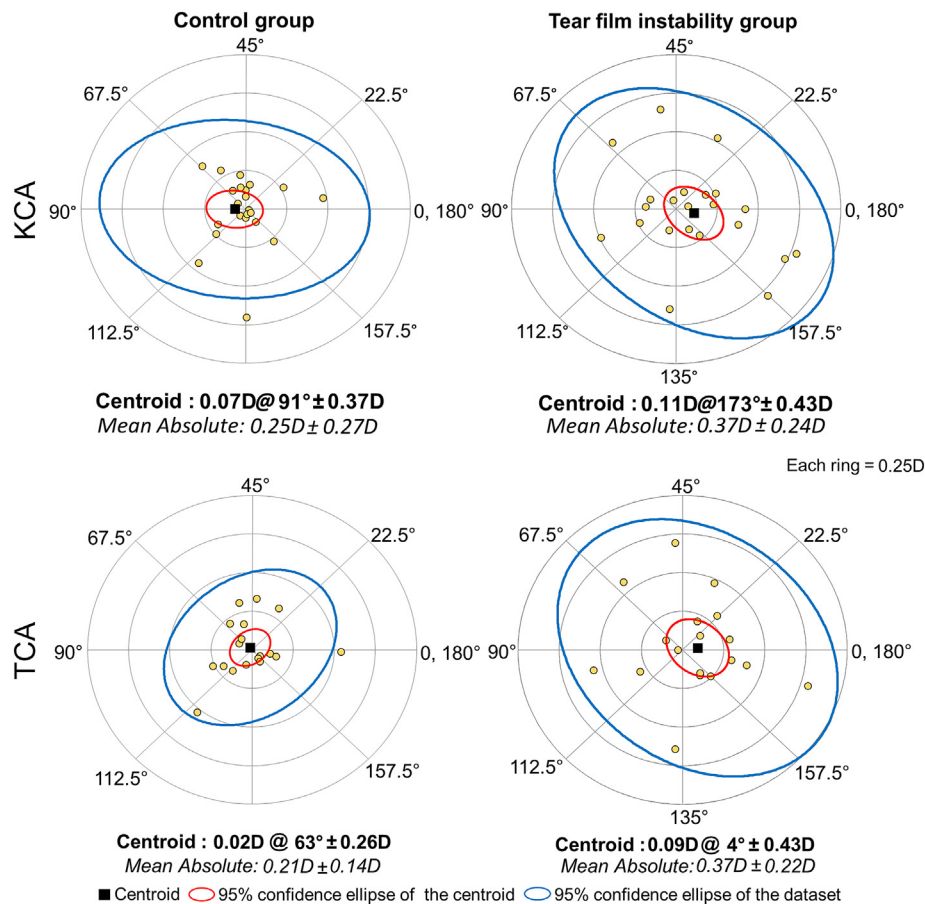
The results of the Spearman rank correlation test showed that ΔKf, ΔK and ΔTK were negatively correlated with NIBUTf and NIBUTav, and positively correlated with the tear film instability level (Table 4). ΔKCA and ΔTKf were negatively correlated with NIBUTf and positively correlated with the tear film instability level. The variabilities of IOL calculation formulas were all negatively correlated with NIBUTf and NIBUTav, while those of TK BU II, HAIGIS and SRK-T formulas were also positively correlated with the tear film instability level.

**4. Discussion**

By observing the variability of repeated measurements with the IOL Master 700, our study demonstrated that an unstable tear film significantly affects the repeatability of preoperative measurements of corneal refractive power and astigmatism. The total keratometry was not exempt from this effect either. This impact further undermined the subsequent IOL calculation, and although only the SRK-T formula was significantly affected, all built-in formulas (of the IOL Master 700) exhibited an increased interquartile range as NIBUT decreased. While the maximum individual variability was not observed within the tear film instability group, it can be concluded that, overall, tear film instability leads to an



**Fig. 1.** Analysis of the consistency between two measurements of the keratometry and the corneal astigmatism. The Bland-Altman analysis results were obtained to evaluate the agreement between the two measurements of K (A), TK (B), KCA (C), and TCA (D) in the control group, as well as K (E), TK (F), KCA (G), and TCA (H) in the dry-eye group. K = standard keratometry; TK = total keratometry; KCA = keratometric corneal astigmatism; TCA = total corneal astigmatism.



**Fig. 2.** Double-angle plots of vectorial variability of corneal astigmatism in the control and dry-eye groups. KCA = keratometric corneal astigmatism; TCA = total corneal astigmatism.

**Table 3**  
Comparison of variability in IOL calculations between the control group and the dry-eye group.

Formulas	Control (23)	Tear film instability (22)	Z value	P
BU II	0.06 (0.09)	0.10 (0.20)	1.457	0.145
TK BU II	0.07 (0.14)	0.11 (0.23)	−1.864	0.062
HAIGIS	0.05 (0.11)	0.12 (0.17)	1.945	0.052
TK HAIGIS	0.07 (0.15)	0.15 (0.27)	−1.903	0.057
SRK-T	0.04 (0.10)	0.09 (0.17)	2.014	0.044*
TK SRK-T	0.05 (0.12)	0.12 (0.18)	−1.815	0.070

Mann-Whitney Rank Sum Test were used. BU II = Barrett Universal II formular. \*, P < 0.05.

increase in variability.

Our results showed that the variability value, represented by  $\Delta K_f$ ,  $\Delta K$ ,  $\Delta KCA$ ,  $\Delta TK_f$ ,  $\Delta TK$ , and  $\Delta TCA$ , were significantly higher in the tear film instability group supporting the theory of that an unhealthy tear film would have a negative impact on corneal measurements. Since 2001, Németh J et al. and Erdélyi B et al. successively observed the dynamic changes of corneal topography with tear film in healthy subjects, and subsequently found that the reproducibility of keratometric measurements decreases over time after blinking.<sup>5,11–13</sup> Epitropoulos AT et al. first objectively grouped the eyes based on tear film quality and discovered that the eyes with high tear osmolarity had poorer repeatability in K-value measurement and a higher proportion of corneal astigmatism variability greater than 1.0D compared to normal eyes.<sup>14</sup> Although this study used the older generation IOL Master, it was highly consistent with our findings. However, the studies conducted by Doğan A et al. and Guven S et al. both demonstrated high repeatability in measuring the

anterior segment in patients with poor tear film stability, which were achieved using Sirius and Pentacam respectively.<sup>15,16</sup> The conflicting results may be primarily due to the differences in the measurement principles of the devices. Devices such as Sirius and Pentacam, which use Scheimpflug cameras for corneal imaging and measurement, do not include the tear film. In contrast, devices that rely on reflection imaging, such as the IOL Master, are inevitably affected by the smoothness of tear film, which forms the first optical interface of the ocular surface. As compared in the study by Kundu G et al., the repeatability of aberrations measured with Pentacam is better than that measured with iTrace, which also relies on the reflection of the corneal surface.<sup>17</sup> In addition, CASIA and Anterior, devices which use swept-source OCT principle similar to IOL master 700, also exhibit greater mean standard keratometry and astigmatism variabilities compared to Pentacam.<sup>18</sup>

Another interesting finding is that the TK and TCA measurements were also affected by the tear film stability. TK has received a lot of attention in recent years, as it is believed to be closer to the true corneal curvature compared to the standard keratometry and theoretically can further reduce postoperative refractive prediction errors.<sup>19,20</sup> Moreover, the measurement of posterior corneal surface is theoretically free from tear film interference. However, in our findings, the variability of TK and TCA in the tear film instability group was highly consistent with K and KCA, and both of which were also significantly higher than that of the control group. This may be related to the method used by the IOL Master to calculate TK. The anterior corneal surface data used to calculate TK still derives from surface reflection, while the posterior corneal surface data is obtained from swept-source OCT scans, with a relatively small contribution to the total corneal refractive power.<sup>21,22</sup> Therefore, this implies that even when incorporating TK into surgical planning, it is crucial to consider the stability of the tear film.



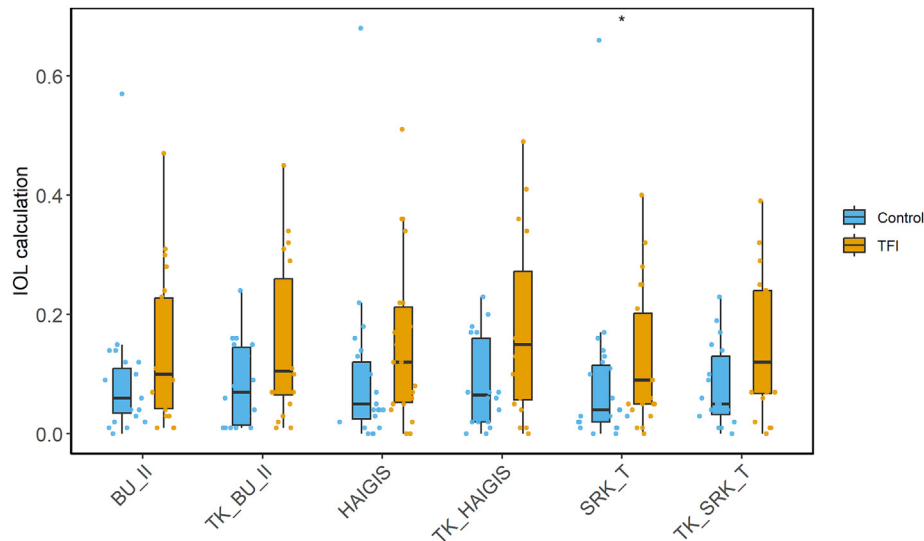


Fig. 3. IOL calculation variability box plot. \*,  $P < 0.05$ ; TFI = tear film instability.

**Table 4**  
Correlation analysis between NIBUTf, NIBUTav and the variability of each parameter.

	NIBUTf		NIBUTav		Tear film instability Level	
	Correlation	P	Correlation	P	Correlation	P
<b>K</b>						
ΔKf, D	−0.439	0.003*	−0.325	0.029*	0.431	0.003*
ΔKs, D	−0.280	0.062	−0.249	0.099	0.260	0.084
steep meridian, °	−0.042	0.786	−0.041	0.789	−0.007	0.964
ΔK, D	−0.373	0.012*	−0.376	0.011*	0.309	0.039*
ΔKCA, D	−0.383	0.010*	−0.238	0.116	0.367	0.013*
<b>TK</b>						
ΔTKf, D	−0.416	0.010*	−0.309	0.059	0.433	0.007*
ΔTKs, D	−0.275	0.095	−0.239	0.148	0.273	0.098
steep meridian, °	−0.079	0.636	0.000	0.998	0.057	0.735
ΔTK, D	−0.471	0.003*	−0.392	0.015*	0.397	0.014*
ΔTCA, D	−0.257	0.119	−0.202	0.225	0.264	0.109
<b>IOL calculator</b>						
BU II	−0.365	0.014*	−0.336	0.024*	0.288	0.055
TK BU II	−0.397	0.014*	−0.377	0.020*	0.325	0.046*
HAIGIS	−0.408	0.005*	−0.364	0.014*	0.365	0.014*
TK HAIGIS	−0.393	0.015*	−0.336	0.040*	0.315	0.054
SRK-T	−0.382	0.010*	−0.348	0.019*	0.350	0.018*
TK SRK-T	−0.398	0.013*	−0.338	0.038*	0.316	0.053

Spearman Rank Correlation Test were used. K = standard keratometry. KCA = keratometric corneal astigmatism. TK = total keratometry. TCA = total corneal astigmatism. Δ, absolute difference between repeated measurements of the same parameter within the same subject. \*,  $P < 0.05$ .

The accelerated changes and increased irregularity in the optical interface of the cornea caused by an unstable tear film may be the main reason for the increase in measurement variability. During the process of tear film formation and rupture, in the areas where thinning and dry spots occur, the interface between the tear film and air becomes irregular, which induces fluctuations in refractive power.<sup>23,24</sup> Such phenomenon was further demonstrated in Erdélyi's study, which observed a continuous increase in the surface regularity index during the 60 s following a complete blink.<sup>13</sup> In a recent study that also used NIBUT grouping, the surface regularity index and surface asymmetry index of Level 2 eyes were slightly higher than those of Level 1 eyes. Moreover, there was an improvement in the short term after the application of low-concentration sodium hyaluronate.<sup>25</sup> In addition, in our study, the K value of the flat meridian was more affected, which should be the major contributor to the increased variability of astigmatism. The underlying mechanism is warrant for further specific clarification.

The accuracy of IOL calculations may be compromised by an unstable tear film, which could be one of the underlying mechanisms contributing to the predictive error of postoperative equivalent spherical power. In

our study, the variability of all included formulas increased as the first and average NIBUT decreased. The SRK-T formula was significantly affected statistically. This may be due to the fact that modern formulas such as Barrett Universal II and Haigis assign less weight to keratometry in their calculations than SRK-T formula.<sup>26</sup> Similar to Epitropoulos' study, Holladay 1 formula exhibited a higher proportion of eyes with calculation errors exceeding 0.5D in the high osmolarity group.<sup>14</sup> This suggests caution should be exercised when applying such formulas for preoperative planning in patients with poor tear film stability.

However, clinically available IOL powers are provided in 0.50D intervals. Our results showed that across all formulas, including the new generation Kane and Hill-RBF formulas, there was no statistically significant difference in the proportion of changes in IOL power selection between the two groups. This may be due to the fact that the tear film instability eyes included in this study did not reach the level of severe dry eye. Therefore, further research focusing on patients with severe dry eye is urgently needed.

As the preoperative tear film stability management has been listed as one important item on the checklist for preoperative planning of modern

precise cataract surgery, our findings further confirm and emphasize the important role of tear film in astigmatism management.<sup>27</sup> Epitropoulos et al. also noted a higher incidence of corneal astigmatism measurements with variability over 1.0D in the high hyperosmolar group.<sup>14</sup> Our study not only confirmed this fact in terms of magnitude but also from a vector perspective. Furthermore, corneal astigmatism measurement errors resulting from tear film instability can contribute to inaccurate prediction of residual astigmatism.

Nonetheless, the related research has a specific prerequisite, which is to ensure that the original tear film state of the subject is not disrupted in order to assess the measurements under such condition. For example, research has shown that fluorescein staining can decrease the stability of the tear film.<sup>28</sup> Previous researches have almost always interfered with the tear film itself to some extent when evaluating its stability. The non-invasive detection method used in our study successfully and objectively avoided this issue.<sup>29</sup>

Other limitations include the relatively small sample size, and the absence of verification of postoperative refractive status. Therefore, the results of the present study should be interpreted with caution. In the future, conducting large-scale, before-and-after comparative studies will be more relevant and persuasive.

In conclusion, based on non-contact assessment of tear film stability, we demonstrated that an unstable tear film reduces the repeatability of preoperative corneal refractive power measurements in cataract patients, resulting in an increase in the variability of IOL calculation formulas. Therefore, for patients with severe tear film instability, appropriate treatment should be actively pursued, such as the use of artificial tears, lipid supplements, and biologic tear substitutes.<sup>8,30,31</sup> Our findings emphasize that ocular surface homeostasis should not be neglected in preoperative planning for precision refractive cataract surgery, including astigmatism management.

## Study approval

This prospective observational study was conducted at a tertiary eye hospital after receiving approval from the institution's research and ethics committee [(2020KY(L)-46)], and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all eligible patients after explanation of the study.

## Author contributions

YJ, XC: Designed the analysis, Analysed and interpreted the data and Wrote the paper. YG, SB: Designed the analysis and Wrote the paper. NG, HW, YF, FL: Wrote the paper. ML, LQ: Data curation. SZ: Designed the analysis. FT: Designed the analysis, Contributed reagents, materials, analysis tools or data and Wrote the paper. All authors read and approved the final manuscript.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.aopr.2025.02.001>.

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