• Clinical Research •

Stability of the Barrett True-K formula for intraocular lens power calculation after SMILE in Chinese myopic eyes

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Abstract

● **AIM:** To compare the Barrett True-K formula with other formulas integrated in Lenstar 900 to predict intraocular lens (IOL) power after small-incision lenticule extraction (SMILE).

● **METHODS:** A theoretical prospective study was performed to predict the ratio of equivalent IOL power before and after SMILE using the SRK/T (Sanders, Retzlaff, Kraff/theoretical), Holladay 1, Haigis, and Barrett True-K formulas and compare the stability of their predictions. The study included 54 eyes (54 cases) with a manifest refraction spherical equivalent (MRSE) of -4.99±1.45 D. They were divided into two groups: 27 eyes with axial length of 24-26 mm in Group A, and 27 eyes with axial length >26 mm in Group B. All subjects enrolled in this study were examined with the Lenstar 900 before and 6mo after SMILE including measurements of axial length, corneal curvature, and anterior chamber depth (ACD).

● **RESULTS:** The prediction of equivalent IOL power of the two groups was more stable for the Barrett True-K formula, especially in long axial length eyes (Group B). The respective percentages for the SRK/T, Holladay 1, Haigis, and Barrett True-K formulas were 7.4%, 7.4%, 85.19%, and 88.89% for a margin of error within 0.5 D; 25.92%, 51.84%, 100%, and 100% for a margin of error within 1.0 D in Group A; 33.33%, 40.74%, 44.44%, and 81.48% for a margin of error within 0.5 D; and 44.44%, 59.26%, 66.66%, and 92.59% for a margin of error within 1.0 D in Group B. The respective percentages for Barrett True-K formulas were 100% for a margin of error within 2.0 D in Group B.

● **CONCLUSION:** Theoretically, the Barrett True-K formula provides more stable predictions than other formulas for cataract eyes after SMILE.

● **KEYWORDS:** intraocular lens; IOL power calculation formula; SMILE; equivalent IOL power; Lenstar 900

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INTRODUCTION

Cornea refractive surgery has been used to correct vision in growing numbers of patients with myopia who may develop age-related cataracts later in life. Studies showed that the intraocular lens (IOL) power calculation in people who underwent cornea refractive surgery often exhibits a hyperopic tendency, usually due to inaccurate K values, improper cornea refractive index, and erroneously estimated effective lens position (ELP)[1-2]. Although several formulas have been introduced, IOL power calculation for patients who previously underwent refractive surgery remains challenging. Over the past decade, more than 20 methods have been described to improve the accuracy of IOL power calculation in eyes with previous refractive surgery[3-10]. Many were integrated into advanced biological measurement instruments like the Lenstar 900, IOLMaster 700, and Pentacam AXL[11].

We previously studied the accuracy of different formulas for predicting IOL power after laser-assisted *in situ* keratomileusis (LASIK) with the SRK/T (Sanders, Retzlaff, Kraff/theoretical), Hoffer Q, Holladay 1, and Haigis-L formulas offered by IOLMaster[12]. The SRK/T, Holladay 1, and Hoffer Q formulas are third-generation formulas, and the newer generation includes the Haigis and Barrett True-K formulas. They all show high accuracy for conventional cataract IOL power calculation.

Small-incision lenticule extraction (SMILE) has been the most popular myopic correction method worldwide, especially in China[13]. SMILE had the same problems observed with LASIK, such as decreased K value, improper refractive index, and wrongly estimated ELP. Subject who underwent SMILE surgery while young have a high demand of vision quality, so ensuring a precise IOL power is very important. However, there is limited research about IOL power calculation after SMILE. The Lenstar 900 is based on new optical low coherence reflectometry (OLCR) technology and can automatically measure the axial length, anterior chamber depth (ACD), K values, white-to-white corneal diameter, central corneal thickness, and lens thickness, as well as other parameters. It was integrated with many IOL power calculation formulas including the latest versions such as the Barrett and Olsen formulas[14]. There were many reports on its use in LASIK and photorefractive keratectomy (PRK) patients[15-16], but fewer data are available for SMILE.

The purpose of the present study was to compare the Barrett True-K formula with other formulas integrated in Lenstar 900 to predict IOL power after SMILE.

SUBJECTS AND METHODS

Ethical Approval The study protocol was approved by Beijing Tongren Hospital Ethics Committee and adhered to the tenets of the Declaration of Helsinki (No.ChiCTR-TOC-17013765). Patients who underwent refractive treatment for myopia at the Beijing Tongren Hospital of Capital Medical University, Beijing, China, between July 2017 and March 2018 were recruited. Before surgery each patient was informed about the surgery and signed informed consent.

Inclusion criteria were based on the latest specialist consensus about SMILE specifications in China[17]. There were no complications during or after surgery. Exclusion criteria were ocular or systemic inflammatory disease, severe dry eye, glaucoma, central corneal depth <480 μm, history of herpes simplex or herpes zoster keratitis, keratoconus or suspicious keratoconus, remaining stromal expected <280 μm, and patients with posterior scleral staphyloma or mental disease (schizophrenia or depression)[18]. In total, 54 patients (54 right eyes) were included and divided into two groups according to their axial length: 27 cases (axial length 24-26 mm) and 27 cases (axial length >26 mm) were classified as Groups A and B, respectively.

Surgery Method All SMILE surgeries were performed by the same surgeon (Zhang FJ). The Visumax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) with a rate of 500 kHz was used for these procedures. The cap thickness was 120 μm, and the lenticule diameter was 6.3-6.5 mm. A small incision (2 mm) was created at the 12 o'clock position.

Examination Method All enrolled subjects underwent examination by the same doctor (Zhu W) with the Lenstar 900 before and 6mo after SMILE, which is based on OLCR technology. Axial length, corneal curvature, lens thickness, and ACD were measured.

Intraocular Lens Power Calculation Method The present work includes the more advanced Barrett True-K Formula. The Hoffer Q formula, which is suitable for short axial length eyes, was not used in this study. The Haigis-L formula derived from the Haigis formula and used for LASIK or PRK was also excluded. IOL power was predicted using the SRK/T, Holladay 1, Haigis, and Barrett True-K formulas.

SMILE is a kind of corneal refractive surgery in which the refractive power of the lens does not change. So, we introduced the concept of equivalent IOL power. For example, if the patients' refraction was -5 D, we calculated an exchange IOL power of +20 D, which means we implant an IOL power of +20 D to obtain refraction of -5 D, then +20 D was the equivalent IOL power. Postoperative refraction was 0, and we calculated exchange IOL power as +19.5 D, which means we implant an IOL power of +19.5 D to obtain refraction of 0, then +19.5 D was the equivalent IOL power. Researchers in China have used this method to predict IOL power after LASIK[19]. We calculated the change rate of the equivalent IOL power as postoperative equivalent IOL power/pre-operative equivalent IOL power. Theoretically, cornea power decreases after refractive surgery, but IOL power should remain the same. When the change rate approaches 1, the formula is more stable. Then we calculated the difference of equivalent IOL power (EILD) absolute value, which can be seen as the error. To decrease the influence of different IOL power constant parameters, this study used the same IOL AcrySof SN60WF (Alcon Laboratories, Inc., Fort Worth, TX, USA).

Statistical Analysis Sample size was calculated to determine the number of eyes required to detect a difference of half of the standard deviation of the difference in EILDs between groups. At a significance level of 5% and a test power of 80%, 25 eyes were required in each group. Statistical analysis was performed using SPSS Statistics 25 (IBM, Armonk, NY, USA). Normality was checked using Kolmogorov-Smirnov tests. Between-group comparisons for normally distributed data were analyzed with two-tailed Student's *t*-tests and Chi-square (χ^2) tests. Differences were considered statistically significant at $P<0.05$.

RESULTS

Patient Demographics We included 54 eyes of 54 patients. Table 1 shows the patient demographics of Groups A and B. We compared the characteristic of age, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) and spherical equivalent by two-tailed Student's *t*-tests, there are no statistically significant found in them (t=0.258, P=0.301; t=-1.798, P=0.147; t=2.217, P=0.091; t=2.698, P=0.054). We compared the characteristic of sex by Chi-square (χ^2) test, there is also no statistically significant found in them (χ^2=0.008, P=0.073). The results of the demographics in Groups A and B showed that there was no significant difference between them.

Table 2 show ACD, axial length, lens thickness, and K-values

Table 1 Patient demographics in Group A and Group B

Characteristics	Group A	Group B	*t*	*P*
Age	27.89±6.23 (19 to 37)	27.78±5.07 (18 to 33)	0.258	0.301
Sex (male: female)	9:18	8:19	χ^2=0.008	0.073
UCVA	0.07±0.05 (0.03 to 0.15)	0.12±0.09 (0.04 to 0.4)	-1.798	0.147
BCVA	1.3±0.14 (1.0 to 1.5)	1.19±0.10 (1.0 to 1.5)	2.217	0.091
Spherical equivalent (D)	-4.18±0.94 (-3.25 to -6.875)	-5.81±1.43 (-2.875 to -8)	2.698	0.054

UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity.

Table 2 Pre- and 6-month postoperative parameters of SMILE in Group A and Group B

Parameters	Group A				Group B			
	Preoperative	Postoperative	*t*	*P*	Preoperative	Postoperative	*t*	*P*
Axial length	24.99±0.37 (24.12 to 25.49)	24.87±0.38 (23.97 to 25.37)	6.082	0.000	26.63±0.29 (26.09 to 27.19)	26.49±0.29 (25.92 to 27.01)	3.370	0.004
ACD	3.12±0.24 (2.81 to 3.59)	3.07±0.28 (2.72 to 3.65)	19.594	0.000	3.33±0.34(2.83 to 4.07)	3.23±0.34 (2.68 to 3.94)	18.912	0.000
Lens thickness	3.74±0.32(3.14 to 4.17)	3.78±0.20(3.15 to 4.13)	0.318	0.766	3.61±0.23 (3.19 to 3.94)	3.60±0.25 (3.17 to 4.05)	0.420	0.703
Flat-K	43.73±1.17 (41.82 to 45.9)	40.01±1.08 (37.94 to 41.46)	40.710	0.000	42.18±1.40 (39.64 to 45.2)	36.96±1.04 (35.38 to 38.35)	27.245	0.000
Steep-K	44.97±1.09 (43.19 to 47.13)	41.05±1.03 (38.99 to 42.74)	5.934	0.000	43.82±1.80 (41.61 to 47.86)	37.82±1.18 (35.8 to 39.74)	7.095	0.000

ACD: Anterior chamber depth.

Table 3 Predicted pre- and postoperative equivalent IOL power outcomes

Items	Group A				Group B			
	SRK/T	Holladay	Haigis	Barrett True-K	SRK/T	Holladay	Haigis	Barrett True-K
Preop.	21.44±1.37	21.5±1.32	20.83±1.29	21.72±1.33	20.86±1.25	20.58±1.25	20.81±1.43	22.14±1.45
Postop.	19.78±1.35	20.19±1.45	20.65±1.46	21.68±1.49	19.58±1.29	19.97±1.43	21.39±1.51	22.11±1.42
Change rate	0.92±0.02	0.94±0.02	0.99±0.01	1.00±0.01	0.94±0.05	0.97±0.05	1.03±0.04	1.00±0.02
t	143.760	12.763	2.120	0.433	44.277	5.870	-12.557	1.732
P	0.000	0.006	0.168	0.707	0.001	0.028	0.006	0.225

before and after SMILE. We can see both steep-K and flat-K values decreased after corneal refractive surgery. We compared the parameters before and after SMILE of axial length, ACD, flat-K and steep-K by paired-samples *t*-tests, there are significant differences between them in Group A (t=6.082, P=0.000; t=19.594, P=0.000; t=40.710, P=0.000; t=5.934, P=0.000) and in Group B (t=3.370, P=0.004; t=18.912, P=0.000; t=27.245, P=0.000; t=7.095, P=0.000). We found that the four parameters are all decreased after the SMILE surgery. We compared lens thickness before and after SMILE by paired-samples *t*-tests, there are no significant difference between them in Group A (t=0.318, P=0.766) and in Group B (t=0.420, P=0.703). SMILE surgery is a kind of cornea refractive surgery so it did not make any change to lens.

Equivalent Intraocular Lens Power Outcomes The pre- and postoperative EILD outcomes obtained with the four formulas in both groups are shown in Table 3. We compared the EILD outcomes before and after SMILE by paired-samples *t*-tests, there are no significant differences between Barrett True-K formula in Group A (t=0.433, P=0.707) and Group B (t=1.732, P=0.225), there are no significant differences between Haigis formula in Group A (t=2.120, P=0.168), but significant differences between in Group B (t=-12.557, P=0.006). We also found that there are significant differences between SRK/T formula in Group A (t=143.760, P=0.000) and Group B (t=44.277, P=0.001), and Holladay formula in Group A (t=12.763, P=0.006) and Group B (t=5.870, P=0.028). We can see in Figures 1 and 2 that the predicted pre- and postoperative EILD outcomes are closest for the Barrett True-K formula. The results also show that the change rate of the EILD closest to 1 was calculated by the Barrett True-K formula. The largest postoperative IOL power was also predicted with the Barrett True-K formula. In Figure 3, the SRK/T and Holladay formulas showed opposite trends of EILD prediction errors, suggesting a hyperopic tendency as reported in other studies[1-2].

Equivalent Intraocular Lens Diopter Distribution Analysis The formula results broken down by group and EILD cut-offs are shown in Table 4. The Barrett True-K and Haigis formulas have the same stability in eyes with axial length between 24 and 26 mm (χ^2=0.310, P=0.578). However, the Barrett True-K formula is more stable for long axial length eyes (>26 mm; χ^2=4.741, P=0.029).

DISCUSSION

SMILE is a predictable, effective, and promising method for myopia treatment[20-21]. More than 1 000 000 patients have undergone the procedure and can now go without glasses,

Table 4 EILD distribution in Group A and Group B Distribution (%)

Formula	Group A			Group B		
	≤0.5	>0.5, ≤1.0	>1.0, ≤2.0	≤0.5	>0.5, ≤1.0	>1.0, ≤2.0
SRK/T	2 (7.4)	5 (18.52)	18 (66.67)	9 (33.33)	3 (11.11)	9 (33.33)
Holladay	2 (7.4)	12 (44.44)	12 (44.44)	11 (40.74)	5 (18.52)	11 (40.74)
Haigis	23 (85.19)	4 (14.81)	0	12 (44.44)	6 (22.22)	8 (29.63)
Barrett True-K	24 (88.89)	3 (11.11)	0	22 (81.48)	3 (11.11)	2 (7.4)
χ^2		0.310			4.741	
P		0.578			0.029	

EILD: Equivalent intraocular lens diopter.

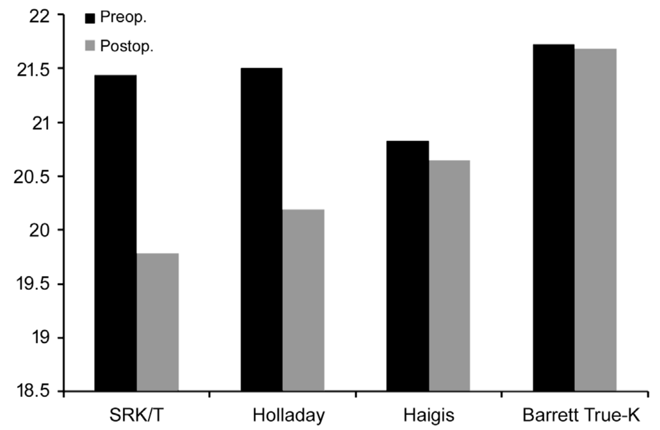

Figure 1 Predicted preoperative and postoperative equivalent IOL power outcomes in Group A.

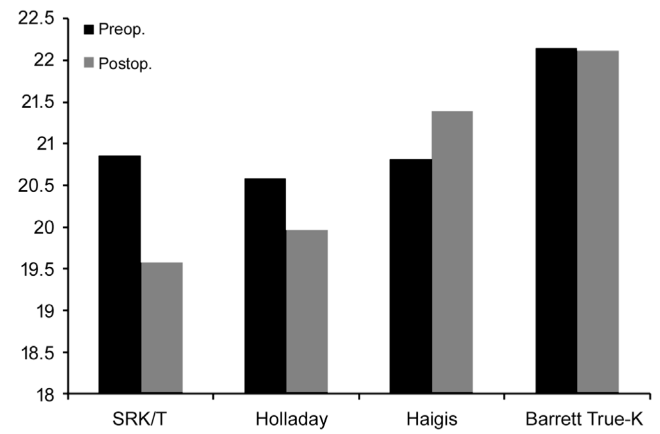

Figure 2 Predicted preoperative and postoperative equivalent IOL power outcomes in Group B.

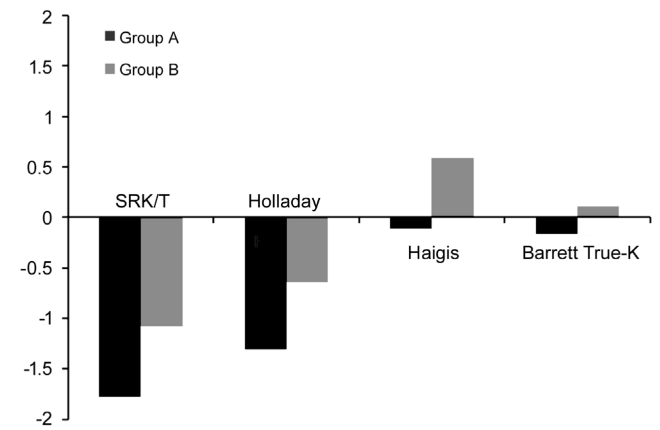

Figure 3 Comparison of equivalent IOL power prediction errors in two groups.

including 750 000 Chinese subjects. Some of these subjects will eventually develop senile cataracts. One study reported that it is difficult to calculate IOL power in people who previously had refractive surgery[22]. There are three main sources of prediction error in IOL calculation after refractive surgery: the corneal radius measurement error, keratometer index error, and IOL power calculation method error[2]. Laser refractive surgery changes the ratio of the anterior and posterior surfaces, hindering accurate K value estimation after SMILE. Cornea substance tissue movement also alters the corneal refractive index. ELP is another important parameter in calculating IOL power. It is derived from the K values and therefore shifts when K values change.

The SMILE approach was invented less than 10y ago, so even the earliest patients are not old enough to have developed senile cataracts. As a result, we cannot perform a historical comparison as for LASIK or PRK. Because of its smaller incision, SMILE induces fewer changes in corneal shape and can better preserve anterior corneal asphericity than other refractive surgeries for the same level of myopia correction[23]. Here we introduced the concept of EILD on the premise that regardless which cornea refractive surgery was performed, the lens would not change. EILD should have the same effect as the real lens, which means they should theoretically be the same. We therefore calculated the change rate of the EILD to estimate the stability of the calculation formula[19]. We chose to perform the second measurement after 6mo to calculate the K values for two reasons. First, after 6mo, dry eye symptoms have largely resolved[24]. Second, lens refraction may be changed if time interval is too long (*e.g.*, 2-3y). A longer interval also increases the likelihood of study dropout. So we chose 6mo as the time interval to avoid subsequent lens refraction changes. We used a single IOL (ALCON SN60WF) to decrease the error induced by the IOL constants. We also excluded patients with posterior scleral staphyloma to avoid axial length measurement errors.

We found that the Barrett True-K and Haigis formulas had similar stabilities in eyes with axial lengths between 24 and 26 mm. The respective percentages for the SRK/T, Holladay 1, and Haigis formulas were 7.4%, 7.4%, and 85.19% for a margin of error within 0.5 D; 25.92%, 51.84%, and 100% for a margin of error within 1.0 D in Group A; 33.33%, 40.74%, and 44.44% for a margin of error within 0.5 D; and 44.44%, 59.26%, and 66.66% for a margin of error within 1.0 D in group B. The respective percentages for the Barrett True-K formula were 88.89% and 100% for margins of error within 0.5 and 1.0 D in group A, respectively. The corresponding values were 81.48% and 92.59% for margins of error within 0.5 and 1.0 D in group B. This means the Barrett True-K formula has the most stability in calculating IOL power in eyes with axial length >26 mm. The SRK/T formula was the least stable; it calculated EILD>1.0 D of 66.67% in group A and 33.33% in Group B. Moreover, 7.41% in Group A and 22.23% in Group B were above 2.00 D. We compared the equivalent IOL power outcomes before and after SMILE by paired-samples *t*-tests, there are no significant differences by Barrett True-K formula in Group A (t=0.433, P=0.707) and Group B (t=1.732, P=0.225), there are no significant differences by Haigis formula in Group A (t=2.120, P=0.168), but significant differences in Group B (t=-12.557, P=0.006). Overall, the Barrett True-K formula was the most stable.

Why do the different formulas show such extreme differences? The SRK/T and Holladay 1 formulas only need the axial length and K-value. The ACD is calculated through the A constant, which is included in the SRK/T formula. The SRK/T formula is highly dependent on the K-value; when it decreases, the SRK/T formula can be inaccurate. We found that there are significant differences between SRK/T formula in Group A (t=143.760, P=0.000) and Group B (t=44.277, P=0.001), and Holladay formula in Group A (t=12.763, P=0.006) and Group B (t=5.870, P=0.028). The SRK/T formula calculated EILD>1.0 D of 66.67% in Group A and 33.33% in Group B. Moreover, 7.41% in Group A and 22.23% in Group B were above 2.00 D. In this study, the small percentage of patients within 0.5 D when calculated with SRK/T and Holladay can be attributed to this reason. If a subject's K-value significantly decreased after corneal refractive surgery (*e.g.*, from 43 to 38), these two formulas are not suitable. We found that IOL power values calculated by SRK/T and Holladay were smaller than preoperative power. According to our hypothesis, IOL power should remain the same. If we implant a lens with small refractive power during subsequent cataract surgery, the total refraction of the eye will become hyperopic. If there is a large difference between pre- and postoperative IOL power, the result is more hyperopic. The Barrett True-K formula yielded the most similar results, indicating it is the most stable. We think that is why the four formulas show such extreme differences; they use various internal mechanisms to maintain stable results. According to previous studies[25], if conventional formulas provide an IOL power that leads to hyperopia, increasing the IOL power may create an emmetropic eye. Compared with other options, the Barrett True-K and Haigis formulas provide greater IOL power, which means they should yield comparable accurate results. However, this should be confirmed with additional investigations.

The Haigis formula is based on the thin optical lens principle, which uses three constants (a0, a1, a2) to predict ELP. Compared with two earlier formulas that used only one constant, the Haigis formula is more accurate and can avoid ELP estimation errors[4]. Indeed, our results confirmed that the Haigis formula was superior to the SRK/T and Holladay formulas. We analyzed the predicted pre- and postoperative EILD outcomes by paired-samples *t*-tests, there are no significant difference between them in Group A (t=2.120, P=0.168). We also found that the Haigis formula had a myopic tendency in Group B (t=-12.557, P=0.006; Table 3, Figures 2 and 5). This interesting finding should be studied in future investigations.

The Barrett True-K formula is based on the Barrett Universal 2 formula and can be used with or without considering the surgically induced change in refraction because it uses an internal regression formula to calculate an estimated change in manifest refraction if those data are not entered[26]. Compared with other formulas, the Barrett True-K requires more parameters such as lens thickness and white-to-white corneal diameter, but it is the most stable formula. We analyzed the predicted pre- and postoperative EILD outcomes by paired-samples *t*-tests, there are no significant difference between them in Group A (t=0.433, P=0.707) and Group B (t=1.732, P=0.225).

Based on our findings, we have some suggestions. First, patients should have appropriate expectations before cataract surgery. They should be informed it is not possible to predict the exact IOL power after corneal refractive surgery. Second, corneal refractive surgeons should preserve patient information before and after refractive surgery so it can be used by cataract surgeons in the future. Third, advanced equipment such as Lenstar 900, Pentacam, or IOLMaster should be used to measure biometric parameters. Fourth, for patients with axial length between 24 and 26 mm, doctors can choose either the Haigis or Barrett True-K formula to calculate the IOL power. For patients with axial length >26 mm, we recommend using the Barrett True-K formula to calculate IOL power. If advanced equipment is not available, doctors can consult a website to use the Barrett True-K formula and calculate IOL power. They should remember that there is no gold standard to calculate IOL power after SMILE. Before making the final decision for choosing IOL power, the surgeon should consider the patient's occupation, age, daily vision habits, binocular balancing, and other factors.

A major limitation of the study is that the patients did not undergo cataract surgery, making the results theoretical. We need time and a large number of cases to verify the present results. Another shortcoming is that we were unable to include some promising methods such as ray tracing, intraoperative aberrometry and other formulas[27]. Finally, our sample size was small, and larger studies should be performed in the future.

In conclusion, our results showed that the Barrett True-K formula provides more stable predictions than other formulas. These findings could serve as a reference for cataract surgeons when choosing IOL formulas.

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