



The accuracy of the trifocal IOL calculation using equivalent K-readings and total corneal power in different zones

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Abstract

Purpose To identify the equivalent K-readings and total keratometry zones that is optimally suitable for calculating the IOL spheroequivalent according to 7 formulas.

Methods The study included 40 patients (40 eyes) who underwent uneventful femtosecond laser-assisted cataract surgery and refractive lens exchange (RLE) with implantation of a trifocal diffractive IOL (PanOptix, Alcon inc.). Targeted emmetropia was achieved in all patients, no distance and near correction was needed. Retrospective IOL calculations were performed utilizing 7 formulas (SRK/T, Holladay 1 and 2, Haigis, Hoffer Q, Barrett Universal 2, Olsen) and Pentacam keratometry data: Holladay equivalent K-readings, total optical power by ray tracing (TCRP) centered on the apex and pupil in 10 zones (from 0.5 to 5 mm in 0.5 mm increments). For each formula/zone/map combination: postoperative predicted refraction (PPRs), mean absolute errors (MAEs), and median absolute errors (MedAEs) were analyzed.

Results According to EKR, the Haigis formula showed the lowest error in the central zones up to 3.5 mm, the TCRP zone for Holladay I and II formulas 4.0–4.5 mm, for HofferQ and SRK/T formulas 4.5–5.0 mm, and for Olsen and Barrett II Universal—5 mm.

Conclusion The use of keratometry data (EKR, TCRP) in the formulas adapted to SimK, with the correct choice of the evaluation zone of keratometric data, will increase the chance of hitting the refractive target.

Key messages

What is known

- Most of the formulas for calculating the spheroequivalent are adapted to standard keratometry, which performs measurements in a ring of a fixed diameter, depending on the biometer used.
- Equivalent K-readings and total cornea refractive power are practically not used to calculate the spheroequivalent, since they can give an error.

What this study

- Equivalent K-readings and total cornea refractive power can be used to calculate the spheroequivalent with the correct choice of the keratometry area
- The use of a keratometry area suitable for a specific formula allows you to improve the accuracy of the calculation

Keywords Equivalent K-readings · Total keratometry · Keratometry zone · IOL calculation

Introduction

In recent years, trifocal IOL has become widespread [1]. Increasingly, more patients have high expectations for the postoperative results and extremely short postoperative recovery time. Trifocal diffractive IOLs have shown the highest practical results at three working distances [2, 3], but they cannot provide complete spectacle independence for all patients. The main reason is blurred vision, caused by residual ametropia. Calculation of the optical power of the MF IOL requires exceptional accuracy. Surgeons cannot afford to get into myopia or hyperopia, even to a small degree, within ± 0.5 D [4].

The accuracy of the IOL calculation depends on many factors. Individual features of the surgical technique include the number of IOL calculation formulas used with optimized or individual constants that minimize the risks of deviation of the target refraction. IOL calculation formulas aim to determine the effective lens position (ELP) [5], which requires a considerable number of biometric data. Most of them (axial length (AL), anterior chamber depth (ACD), lens thickness, white-to-white (WTW)) depend on the accuracy of the used measurement method (ultrasonic, optical) or device used [6]. The exception is keratometry. The modern cornea tomography allows the surgeon to choose the exact data used in the IOL calculation [6, 7]. Thus, the determination of ELP mainly depends on the chosen formula and optimized constants [8], the accuracy of the measurement of the AL, ACD, and lens thickness [6], and the keratometry data used for the calculation largely depends on the choice of the surgeon. Moreover, the K mean (K_m) value is just a single number that must be selected from a large data sample [9–12].

The rotational Scheimpflug camera obtains more than 100 thousand keratometric measurements of one cornea in an 8-mm zone. Measured data can be pupil-centered or apex-centered and describe keratometric data in a ring or local zone. The main question is which corneal zone most accurately reflects the total optical power required for the IOL calculating.

In recent years, the total keratometry or total cornea power, or the total cornea refractive power (TCRP), has been actively studied to calculate the IOL [13, 14]. However, most old and modern formulas are designed to use classical SimulatedK (SimK) data and are not adapted to TCRP [15].

It is important to note that corneal power measurements of Pentacam differ from standard keratometry. Pentacam SimK has a different measurement principle, but the calculation aspect remains standard using the keratometric index of 1.3375. With TCRP, both the measurement principle and the calculation principle differ. The use of TCRP

data is justified after keratorefractive surgery. Thus, the use of keratometry data from Pentacam for the calculation of IOL should be treated with caution, but potentially the relevant use of these data can improve the accuracy of the calculation.

Modern corneal tomography systems provide a considerable amount of data on the total power of the cornea; it is challenging to choose the most accurate value for the specific IOL calculation formula. It is a problem that we have tried to solve in this study.

Materials and methods

As part of this study, we performed a retrospective analysis of the femtosecond laser-assisted cataract surgery and refractive lens exchange (RLE) performed in the S. Fyodorov Eye Microsurgery Federal State Institution, St. Petersburg in the period from 01.09.2018 to 01.02.2020. Fifty-one patients with high visual acuity (better than 0.1 LogMAR) in the early postoperative period were selected. These patients were invited for additional examination three or more months after the surgery. All participants signed informed consent; the work was approved by the local ethics committee and performed in accordance with the Declaration of Helsinki.

In addition to the standard examinations, patients underwent examinations with the following devices: optical biometer (OA-2000, Tomey, Corp. Ver. 3B), Image Guided System (Verion, Alcon inc., Ver. 2.6), and rotating Scheimpflug camera (Pentacam HR, Oculus ver 1.21r65). Six months (6 ± 2.3) postoperatively uncorrected and best-corrected distance visual acuity (UDVA, BCDVA), uncorrected and best-corrected near visual acuity (UNVA, BCNVA) were measured.

Patients with uneventful femtosecond laser-assisted cataract surgery and refractive lens exchange were included. Axial length (AL) range was 22–25mm. Patients with postoperative uncorrected distance visual acuity not lower than 0.05 (0.9) LogMAR (decimal) and no correction needed in the long-term follow-up were included. Thus, the error was either wholly excluded or minimized in assessing subjective postoperative refraction [16].

Exclusion criteria for the study were: total corneal astigmatism more than 0.7 D, any previous surgical treatment, trauma, corneal scars and opacities, and lens subluxation. If both eyes of a single patient met the inclusion criteria, one eye was randomly selected in the study.

IOL calculation

The pre-surgery IOL calculation was based on optical biometric data using several modern formulas and the optical

power of the IOL was selected at the discretion of the surgeon. In the long term, for patients who met the inclusion and exclusion criteria, IOL was retrospectively calculated with seven different formulas: Haigis, Hoffer Q, Holladay 1, SRK/T, Barrett 2 Universal, Olsen, and Holladay 2. Biometric data (AL, ACD, lens thickness, WTW) were used with an OA-2000, keratometric data with Pentacam HR. The analysis used postoperative predicted refraction (PPR) for the implanted IOL.

Three Pentacam maps were used to obtain keratometric data:

1. Holladay equivalent K-readings detail report (EKR 65%)
2. TCRP with apex centration (TCRP-apex)
3. TCRP with pupil centration (TCRP-pupil)

The first map is the Holladay equivalent K-readings detail report (EKR 65%). This map is an upgrade of an actual net power map for practical use. For regular corneas (posterior radius equals 82% of anterior radius), cornea optical power values shift to the range of SimK values for the same eye. Thereby, resultant EKR values are suitable for standard IOL formulas.

The second and third are TCRP values from the power distribution map with an apex and pupil centration. Ray Tracing's approach calculates the focal length and then calculates the power at each point of the cornea in diopters.

Each map utilized the data of zones from 0.5 to 5 mm with a step of 0.5 mm. Thus, 30 keratometry data and seven formulas were used to calculate the IOL: 210 calculation options for each patient. Formulas were used from the following sources: Tomey OA2000 (SRK/T, Haigis, Hoffer Q, Holladay 1, Olsen), Image Guided System Verion (Holladay 2), apacrs.org (Barrett Universal II).

Surgery

The femtosecond laser-assisted cataract surgery or RLE was performed using femtosecond laser LenSx and Verion image-guided system. One surgeon (SSV) performed all procedures on the phaco machine Centurion Vision System (Alcon inc.) using the same surgical technique and ultrasound and hydrodynamic settings. Main incisions were

located at 110°, in the bag implantations of the trifocal IOL Acrysof IQ PanOptix (Alcon inc.) were performed.

Statistical analysis

G*power 3.1.9.7 software was used to calculate the sample size. For the *t*-test families' two-tailed Wilcoxon signed-rank test with one sample case and a normal parent distribution, assuming a significance level of 5% and a power of 80% the sample size was calculated to be 34 eyes to determine the medium effect size (0.5).

The following values were calculated for each formula/zone/map combination: PPRs, mean absolute errors (MAEs), and median absolute errors (MedAEs). MAEs and MedAEs were calculated with data derived after lens constant optimization. The systematic error was eliminated by adjusting the refractive prediction error for each eye up or down by an equal to the group's arithmetic mean error. For calculated MAEs and MedAEs values, the following characteristics were calculated for each map-zone and map-formula pairs: mean, standard deviation, standard error mean, Student's *t*-coefficient, significance level (2-tailed) using IBM SPSS Statistics 26 software.

Wilcoxon signed-rank test was used to test if mean PPR values at each zone-formula combination are significantly different from zero. A *p*-value less than 0.05 was considered statistically significant. Data preparation, statistical tests, and visualization were performed using Python programming language (version 3.9) and the following packages: NumPy, Pandas, SciPy, Matplotlib, and seaborn.

Results

Out of 51 patients invited for examination in the long-term period, 40 eyes of 40 patients were included in the study in accordance with the inclusion and exclusion criteria. The average age of the patients was 51.5 ± 10.8 . The group included 23 females and 17 males with 23/17 right/left eyes. The data of the preoperative examinations is shown in Table 1.

There were no complications in the early postoperative period. The average UDVA and UNVA LogMAR (decimal) in the long-term period were as follows: 0.0075 ± 0.03 (1.02

Table 1 Eye parameters before surgery

Mean parameter	Value (mean±SD)
Visual acuity without correction (LogMAR (decimal))	0.88 ± 0.35 (0.178 ± 0.15)
Axial length (mm)	23.17 ± 0.99 (from 22.05 to 25.65)
Anterior chamber depth (mm)	3.28 ± 0.26
K mean (diopters)	43.44 ± 1.39 (with 40.35 min and 45.42 max)
IOL power (spherical equivalent, diopters)	23.78 ± 4.14

± 0.08) and 0.064 ± 0.05 (0.87 ± 0.09) respectively. The spectacle correction did not improve vision; therefore, targeted emmetropia was achieved in all patients. The comparison results of the predicted and actual refraction are presented in Fig. 1.

Two main trends can characterize IOL calculation based on EKR data (Fig. 1a). The first one is a tendency to myopic results: mean PPR values given by almost all zone-formula combinations are minus. The notable exception is the Haigis formula: mean PPR values in 0.5–1.0 mm zones are above

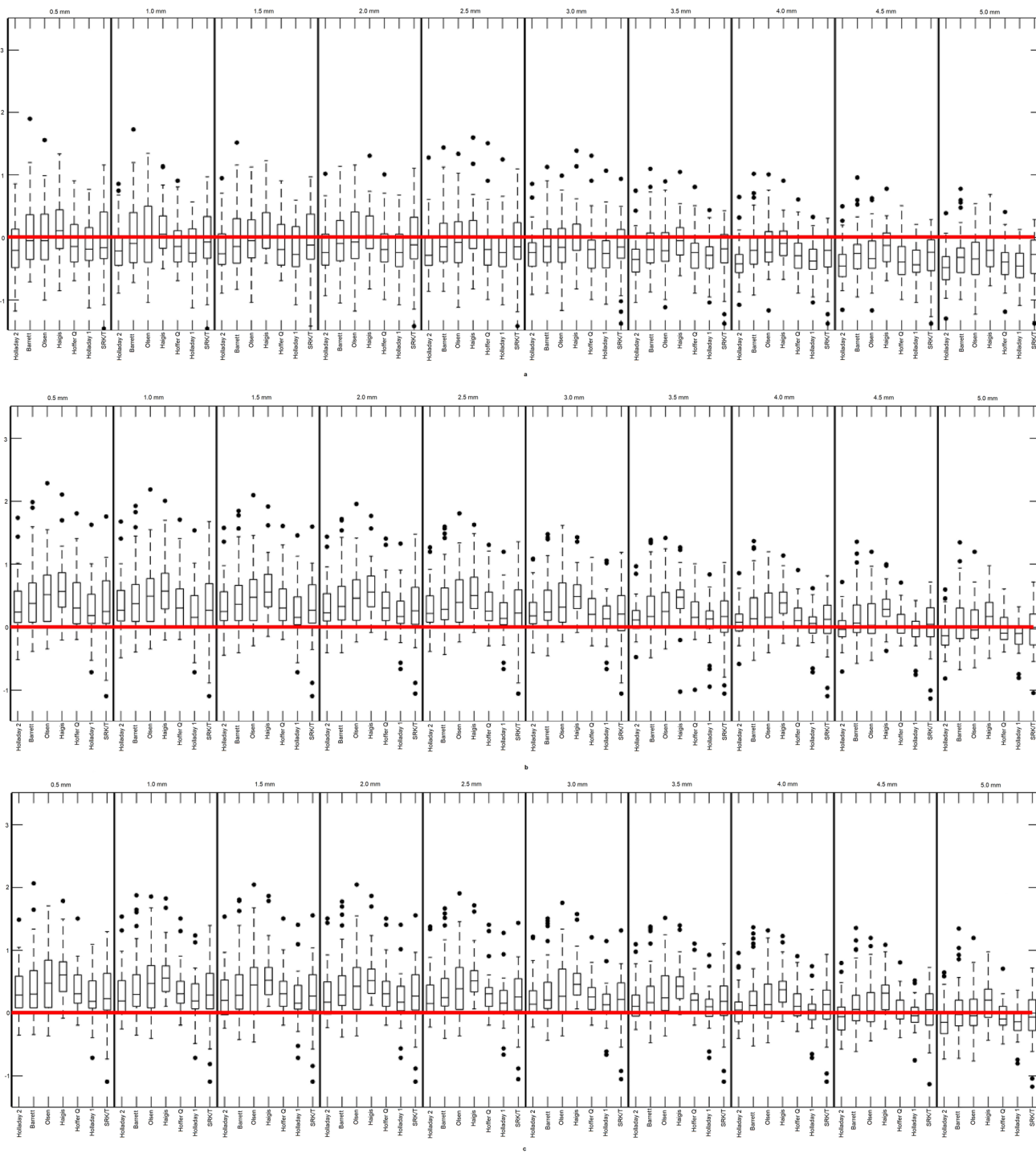


Fig. 1 Errors of predicted postoperative refraction values across ten zones using seven formulas (each cell represents an error between actual and predicted refraction for a single patient). Boxplots summar-

ize PPR distributions across individuals. **a** Based on EKR 65% mean data; **b** based on TCRP-Apex mean data; **c** based on TCRP-pupil mean data

zero plus. The second trend is that the myopic shift increases when increasing the zone radius; however, the pronounced deviation is observed only in zones more than 2.5 mm. Mean PPR values obtained by Haigis, Barrett 2 Universal, Olsen, and SRK/T formulas demonstrate the slightest difference from zero in central zones (0.5–2.5 mm).

In contrast to EKR data, TCRP-apex data leads to the overrepresentation of hypermetropia in PPR across all zone-formula combinations (Fig. 1b). Specifically, no zone-formula combination gives a mean PPR minus value in 0.5–4.0-mm zones. Holladay 1 formula gives the closest to zero PPR values with low variance in all zones. Similarly to EKR, the bigger the zone is, the more myopic result will it provide.

The main trends in IOL calculation based on TCRP-pupil centration data are almost the same as on TCRP-apex centration data: prevalence of hypermetropic results in PPR in 0.5–4.0-mm zones and the decrease of mean PPR values towards the peripheral zones (Fig. 1c).

We applied the Wilcoxon signed-rank test to identify whether mean PPR values at each zone-formula combination significantly differ from zero (Fig. 2, left). We found that based on EKR data, all formulas except Holladay 2 give high *p*-values (>0.05) in the central zone (0.5–3.5 mm), indicating that PPR is not significantly different from zero. For TCRP-apex and -pupil data, non-significant deviations from zero are reached only in 4.0–5.0-mm zones.

SD is another very important indicator determining the accuracy of the formula calculation, the mean absolute deviation and the median of absolute values [17]. The

highest variance is observed in SKR/T, Olsen, and Barrett II Universal formulas for all datasets, implying a comparatively high instability in these calculations. All formulas tend to decrease the variance with increasing zone size, with the best performance in the 4–5 mm zone of the Holladay 1, Hoffer Q, and Holladay 2 formulas.

Together with the deviation from the mean (variance), we analyzed the deviation from zero (Fig. 2, right) and found that calculations using EKR provided the lowest overall deviation from zero. The IOL calculations on TCRP-apex and TCRP-pupil data revealed that Hoffer Q, Holliday 1, and 2 formulas give the lowest deviation from zero. As well as the deviation from the mean, the deviation from zero tends to decrease with increasing zone radius, but only in TCRP maps.

The comparison results (MAE, MedAE) of the predicted and actual refraction are presented in Figs. 3, 4. Maps for MAE and MedAE values calculated without constant optimization are presented in Appendix 1.

MAE characterizes the average deviation of the predicted refraction from the actual one in the study group and is one of the main indicators determining the accuracy of the formula. However, MAE is most sensitive to outliers, which can significantly affect this indicator. MedAE is the middle in the data line, which displays the central indicators of deviation from the target refraction and does not characterize the average error of the formula, but this indicator is minimally affected by outliers.

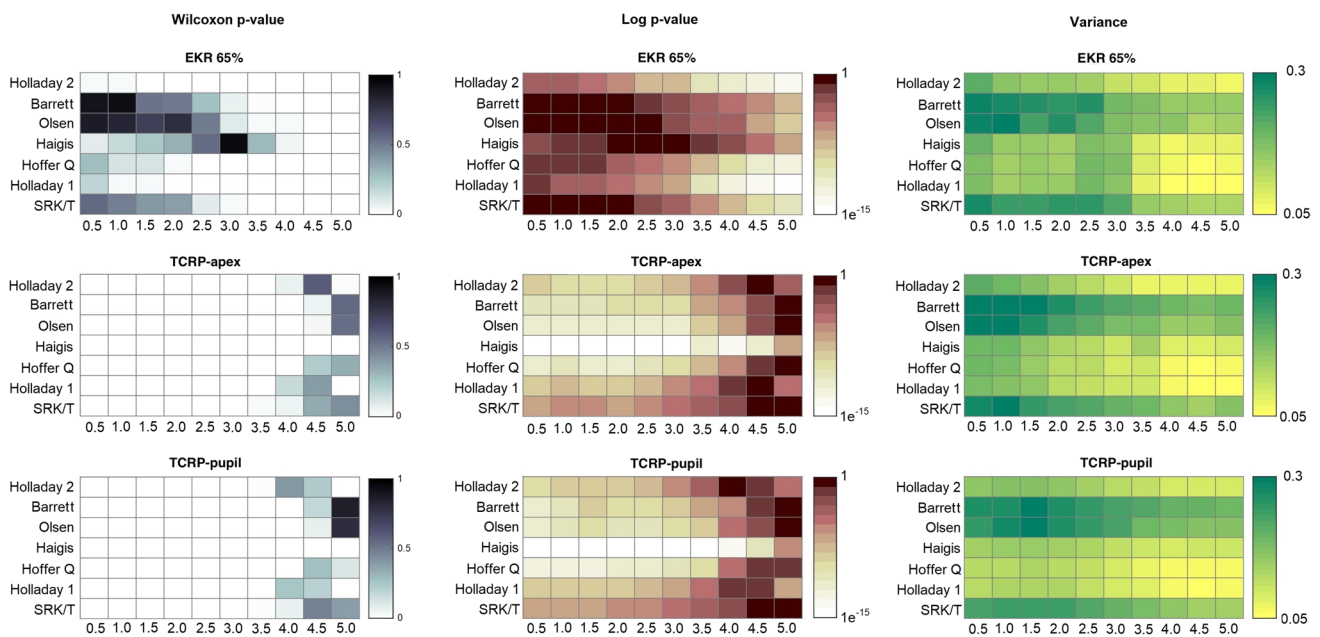


Fig. 2 (Left) Comparison of mean PPR values with zero at each zone-formula combination by Wilcoxon signed-rank test (*p*-values are presented). (Center) A variance of PPR values at each zone-formula

combination. (Right) Root square deviation from zero of PPR values for each pair of zone-formula. The scale to the right of each figure shows the color distribution (from minimum to maximum values)

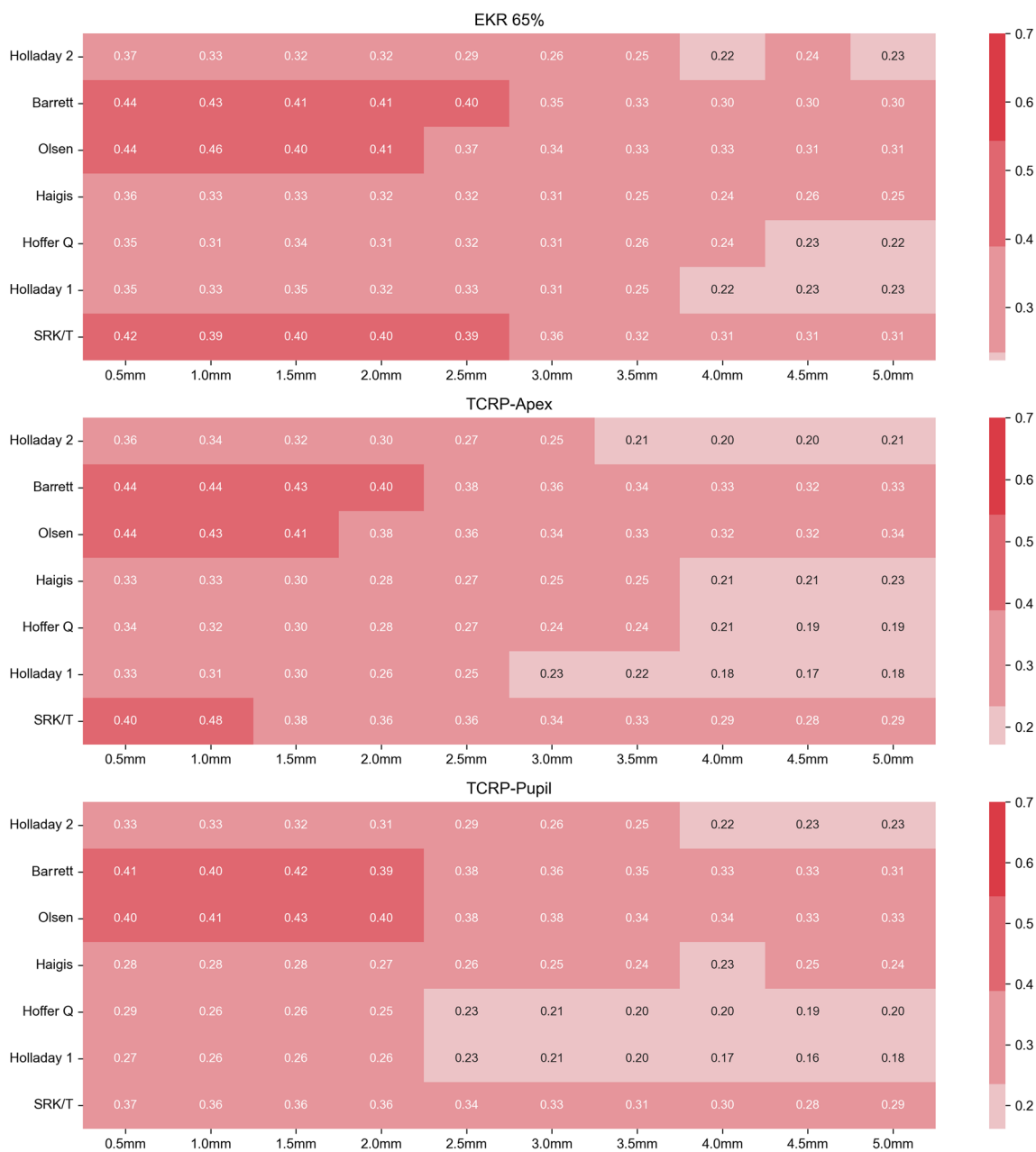


Fig. 3 MAEs of predicted postoperative refraction values across ten zones using seven formulas based on EKR 65%, TCRP-apex, and TCRP-pupil mean data

According to the EKR keratometry values, a uniform distribution of MAE should be noted in all zones, with minimum values according to the Haigis, Hoffer Q, Holladay 1, and 2 formulas (less than 0.3) in the zones of 3.5–5.0 mm. According to TCRP-apex and TCRP-pupil, MAE tends to decrease to the periphery for all formulas. Barrett 2 Universal and Olsen formulas show high stability of MAE with zones more than 3mm in TCRP-apex. The Hoffer Q, Haigis, Holladay 1, and 2 demonstrate minimal MAE with zones more than 2.5mm. The Holladay 1 and Hoffer Q formulas show the lowest MAE value (less than 0.2) compared to

other zone-formula for TCRP-apex and TCRP-pupil in the 4.5-mm zone (0.16–0.19).

Olsen, Haigis, Hoffer Q, Holladay 1, and 2 formulas using EKR data demonstrate the minimum MedAE (less than 0.3) values with zones more than 2.5mm compared with other formulas. The lowest MedAE shows Holladay 2 formula at 4 mm. TCRP-apex and TCRP-pupil, similarly to MAE, show a tendency to decrease MedAE from the center to the periphery for all zone-formula combinations. The Holladay 1 and 2 formulas give the lowest MedAE values for all TCRP-Apex and TCRP-pupil zones compared to other formulas, with minimum

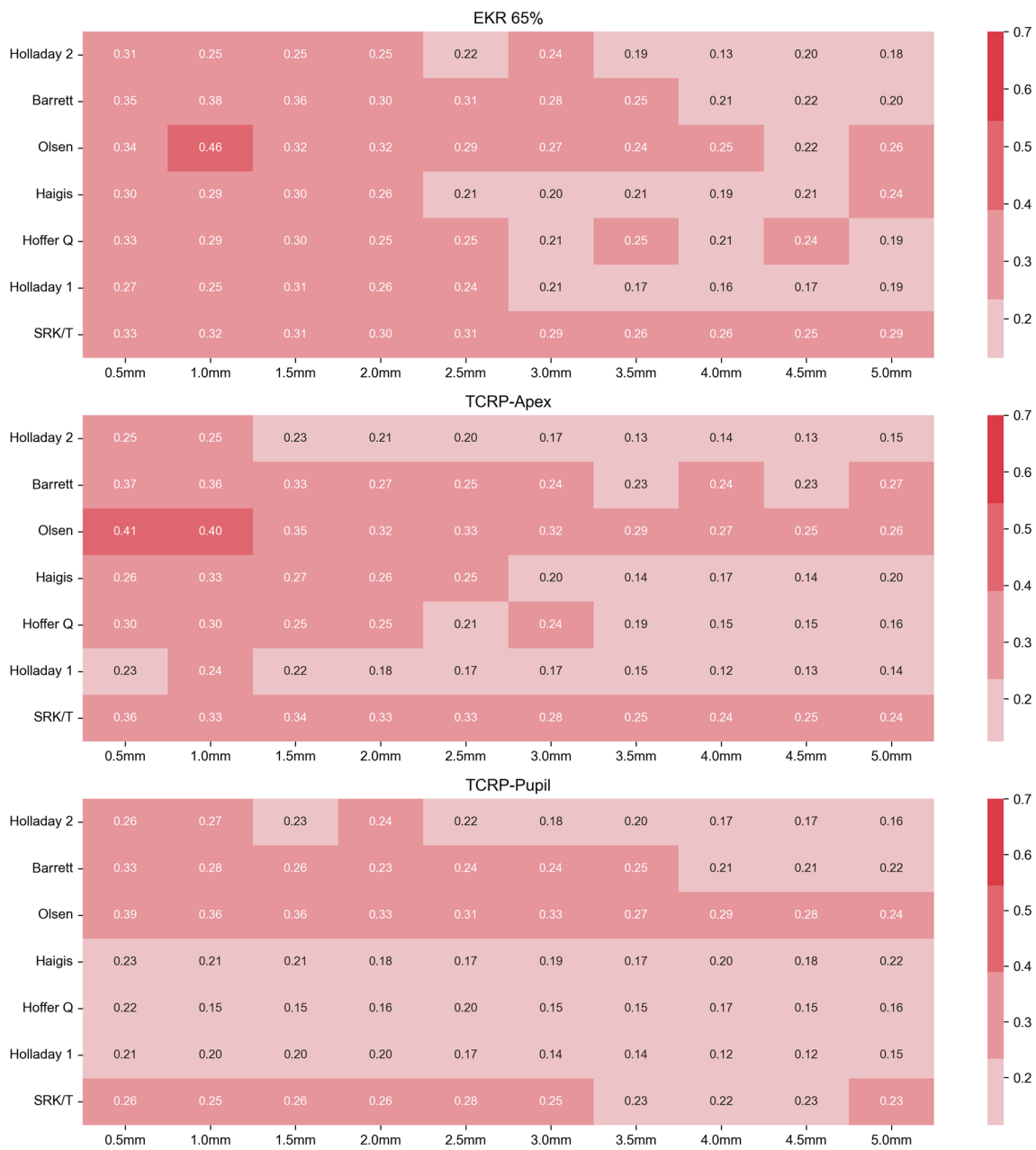


Fig. 4 MedAEs of predicted postoperative refraction values across ten zones using seven formulas based on EKR 65%, TCRP-apex, and TCRP-pupil mean data

values in the 4.0–4.5 mm zone (0.12–0.14). Almost all formulas (except Olsen) showed MedAE below 0.3 in all zones when using TCRP-pupil.

Discussion

The present study examined keratometry data derived from three Pentacam maps (EKR, TCRP-apex, TCRP-pupil), the main regularities of the distribution of the

trifocal IOL calculation error from the center of the cornea (0.5 mm) to the middle periphery (5 mm). The goal was to find the most accurate calculation of the spheroequivalent using the seven most frequently used formulas.

In the present study, we tried to exclude the error of spectacle correction by including only patients with no VA improvement using spectacles, even within 0.25 D. We also attempted to systematize the approach to choosing a keratometry zone using the complete set of zones within a 5-mm

diameter, which allowed us to trace the change in the calculation error from the center to the periphery in detail.

EKR data at central zones with a diameter of 0 to 3.5 mm gave no statistically significant difference from zero in most formulas for IOL calculation (except Holladay 2). Still, all the formulas had a relatively high variance (Fig. 2). Haigis formula, according to EKR data, demonstrated the lowest error at central zones up to 3.5 mm; this is the only formula that has no significant difference from 0 on average for all zones, and the minimum values of MAE and MedAE in the zones of 3.5–5 mm (Figs. 3, 4). The Haigis formula converts the radius of the anterior corneal curvature using keratometric index 1.3315. It does not calculate ELP based on keratometric data, which could explain the results obtained in this study [18]. According to Savini et al., the lowest MedAE was obtained at a 3-mm zone EKR with the Hoffer Q and Holladay 1 formulas, 0.18 and 0.17, respectively [19]. In the present study, Hoffer Q and Holladay 1 at a 3.0-mm EKR zone showed a significant difference from zero, with high variance, but the values of MedAE are very close to the Savini data—0.21 (Fig. 4). Another study showed calculation with the SRK/T formula according to EKR data with optimized A-constant, demonstrating higher MAE than SimK-based estimate. At the same time, MAEs decreased from the center to the periphery [9]. In this study, SRK/T formula with EKR demonstrates high MAE values that also

fall from the center to the edge with a minimum value at a 4.0–5.0-mm zone—0.31 (Fig. 3).

This study shows that the most accurate calculation using EKR, with the lowest variance, MAE and MedAE values, was obtained with the Haigis formula at the 3.5-mm zone (Fig. 2).

All three maps lead to myopic results in with the periphery. TCRP, compared to SimK, has a different eccentricity. According to TCRP, the cornea gets steeper to the periphery [20]; the steeper the cornea—the less IOL optical power. In the present study, IOL power was fixed, which led to a myopic shift to the periphery (Fig. 1).

Calculation according to TCRP data centered on the apex (Fig. 1b) and the pupil (Fig. 1c) demonstrated similar results. Except for the Haigis formula, there were no significant differences from 0 at zones 4–5 mm. The absence of a statistically significant difference from 0 and the minimum values of variance and deviations from zero were obtained for the formula Holladay 1 and 2 at 4–4.5 mm, Hoffer Q and SRK/T at 4.5–5 mm, Barrett II Universal and Olsen formulas at the 5-mm zone. Savini et al. had obtained a higher MAE of calculation based on TCRP at 2-mm and 3-mm zones with the Hoffer Q, Holladay 1, and SRK/T compared with EKR (3, 4.5 mm) but with no significant difference [19]. Only the SRK/T formula showed similar results (3.0 mm TCRP-apex and TCRP-pupil, 4.5 mm EKR). The Holladay 1 and Hoffer

Table 2 The value of MAE and MedAE in previously performed studies in various zones using EKR and total cornea power in comparison with the results of our study in the recommended zones

Study	n	Results: formula/measurement/MAE(MedAE)/zone - value	This study data in recommended zones
EKR			
Savini et al. [19]	41	HofferQ/MAE(MedAE)/4.5(3)mm—0.33 (0.18)	0.25 (0.21) ⁺
		Holladay 1/MAE(MedAE)/3mm—0.32 (0.17)	-
		SRK/T/MAE(MedAE)/4.5 (3)mm—0.33 (0.23)	-
Karunaratne et al. [9]	45	Holladay 2/MAE/3, 4.5mm—0.25	-
		SRK/T/MAE/4.5mm—0.25	-
Total cornea power (ray tracing)			
Savini et al. [19]	41	HofferQ/MAE(MedAE)/3mm—0.34 (0.19)	0.19 (0.15)
		Holladay 1/MAE(MedAE)/3(2)mm—0.34 (0.24)	0.16 (0.12)
		SRK/T/MAE(MedAE)/2 (3)mm—0.34 (0.19)	0.28 (0.23)
Savini et al. [15]	43	HofferQ/MAE to 0.27	0.19
Saad et al. [7]	50	HofferQ, Holladay 1, SRK/T*/MedAE/3–4mm—0.48	0.12–0.23
Savini et al. [18]	107	Haigis/MedAE/2–5mm—0.34	-
		HofferQ/MedAE/2–5mm—0.31	0.15
		Holladay 1/MedAE/2–5mm—0.29	0.12
		SRK/T /MedAE/2–5mm—0.30	0.23

⁺The most accurate EKR calculation was shown by the Haigis formula in the 3.5mm zone

*The Hoffer Q formula was used in eyes with an AL shorter than 22.0 mm; the Holladay 1 formula was used in eyes with an AL between 22.0 mm and 26.0 mm; and the SRK/T formula was used in eyes with an AL longer than 26.0 mm

Q formulas showed lower MAE values when using TCRP-apex and TCRP-pupil data compared to EKR (Fig. 3). In the same study [19], the TCRP MedAE was minimal at the 3.0-mm zone for Hoffer Q and SRK/T, which is inconsistent with the results of this study, which showed minimal MedAE values in the 4.0–4.5-mm zone (Fig. 4). Saad et al. used the Hoffer Q, Holladay 1, SRK/T formulas depending on axial length and demonstrated the lowest MedAE (0.44) when using SimK data on a 2-mm ring (Pentacam HR), which closely matches SimK from the IOL-Master 500 that measures the anterior corneal curvature in an almost similar area [7]. According to TCRP, MedAE was minimal at a 3–4-mm zone (0.48), with no valid differences from SimK, true net power at zone and ring ($p > 0.05$), which partly matches the results of the present study, where the lowest MedAE was obtained in 4–5-mm zones (Fig. 4).

Table 2 specifies the outcomes of several studies performed previously in which unconventional keratometry data were used for IOL calculation. The minimal values of MAE and MedAE identified in a certain zone-formula combination are shown. To compare, the data of this study are presented according to the same formula in the recommended zone.

In accord with Table 2, the magnitude of the prediction error is often less when choosing the optimal keratometry zone than when using a randomly selected zone.

In this study, non-standard keratometry data were used, while conventional keratometry has been used for many years in both old and modern formulas with high calculation accuracy, whether unconventional keratometric data in a particular zone will improve the accuracy of refractive prediction. The old formulas SRK/T, Hoffer Q, Holladay 1 with standard data showed high values of MAE (0.42) and MedAE (0.52) compared to the data of our study with TCRP in the recommended zone, 0.28 and less than 0.24, respectively [7, 21]. According to Savini et al., the values of MAE and MedAE were less than in the present study when using SRK/T, Olsen, and Barrett formulas, but more when using Hoffer Q, Haigis, Holladay 1, and 2 formulas [6]. The accuracy of calculation according to 9 formulas was compared by Darcy et al. using standard keratometry on a large sample [8]. The minimal value of MAE and MedAE were obtained using the Kane formula 0.38 and 0.30, respectively, other formulas showed higher values. According to our study, for each formula in the recommended zones, MAE and MedAE did not exceed 0.34 and 0.27, respectively. Thus, the use of unconventional keratometry data, based on the total cornea refractive power obtained by Pentacam potentially can improve the accuracy of calculating the IOL with the correct choice of the measurement zone. Further research is needed in this area.

This study has some limitations. The sample size was relatively small. The study did not analyze several

modern formulas based on artificial intelligence [1, 8, 22]. The study included only patients with low ametropia. Additional studies are needed to evaluate eyes with high degrees of ametropia. The maximum diameter of the keratometry evaluation zone is limited to 5 mm; the expanded zone might lead to minor calculation errors.

In conclusion, it should be noted that based on the results of this study, it is possible to recommend the Haigis formula for calculating the trifocal IOL using EKR data derived from the zones ≤ 3.5 mm. It is advisable for Holladay I and II formulas to use a TCRP zone of 4.0–4.5 mm, for Hoffer Q and SRK/T formulas 4.5–5.0 mm, and for Olsen and Barrett II Universal—5 mm. Modern corneal tomography systems provide a variety of keratometry data. The goal of future research will be a detailed assessment of these data and the development of calculation formulas based on the measured total optical power of the cornea.

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Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00417-023-06198-8>.

Declarations

Ethics approval This article does not contain any studies with animals performed by any of the authors. All procedures performed in studies involving human participants were in accordance with the ethical standards of the local ethics committee of Northwestern State Medical University named after I.I. Mechnikov and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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