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ORIGINAL ARTICLE

Agreement between Pentacam and handheld Auto-Refractor/Keratometer for keratometry measurement

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KEYWORDS
Keratometery;
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Abstract
Objective: This study was conducted to evaluate the level of agreement in keratometry measurements between a rotating Scheimpflug imaging-based system (Pentacam) and a handheld auto-refractokeratometer (handheld NIDEK ARK-30).
Method: This analytical cross-sectional study was conducted in the right eyes of 579 subjects. Keratometry measurements were conducted with the Pentacam and the handheld NIDEK ARK-30 systems. The SPSS Software version 22 and MedCalc V3 were applied to estimate descriptive statistics using paired *t*-test, Pearson correlation coefficient, 95% limits of agreement (LoA), and Bland–Altman plot.
Results: In the total sample, the inter-device difference in the mean flat and steep keratometry values was −0.266 diopter (D) (*P*-value < 0.001) and 0.052 D (*P*-value = 0.093), respectively. There was a significant difference in mean flat keratometry between the two devices in all groups of refractive errors (paired difference <0.5 D and *P*-value < 0.001). The difference in mean steep keratometry was significant only in myopic subjects (*P*-value = 0.046). The 95% LoA between the two devices measurements was 2.51 D, 3.98 D, and 6.37 D for flat keratometry and 2.6 D, 3.2 D, and 3.9 D for steep keratometry in emmetropic, myopic, and hyperopic subjects, respectively.

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Conclusion: Our study showed relatively wide limits of agreement between handheld NIDEK ARK-30 and Pentacam; therefore, these devices cannot be used interchangeably for measuring corneal curvature.

PALABRAS CLAVE
Queratómetro;
Pentacam;
Auto-refractoqueratómetro portátil

Concordancia entre el sistema Pentacam y un auto-refractómetro/queratómetro portátil para la medición de queratometría

Resumen
Objetivo: Se realizó este estudio para evaluar el nivel de concordancia de las mediciones queratométricas obtenidas mediante un sistema de cámara rotatoria Scheimpflug (Pentacam) y un auto-refractoqueratómetro portátil (NIDEK ARK-30 portátil).
Método: Este estudio analítico transversal fue realizado en los ojos derechos de 579 sujetos. Las mediciones queratométricas se obtuvieron con Pentacam y NIDEK ARK-30 portátil. Se aplicó el software SPSS versión 22 y MedCalc V3 para calcular las estadísticas descriptivas utilizando la prueba t pareada, el coeficiente de correlación de Pearson, los límites de concordancia (LoA) al 95%, y el análisis gráfico de Bland-Altman.
Resultados: En la muestra total, la diferencia inter-dispositivo en cuanto a valores queratométricos planos y curvos medios fue de −0,266 dioptrías (D) (valor $P < 0{,}001$) y 0,052 D (valor $P = 0{,}093$), respectivamente. Se produjo una diferencia significativa en términos de queratometría plana media entre los dos dispositivos para todos los grupos de errores refractivos (diferencia pareada < 0,5 D y valor $P < 0{,}001$). La diferencia en cuanto a queratometría curva media fue significativa únicamente en sujetos miopes (valor $P = 0{,}046$). Los LoA al 95% entre las mediciones de los dos dispositivos fue de 2,51 D, 3,98 D, y 6,37 D para la queratometría plana, y de 2,6 D, 3,2 D, y 3,9 D para la curva, en los sujetos con emetropía, miopía e hipermetropía, respectivamente.
Conclusión: Nuestro estudio reflejó unos límites de concordancia relativamente amplios entre NIDEK ARK-30 portátil y Pentacam; por tanto, estos dispositivos no pueden utilizarse indistintamente para medir la curvatura de la córnea.

Introduction

Keratometry, which is used to measure the radius of the corneal curvature, is an important and useful method of corneal examination.[1] Precise keratometry readings are important for prescribing appropriate contact lenses with a proper curvature and for determining the power of intraocular lenses (IOL) because even small errors can lead to unexpected refractive errors after surgery.[2] It is also necessary to consider keratometric values during preoperative screening examinations to achieve the desired visual quality after surgery.[3] A mean keratometry >47 diopter (D) is one of the main risk factors for the progression of corneal ectasia after refractive surgery.[4] In addition, keratometric readings are very important in the diagnosis of ectatic disorders, including keratoconus. Among various corneal values, keratometric measurements are important for grading, monitoring disease progression, and designing treatment plans in keratoconus patients.[5]

Given the importance of the accuracy and precision of keratometric readings, it is necessary to use a device that can measure the corneal curvature with high accuracy. In recent years, a variety of techniques were introduced to measure the corneal curvature and shape. Placido-disc-based keratoscopy, slit-scanning topography, and Scheimpflug imaging tomography are some examples.[6]

In the present study, we compared the handheld NIDEK ARK-30 auto-refractokeratometer and Pentacam results. Our purpose was to investigate the agreement and interchangeability of these devices. If the accuracy of the keratometric readings using the handheld NIDEK ARK-30 is confirmed compared to the Pentacam, it can be used as a suitable alternative, especially for screening purposes.

Methods

Multi-stage cluster sampling was applied to select the participants for this cross-sectional study conducted in 2015. National data were used to randomly select two underserved districts in the north and southwest of Iran, including Kojour District (Nowshahr County, Mazandaran Province) and Shahyoun District (Dezful County, Khuzestan Province). Then, using a list of all villages in the districts, a number of villages were randomly selected in each district (15 villages in Shahyoun and 5 villages in Kojour District).

In each village, a systematic approach was applied to select the households. In each household, all subjects older than one year of age were invited to join in the study. The examinations were done on a predetermined day in one place. Then, interviews were done with all individuals and the household heads to obtain demographic data prior to examinations.

Exclusion criteria were history of eye surgery including cataract or any type of corneal surgery, a history of ocular trauma, tropia, amblyopia, pterygium, ptosis, and error in Pentacam measurements. Moreover, those measurements presenting as outliers in the data were also excluded from the study.

Informed consent was obtained from all participants. For those under 18 years, consent was obtained from the head of the household. For those who consented to participate in the study, a date was scheduled for examinations.

In each rural area, examinations were carried out in one study site. First, for each individual, distance visual acuity was measured using a Snellen chart and then refraction was measured using table-mounted Nidek ARK-510A auto-refractokeratometer (Nidek Co. Ltd, Gammagori, Aichi, Japan). Non-cycloplegic refraction was measured using the Nidek ARK-30 handheld auto-refractokeratometer (Nidek Co. Ltd, Gammagori, Aichi, Japan) in a number of randomly selected participants (age group strata). Subjective refraction was performed after determining manifest refraction, and finally, corrected visual acuity was measured. Measurements with both handheld and table-mounted auto-refractometers were repeated three times. Handheld auto-refractokeratometers are suitable for measuring keratometry in those who are unable to fix their heads on table mounted devices. Keratometry values measured by the handheld NIDEK ARK-30 were recorded as K1 (flat keratometry) and K2 (steep keratometry).

After this stage, the participants underwent slit lamp biomicroscopy examination (Model BQ 900: Haag Streit, Bern, Switzerland) by an ophthalmologist. Corneal imaging analysis was done in all participants over the age of 5 years using the Pentacam HR (Oculus Inc., Lynnwood, WA), which provides highly accurate measurements of the corneal curvature in a shorter time compared to the manual method. All images were acquired by the same examiner throughout the study in accordance with the manufacturer's instructions. The latest version of the device (6.03r11) and Pentacam software (1.17r72) were used. If there were errors in Pentacam results, artificial tears were instilled and imaging was repeated after 10 min. To minimize the effect of diurnal variations on test results, eye examinations (both eyes) were done between 9:00 am and 2:00 pm, at least 3 h after waking up.[7,8]

In this study, refractive errors were defined based on non-cycloplegic auto-refraction. Myopia was defined as a spherical equivalent (SE) of −0.5 diopter (D) or worse, and hyperopia was defined as an SE of +0.5 D or more. Emmetropia was defined if neither eye was myopic or hyperopic.

Statistical analyses were performed using the SPSS software version 22 and MedCalc V3 software. First, we determined the mean values of the flat and steep keratometry readings along with their standard deviations. The Kolmogorov–Smirnov test was applied to check data normality. Paired *t*-test was used to compare the keratometry readings between the two devices. Pearson test was applied to investigate the correlation of K-readings with the two devices. The 95% limits of agreement (95% LOA) was used to demonstrate the agreement between the two devices and was calculated as ''Mean ± SD* 1.96″ of the difference between the two devices. Moreover, a linear regression model was applied to present the formula for predicting agreement between two devices using constant, beta coefficient and *R* square.

Ethical issues

The Ethics Committee of Shahid Beheshti University of Medical Sciences approved the study protocol, which was conducted in accordance with the tenets of the Helsinki Declaration. All participants or their parents/legal guardians signed a written informed consent.

Results

In this study, 3851 samples were selected, of whom 3314 participated in the study. The Pentacam measurements and handheld auto-refractokeratometry were done in 652 individuals selected randomly. After applying the exclusion criteria, the data from 579 right eyes were analyzed. The mean age of the subjects was 32.36 ± 18.72 years (6–90 years) and 60.3% (n = 349) were female. In terms of refractive errors, 380 subjects (65.6%) were emmetropic, 113 (19.5%) were myopic, and 86 (14.9%) were hyperopic.

Keratometry readings achieved with Pentacam and ARK-30 handheld auto-refractokeratometer followed a normal distribution: K1 (P = 0.195 and P = 0.200 respectively) and K2 (P = 0.170 and P = 0.200 respectively) values.

Table 1 shows the comparison of mean flat keratometry values measured by the Pentacam and ARK-30 auto-refractokeratometer in the total sample and also according to age and refractive error. As presented, the mean flat keratometry was 0.266 D lower with Pentacam. Paired *t*-test showed a significant difference between the two devices (P < 0.001). However, the difference in steep keratometry readings was not statistically significant, and the correlation between steep keratometry readings between the two devices was higher than found for flat keratometry. The estimated 95% LoA for the two devices ranged from −2.092 to 1.560 for flat keratometry and from 1.431 to −1.535 for steep keratometry. Fig. 1 presents the plot of agreement between the two devices for the measurement of flat and steep keratometry using the Bland–Altman plot.

As demonstrated in Tables 1 and 2, the inter-device difference in the keratometry readings was less than one in all age groups, except for flat keratometry in subjects over 70 years of age. The results showed a high inter-device correlation (r > 0.8 and P < 0.001) in age groups under 60 years, while the correlation and agreement between the two devices was reduced in age groups over 60 years of age.

Tables 1 and 2 summarize flat and steep keratometry readings measured with the two devices in different

Table 1 Mean, paired differences, Pearson's correlation coefficient (PCC) and 95%limmit of agreement(LOA) of Flat keratometry measured by the Auto Ref/Keratometer Nidek ARK-30 and Pentacam.

		Auto ref/keratometer	Pentacam	Paired differences	*P*-value[*]	PCC	*P*-value[**]	95%LOA		
		Mean ± SD	Mean ± SD	Mean ± SD				Lower	Upper	Width
	Total	43.32 ± 1.51	43.06 ± 1.56	−.26 ± 0.93	<0.001	0.817	<0.001	−2.09	1.56	3.65
Age (years)	6–20	43.01 ± 1.36	42.77 ± 1.36	−.23 ± 0.56	<0.001	0.915	<0.001	−1.33	0.86	2.19
	21–30	43.16 ± 1.55	42.84 ± 1.51	−.31 ± 0.95	0.003	0.806	<0.001	−2.18	1.56	3.74
	31–40	43.37 ± 1.50	43.18 ± 1.52	−.18 ± 0.57	<0.001	0.928	<0.001	−1.31	0.94	2.25
	41–50	43.72 ± 1.43	43.38 ± 1.64	−.34 ± 0.99	<0.001	0.802	<0.001	−2.25	1.62	3.88
	51–60	43.32 ± 1.85	43.49 ± 1.76	.16 ± 0.62	0.102	0.941	<0.001	−1.05	1.39	2.45
	61–70	43.82 ± 1.56	43.53 ± 1.53	−.29 ± 1.43	0.206	0.569	<0.001	−3.11	2.52	5.63
	>70	43.76 ± 1.70	42.58 ± 2.21	−1.17 ± 2.39	0.036	0.274	0.229	−5.87	3.52	9.39
Refractive errors	Emmetropia	43.23 ± 1.46	43.03 ± 1.46	−.19 ± 0.64	<0.001	0.904	<0.001	−1.45	1.05	2.51
	Myopia	43.49 ± 1.53	43.15 ± 1.59	−.34 ± 1.01	<0.001	0.789	<0.001	−2.33	1.64	3.98
	Hyperopia	43.52 ± 1.67	43.06 ± 1.94	−.46 ± 1.62	0.010	0.606	<0.001	−3.64	2.72	6.37

[*] The *P*-value calculated by pair-*t*-test.
[**] The *P*-value calculated for Pearson's correlation coefficient.

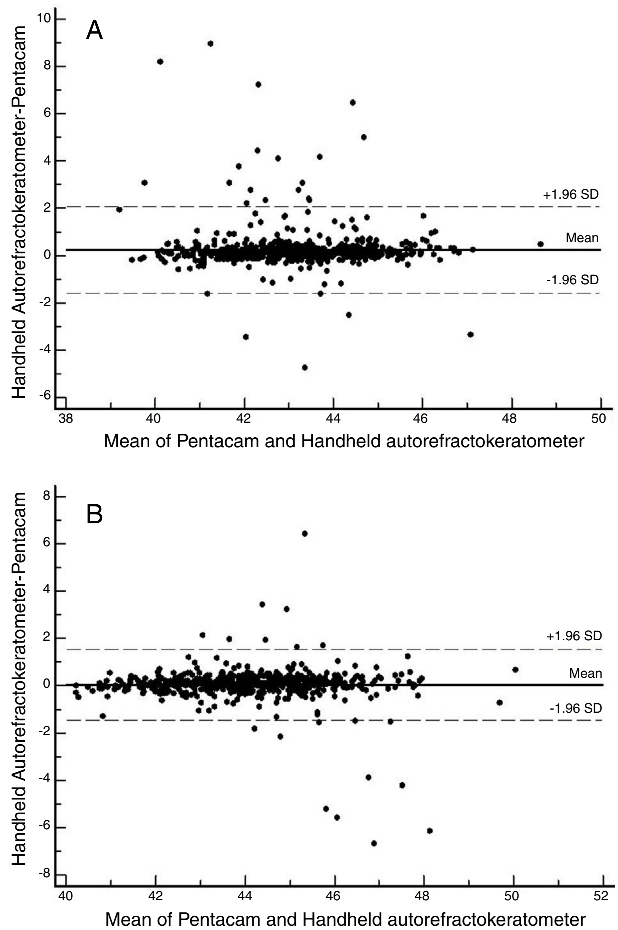

Figure 1 Agreement between Nidek ARK-30 handheld auto-refractokeratometer and Pentacam for the measurements of the flat (A) and steep (B) keratometry. The middle line indicates the mean difference and the two dashed side lines show the 95% limits of agreement.

refractive groups (emmetropia, myopia, and hyperopia). In all refractive groups, the mean keratometry measured by the Pentacam was less than that measured by the handheld auto-refractokeratometer, except for steep keratometry in hyperopic cases. The difference in mean flat keratometry measured with the two devices was significant in all emmeropia, myopia, and hyperopia groups (*P*-value $\leq$0.01). However, the difference in mean steep keratometry was significant only in the myopic group (*P*-value = 0.046). According to Tables 1 and 2, based on the 95% LoA, the two devices had the best agreement in emmetropic cases and the worst agreement in hyperopic cases.

Table 3 shows the formula for predicting agreement between two devices considering keratometry readings by the Pentacam as an independent variable (*x*) using a linear regression model.

Discussion

In this study, we evaluated the agreement and interchangeability of handheld NIDEK ARK-30 and Pentacam systems. Our results showed relatively wide limits of agreement between handheld NIDEK ARK-30 and Pentacam, so these devices cannot be used interchangeably for measuring corneal curvature.

To the best of our knowledge, no study has compared keratometry measurements between Pentacam and handheld auto-refractokeratometers. Chang et al.[9] studied patients undergoing cataract surgery and toric IOL implantation, and found a very small difference (0.17 D) in the mean keratometry measured with Pentacam and auto-keratometry results. However, this difference was larger in a study performed by Whang et al.[10] (0.99 D).

In our study, the Pentacam and handheld NIDEK ARK-30 showed a small difference in mean flat and steep keratometry readings (−0.26 D and −0.05 D, respectively). In other words, the handheld NIDEK ARK-30 measurements of the steep and flat meridians were higher compared to the results of the Pentacam. Given that both devices apply a refractive index of 1.3375 for converting the anterior corneal curvature to corneal power,[11] the observed difference may be due to different optical structures and imaging techniques in the two devices. In addition, imaging time may be a factor influencing the agreement between the two devices; the longer keratometry takes, the more likely it is to affect fixation and data accuracy, with the potential of reducing the level of inter-device agreement.[12] The effect of tear film on the agreement between the two devices should also be considered.[13] Of course, the main mechanism for measuring keratometry should not be overlooked; with Pentacam, the curvature data are indirectly calculated from elevation maps or corneal elevation, which may cause differences between measurements of the two devices, even when an equal refractive index is used.

Moreover, it is reported that the closer to the center the measurements are done, the steeper is the cornea and the higher are the K-reading values.[14] With the Pentacam, since keratometric measurements are performed in the peripheral cornea in addition to the central region, the reported values are generally slightly lower than with other devices which measure keratometry in the 3 mm central zone.[15]

The difference of 0.26 D observed in flat keratometry measured with the two devices was statistically significant and sometimes clinically relevant, as well. For example, when calculating the IOL power for cataract surgery, a 0.25 D error in refractive power could result in a correction error of about 0.28−0.31 D.[16] Moreover, although the difference between the two devices was small, it could be of importance in some cases, such as contact lens fitting.[17] Nevertheless, for purposes such as keratoconus screening, this slight difference may have no clinical significance. However, although the difference between the two devices was clinically acceptable, considering the 95% LoA, the agreement between the two devices was not good.

Based on the results of this study, there was a significant difference in mean flat keratometry readings measured with the two devices (between −0.19 D and −0.46 D) in all refractive error groups. As mentioned previously, the mean flat keratometry measurements by the Pentacam were lower in all refractive error groups. The same trend was observed in previous studies comparing auto-keratometers and Pentacam.[18,19] However, this difference was not significant in studies by Elbaz et al.[20] and Shammas et al.[21]

Table 2 Mean, paired differences, Pearson's correlation coefficient (PCC) and 95%limmit of agreement (LOA) of Steep keratometry measured by the Auto Ref/Keratometer Nidek ARK-30 and Pentacam.

		Auto ref/keratometer	Pentacam	Paired differences	*P*-value*	PCC	*P*-value**	95%LOA		
		Mean ± SD	Mean ± SD	Mean ± SD				Lower	Upper	Width
	Total	44.12 ± 1.61	44.07 ± 1.67	−.05 ± 0.75	0.093	0.894	<0.001	−1.53	1.43	2.96
Age (years)	6–20	43.82 ± 1.45	43.72 ± 1.45	−.09 ± 0.40	0.002	0.962	<0.001	−0.87	0.69	1.57
	21–30	43.88 ± 1.64	43.86 ± 1.69	−.01 ± 0.87	0.845	0.862	<0.001	−1.74	1.70	3.44
	31–40	44.29 ± 1.59	44.25 ± 1.66	−.03 ± 0.68	0.535	0.914	<0.001	−1.37	1.29	2.66
	41–50	44.40 ± 1.52	44.26 ± 1.60	−.14 ± 0.57	0.014	0.935	<0.001	−1.26	0.97	2.24
	51–60	44.34 ± 1.90	44.40 ± 1.97	0.06 ± 1.12	0.735	0.832	<0.001	−2.14	2.26	4.41
	61–70	44.54 ± 1.74	44.55 ± 1.89	0.00 ± 1.54	0.981	0.643	<0.001	−3.02	3.03	6.05
	>70	44.47 ± 1.86	44.61 ± 2.11	0.13 ± 0.71	0.380	0.943	<0.001	−1.26	1.53	2.79
Refractive error	Emmetropia	43.97 ± 1.52	43.93 ± 1.63	−0.03 ± 0.66	0.248	0.913	<0.001	−1.34	1.26	2.61
	Myopia	44.60 ± 1.65	44.44 ± 1.64	−0.15 ± 0.82	0.046	0.875	<0.001	−1.76	1.45	3.26
	Hyperopia	44.17 ± 1.82	44.20 ± 1.80	.02 ± 1.00	0.821	0.848	<0.001	−1.94	1.98	3.93

* The *P*-value calculated by pair-*t*-test.
** The *P*-value calculated for Pearson's correlation coefficient.

Table 3 The formula prediction between keratometry by Pentacam (*Y*) and Auto Ref/Keratometer Nidek ARK-30 (X1) and *R* square.

		Constant + B-Coefficients × (X1)	*R* square	*P*-value	Constant + B-Coefficients × (X2)	*R* square	*P*-value
	Total	9.29 + 0.79 × (X1)	0.67	<0.001	6.12 + 0.86 × (X2)	0.80	<0.001
Age (years)	6–20	4.02 + 0.91 × (X1)	0.84	0.002	1.78 + 0.96 × (X2)	0.93	0.050
	21–30	7.83 + 0.83 × (X1)	0.65	0.007	7.11 + 0.84 × (X2)	0.74	0.003
	31–40	3.92 + 0.91 × (X1)	0.86	0.010	5.54 + 0.88 × (X2)	0.84	<0.001
	41–50	13.49 + 0.70 × (X1)	0.64	<0.001	5.09 + 0.89 × (X2)	0.87	<0.001
	51–60	0.40 + 0.98 × (X1)	0.89	0.875	8.66 + 0.80 × (X2)	0.69	0.033
	61–70	18.61 + 0.58 × (X1)	0.32	0.004	18.14 + 0.59 × (X2)	0.41	<0.001
	>70	34.74 + 0.21 × (X1)	0.08	<0.001	7.40 + 0.83 × (X2)	0.89	0.023
Refractive error	Emmetropia	4.26 + 0.91 × (X1)	0.82	<0.001	6.66 + 0.85 × (X2)	0.83	<0.001
	Myopia	10.72 + 0.76 × (X1)	0.62	<0.001	5.53 + 0.88 × (X2)	0.77	0.008
	Hyperopia	21.05 + 0.52 × (X1)	0.37	<0.001	6.42 + 0.85 × (X2)	0.72	0.015

X1: flat keratometry by Pentacam.
X2: steep keratometry by Pentacam.

On the other hand, despite our finding for flat meridian, we did not find significant differences between the mean steep keratometry measured with the two devices in different refractive error groups except in the myopic group. The difference between findings related to the agreement of the two devices in flat and steep keratometric measures could be due to the different effects of accommodation on different regions of the cornea.[22–24]

Correlation coefficients can be used as a statistical index of the agreement between two variables. However, a high correlation coefficient does not itself indicate a high agreement between the results of two devices. The limits of agreement is a better indicator for agreement between two devices.[25] Of course, with the Bland–Altman method, only the interval of the agreement is calculated, and the acceptability of this interval should be determined based on clinical considerations. In terms of keratometry, a narrow LoA less than 1 is a good agreement, and less than 0.5 represents excellent inter-device agreement, indicating that the measurements with the two devices are in great agreement and the two devices can be used interchangeably. However, if this interval is more than one diopter, the two devices cannot be used interchangeably.[26]Accordingly, the LoA interval between the two devices measurements was 2.51 D, 3.98 D, and 6.37 D for flat keratometry and 2.6 D, 3.2 D, and 3.9 D for steep keratometry in emmetropic, myopic, and hyperopic subjects, respectively, which shows that despite the small paired difference in readings between the two devices, they cannot be used interchangeably to measure flat and steep keratometry in different refractive error groups. Moreover, based on the 95% LoA, the two devices had the best agreement in emmetropic cases and the worst agreement in hyperopic cases.

The reason for larger differences in hyperopic subjects could be that proximally induced accommodation is stronger in hyperopic cases, which can cause closed-loop fluctuations,[1] especially in keratometry with handheld devices. Given the different targets used in these two devices, it may be thought that accommodation is stimulated to a greater extent during handheld keratometry compared to the Pentacam that uses an optical target. Given the effect of accommodation on corneal curvature and keratometric measurements,[22,24] accommodation fluctuations can lead to significant differences between the two devices, especially in hyperopic individuals.

In this study, the difference in the keratometry measurements of the two devices was less than one diopter in all age groups, except in subjects over 70 years of age. However, it should be noted that the age group under 15 years is more likely to be emmetropic, myopic cases are generally under 50 years of age, and hyperopics are often older than 60 years. This group has problems such as dry eye or fixation problems that can affect keratometry results. Therefore, the observed difference in the agreement between the two devices (Paired Difference = −1.175 D) may be related to dry eye or fixation problems at older ages.[12] However, in all studied age groups, the 95% LoA was more than one for measuring flat and steep keratometry with the two devices and given the wide interval of the 95% LoA, using the two devices interchangeably is not recommended.

Conclusion

According to the results of this study, the differences in keratometry readings between the Pentacam and handheld NIDEK ARK-30 auto-refracto-keratometer were small and clinically acceptable in the total sample and in different refractive error groups. However, since the LoA was wide in these groups, interchangeable use of the two devices is not recommended.

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Conflict of interest

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