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Original research

Are the results of handheld auto-refractometer as valid as the result of table-mounted refractometer?

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Abstract

Purpose: To determine the agreement of table-mounted and handheld auto-refractometers and to evaluate the effect of age and different types of refractive errors on this comparison.

Methods: In this cross-sectional study conducted in 2015 using multi-stage cluster sampling, two underserved villages were selected randomly in the north and southwest of Iran. All the selected participants underwent optometric and ophthalmic examinations. Refraction was measured using handheld and table-mounted auto-refractometers in 652 subjects.

Results: The mean age of the subjects was 32.7 ± 18.72 years, and 58.3% of them were female. A significant difference was observed in the results of sphere, spherical equivalent (SE), and J45 vector between the two devices ($P < 0.012$), but there was no significant difference in J0 vector. There was a significant difference in the results of sphere between the two devices in all age groups under 50 years ($P = 0.005$), but there was no difference in age groups above 50 years. Correlation coefficients of the two devices were 0.989, 0.986, 0.908, and 0.951 for the results of sphere, SE, J0 vector, and J45 vector, respectively ($P < 0.0001$). The 95% limit of agreement (LOA) of the two devices was −0.31 to +0.53 for sphere, −0.27 to +0.63 for SE, −0.27 to +0.27 for J0 vector, and −0.16 to −0.17 for J45 vector.

Conclusions: According to our findings, the spherical error and cylindrical power measurements of the two devices have a significant correlation. Although there is a significant difference in the mean values between the two devices, this difference may be considered clinically insignificant, and considering the narrow 95% LOA between the two devices, the results may be used interchangeably.

Keywords: Handheld auto-refractometer; Table-mounted auto-refractometer; Refraction; Astigmatism

Introduction

There are different methods like retinoscopy, autorefraction, and photorefraction for the measurement of refractive errors as the most common cause of visual impairment in the world.[1,2]

Retinoscopy is the main method of measuring refractive errors and has the highest validity in children.[3–5] Auto-refractometers are digital devices for automatic and fast measurement of refractive errors[6] while measurement of refraction with a retinoscope takes a much longer time, which makes retinoscopy inappropriate for screening purposes.[7]

The first generations of auto-refractometers were rather heavy, table-mounted devices,[8] and they are now widely used in most eye clinics worldwide.[7,8] Since these devices were heavy and difficult to move,[9] smaller and portable devices

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were developed as handheld auto-refractometers by different companies.[10,11] The validity of different auto-refractometers varies depending on the cylindrical power, astigmatic axis, and type and magnitude of spherical refractive error.[12,13] Moreover, the results of each device are different in the presence or absence of cycloplegia.[13]

Meticulous screening and detection of individuals suffering from refractive errors, especially in childhood, may prevent amblyopia and visual impairment. Therefore, it is vital to use a proper method and device to carefully detect the cases of refractive errors.[2] Handheld auto-refractometers are now widely used for screening of refractive errors.[14,15] An important question here is whether the results of handheld auto-refractometers are as reliable as the results of table-mounted ones. The aim of this study was to compare the spherical and cylindrical results measured by handheld and table-mounted auto-refractometers at different ages.

Methods

The present study is part of the study of visual problems in Iranian villages, and its methodology has been detailed in some previous reports.[16,17]

It is also briefly presented in the following. This cross-sectional study was conducted in 2015 using multi-stage cluster sampling. Using national data, two underserved districts were selected randomly in the north and southwest of Iran out of all underserved districts of the country. These districts were Kojur District (Nowshahr County, Mazandaran Province) and Shahyoun District (Dezful County, Khuzestan Province). After selecting the districts, a list of all villages in the districts was prepared, and a number of villages were randomly selected in each district (15 villages in Shahyoun and 5 villages in Kojur District).

In each village, the household was selected systematically, and all individuals above one year of age in each household were invited to participate in the study. The examinations were done on one predetermined day in one location. Informed consent was obtained from all participants. Individuals aged 18 years and above signed the informed consent form while the consent was obtained from the parents or guardians of children below 18 years. Then all individuals and the household heads were interviewed to obtain some demographic data, and examinations were performed. The exclusion criteria were a history of ocular surgery including cataract, any type of corneal surgery, and a history of ocular trauma.

Fig. 1 presents the sampling method and examinations. Examinations started with objective refraction using Nidek table-mounted auto refractometer (Nidek ARK-510A auto refractor/keratometer, Gamagori, Japan) under non-cycloplegic conditions. In this stage, some individuals from different age and sex groups were randomly selected to undergo non-cycloplegic objective refraction using the Nidek ARK-30 handheld auto refractometer (NidekARK-30 auto refractor/keratometer, Gamagori, Japan). Lensometry was done if the subjects wore glasses. In the next step, uncorrected visual acuity was measured for all participants using a Snellen

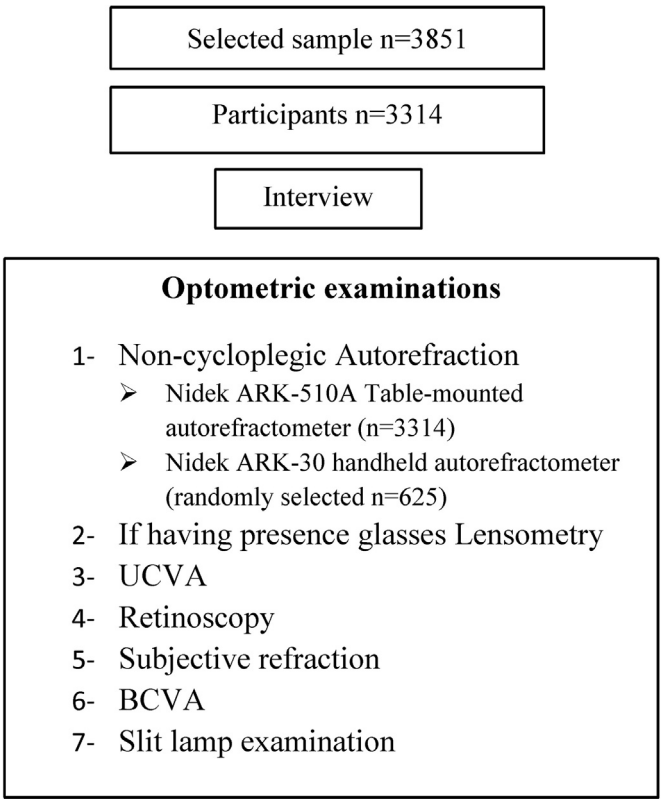

Fig. 1. Sampling and examination process flowchart. UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity.

chart at 6 m in appropriate light conditions. Then according to some studies[16,18,19] the results of table-mounted autorefraction were refined with retinoscopy (Heine Beta 200, HEINE Optotechnik, Herrsching, Germany) in non-cycloplegic conditions. The examinations were continued with subjective refraction, and the best corrected visual acuity (BCVA) was recorded. Slit-lamp biomicroscopy was the last examination.

Three measurements were done in each person to assess the repeatability of the Nidek ARK-30 handheld auto refractometer. The repeatability of the device for sphere and cylinder measurement according to intraclass correlation coefficient (ICC) was 0.931 and 0.894, respectively (Unpublished data).

Statistical analysis

In this study, the results of handheld and table-mounted auto-refractometers in non-cycloplegic conditions were compared. In this study, the spherical error and spherical equivalent (SE) of the two devices were compared, and vectors analysis was used to compare the cylindrical power.[20–22] According to vector principles, astigmatism has two orthogonal vectors known as J0 and J45. J0 is the horizontal and vertical component of astigmatism, and J45 is the oblique component of astigmatism. The following equations are used to calculate the vectors:

$$J_0 = (-C/2)\,\mathrm{cosinus}(2\alpha)$$

$J_{45} = (-C/2)\,\text{sinus}(2\alpha)$

where C = cylinder power, α = axis of astigmatism in objective refraction. In this study, spherical value was categorized as follows: ≤-2 diopter (D), −1.99 to −0.5 (D), −0.49 to +0.49 (D), +0.5 to +1.99 (D), and ≥+2 (D).

The Stata V.11 and Medcalc V13.0.6 were used for statistical analysis. First, the spherical error, SE, J0, and J45 were compared between the methods using the paired *t*-test. Pearson correlation coefficient was used to show the correlation of values obtained from the two devices, and the Bland and Altman plot and 95% limits of agreement (LOA) were used to show the agreement of the devices. In the Bland and Altman graph, the horizontal axis is the mean sphere, SE, J0, and J45 of the two methods and the vertical axis is the difference of the methods in sphere, SE, J0, and J45.[23] The 95% LOA was calculated as Mean ± 1.96 * standard deviation of the inter-device difference.

Ethical issues

The Ethics Committee of Iran University of Medical Sciences approved the study protocol, which was conducted in accord with the tenets of the Declaration of Helsinki. All participants signed a written informed consent.

Results

In this study, 3851 samples were selected, 3314 of whom participated in the study. As shown in Table 1, all participants underwent non-cycloplegic refraction using a table-mounted auto-refractometer. Handheld autorefraction was done in 652 individuals that were selected randomly. The mean age of the participants whose data were analyzed was 32.7 ± 18.72 years (range, 3–90 years), and 58.3% of them (n = 380) were female.

Since the results of the left and right eye had a high correlation (r for sphere = 0.825, r for cylinder = 0.719), we only analyzed the results of the right eye.

Tables 1 and 2 show the overall mean of spherical refractive errors and SE measured by the table-mounted and handheld auto-refractometers, respectively.

Paired *t*-test showed a significant difference in spherical refractive errors and SE ($P < 0.001$) as well as J45 ($P = 0.012$) between the two methods while J0 showed no significant difference.

Paired *t*-test was also used to investigate the difference in the results of sphere and SE between the two methods in different age groups. A significant difference was seen in the results of sphere between the two devices in all age groups below 50 years (for all age groups $P < 0.001$) while there was no significant difference in participants above 50 years of age. There was a significant difference in the results of SE between the two methods in all age groups (for all age groups $P < 0.001$).

Then paired-t test was used to evaluate the difference in the results of spherical error and SE between refractive error groups. The test showed the results of spherical error were significantly different in emmetropia ($P < 0.001$), hyperopia ($P = 0.026$), and myopia up to −2 D ($P < 0.001$) while there was no significant difference in myopia more than −2 D ($P = 0.104$). For SE, the results showed a significant difference in all individuals with ametropia, myopia, and hyperopia ($P < 0.001$ for all groups). Paired *t*-test was also applied to study the difference of J0 and J45 vectors in different age and refractive error groups. The results are presented in Tables 3 and 4. There was no significant difference in J0 and J45 vectors between different groups of refractive errors between the two devices. We only found a significant difference in J45 between the two devices for hyperopia 0.5–2 D ($P = 0.025$).

We studied the correlation of the two devices for sphere, SE, J0, and J45 vector, and found a significant correlation in

Table 1
Mean, paired differences, Pearson's correlation coefficient (PCC), and 95% limit of agreement (LOA) of spherical errors (average of 3 measurements) measured by the Auto Ref/Keratometer Nidek ARK-510A (Table-mounted) and Auto Ref/Keratometer Nidek ARK-30 (Handheld).

	n	Table-mounted	Handheld	Paired differences	*P*-value[a]	PCC	*P*-value[b]	95% LOA
		Mean ± SD	Mean ± SD	Mean				
Total	652	0.39 ± 1.41	0.28 ± 1.42	0.11	<0.001	0.989	<0.001	−0.31 to 0.53
Age (Year)								
<=10	97	0.49 ± 0.54	0.31 ± 0.59	0.18	<0.001	0.895	<0.001	−0.34 to 0.70
10–20	113	0.36 ± 0.82	0.20 ± 0.85	0.16	<0.001	0.962	<0.001	−0.29 to 0.62
20–30	93	−0.05 ± 1.44	−0.25 ± 1.40	0.19	<0.001	0.987	<0.001	−0.27 to 0.66
30–40	119	0.14 ± 0.90	0.03 ± 0.90	0.11	<0.001	0.975	<0.001	−0.28 to 0.51
40–50	108	0.36 ± 1.17	0.33 ± 1.17	0.03	0.005	0.994	<0.001	−0.21 to 0.28
>50	122	0.97 ± 2.40	0.96 ± 2.38	0.01	0.332	0.998	<0.001	−0.26 to 0.29
Spherical category (Diopter)								
<=-2	21	−3.70 ± 1.92	−3.75 ± 1.90	0.04	0.104	0.998	<0.001	−0.20 to 0.30
−1.99 to −0.5	60	−0.82 ± 0.32	−0.88 ± 0.35	0.06	<0.001	0.904	<0.001	−0.23 to 0.36
−0.49 to 0.49	166	0.06 ± 0.18	0.00 ± 0.25	0.06	<0.001	0.676	<0.001	−0.30 to 0.42
0.5 to 1.99	365	0.63 ± 0.26	0.47 ± 0.38	0.15	<0.001	0.789	<0.001	−0.31 to 0.61
>=2	40	3.64 ± 2.73	3.57 ± 2.74	0.06	0.026	0.998	<0.001	−0.30 to 0.44

SD: Standard deviation; PCC: Pearson's correlation coefficient; LOA: Limit of agreement.
[a] The *P*-value calculated by pair-t-test.
[b] The *P*-value calculated for Pearson's correlation coefficient (PCC).

Table 2
Mean, paired differences, Pearson's correlation coefficient (PCC), and 95% limit of agreement (LOA) of spherical equivalent (SE) errors measured by the Auto Ref/Keratometer Nidek ARK-510A (Table-mounted) and Auto Ref/Keratometer Nidek ARK_30 (Handheld).

	n	Table-mounted	Handheld	Paired differences	*P*-value[a]	PCC	*P*-value[b]	95% LOA
		Mean ± SD	Mean ± SD	Mean				
Total	652	0.08 ± 1.37	−0.08 ± 1.38	0.18	<0.001	0.986	<0.001	−0.27 to 0.63
Age (Year)								
<=10	97	0.29 ± 0.50	0.05 ± 0.53	0.24	<0.001	0.849	<0.001	−0.32 to 0.80
10–20	113	0.10 ± 0.75	−0.08 ± 0.86	0.22	<0.001	0.948	<0.001	−0.26 to 0.70
20–30	93	−0.31 ± 1.47	−0.57 ± 1.43	0.26	<0.001	0.986	<0.001	−0.22 to 0.75
30–40	119	−0.21 ± 1.02	−0.37 ± 1.03	0.18	<0.001	0.977	<0.001	−0.23 to 0.61
40–50	108	0.05 ± 1.20	−0.06 ± 1.18	0.10	<0.001	0.992	<0.001	−0.20 to 0.41
>50	122	0.49 ± 2.26	0.45 ± 2.21	0.07	<0.001	0.998	<0.001	−0.23 to 0.39
Spherical category (Diopter)								
<=-2	21	−4.23 ± 2.06	−4.32 ± 1.98	0.08	0.025	0.997	<0.001	−0.24 to 0.42
−1.99 to −0.5	60	−1.33 ± 0.60	−1.44 ± 0.62	0.10	<0.001	0.967	<0.001	−0.20 to 0.42
−0.49 to 0.49	166	−0.23 ± 0.34	−0.35 ± 0.38	0.11	<0.001	0.854	<0.001	−0.27 to 0.51
0.5 to 1.99	365	0.43 ± 0.27	0.20 ± 0.34	0.22	<0.001	0.691	<0.001	−0.26 to 0.71
>=2	40	2.88 ± 2.53	2.74 ± 2.36	0.12	<0.001	0.997	<0.001	−0.23 to 0.48

SD: Standard deviation; PCC: Pearson's correlation coefficient; LOA: Limit of agreement.
[a] The *P*-value calculated by pair-t-test.
[b] The *P*-value calculated for Pearson's correlation coefficient (PCC).

Table 3
Mean, paired differences, Pearson's correlation coefficient (PCC), and 95% limit of agreement (LOA) of J0 vector measured by the Auto Ref/Keratometer Nidek ARK-510A (Table-mounted) and Auto Ref/Keratometer Nidek ARK_30 (Handheld).

	n	Table-mounted	Handheld	Paired differences	*P*-value[a]	PCC	*P*-value[b]	95% LOA
		Mean ± SD	Mean ± SD	Mean				
Total	652	0.04 ± 0.41	0.04 ± 0.44	0.00	0.542	0.908	<0.001	−0.27 to 0.27
Age (Year)								
<=10	97	0.10 ± 0.27	0.12 ± 0.29	−0.019	0.098	0.915	<0.001	−0.25 to 0.21
10–20	113	0.08 ± 0.34	0.09 ± 0.37	−0.008	0.370	0.966	<0.001	−0.20 to 0.18
20–30	93	0.14 ± 0.36	0.17 ± 0.38	−0.030	0.005	0.964	<0.001	−0.23 to 0.17
30–40	119	0.10 ± 0.42	0.12 ± 0.45	−0.017	0.049	0.980	<0.001	−0.20 to 0.17
40–50	108	0.02 ± 0.49	0.00 ± 0.52	0.013	0.493	0.923	<0.001	−0.38 to 0.41
>50	122	−0.19 ± 0.42	−0.23 ± 0.45	0.077	0.013	0.737	<0.001	−0.58 to 0.73
Spherical category (Diopter)								
<=-2	21	0.19 ± 0.53	0.12 ± 0.59	0.223	0.209	0.252	0.271	−1.33 to 1.77
−1.99 to −0.5	60	0.13 ± 0.58	0.14 ± 0.59	−0.011	0.353	0.988	<0.001	−0.19 to 0.17
−0.49 to 0.49	166	0.08 ± 0.33	0.08 ± 0.38	0.000	0.984	0.938	<0.001	−0.27 to 0.27
0.5 to 1.99	365	−0.01 ± 0.27	−0.01 ± 0.32	−0.001	0.865	0.931	<0.001	−0.23 to 0.23
>=2	40	0.08 ± 1.03	0.07 ± 0.98	−0.023	0.266	0.994	<0.001	−0.26 to 0.21

SD: Standard deviation; PCC: Pearson's correlation coefficient; LOA: Limit of agreement.
[a] The *P*-value calculated by pair-t-test.
[b] The *P*-value calculated for Pearson's correlation coefficient (PCC).

all items ($P < 0.0001$) except for J0 in spherical refractive errors more than −2 D.

Finally, the agreement of the two devices was assessed using the 95% LOA and Bland and Altman plot. The 95% LOA of the two devices for spherical refractive errors, SE, J0, and J45 vector is presented in the following plots in Figs. 2 and 3 using the Bland-Altman plots.

Discussion

This is one of the few studies on the validity of handheld auto-refractometers. The results of this study may be very valuable considering its large sample size, population-based nature of the study, and use of modern methods (power vector calculation) for refraction analysis.

According to the results, the difference in spherical errors and SE was significant between the two devices while the difference was clinically non-significant. The most probable reason for the significance of the difference may be the large sample size of the study. Similarly, Arici et al.[24] also reported a significant difference in the spherical error and SE between Nidek handheld and Potec table-mounted auto-refractometers. Prabakaran et al.[11] also found a significant difference in SE between handheld and table-mounted auto-refractometers; the

Table 4
Mean, paired differences, Pearson's correlation coefficient (PCC), and 95% limit of agreement (LOA) of J45 vector measured by the Auto Ref/Keratometer Nidek ARK-510A (Table-mounted) and Auto Ref/Keratometer Nidek ARK_30 (Handheld).

	n	Table-mounted	Handheld	Paired differences	*P*-value[a]	PCC	*P*-value[b]	95% LOA
		Mean ± SD	Mean ± SD	Mean				
Total	652	0.00 ± 0.28	−0.01 ± 0.3	0.010	0.012	0.951	<0.001	−0.16 to 0.17
Age (Year)								
<=10	97	0.01 ± 0.14	0.00 ± 0.15	0.011	0.143	0.876	<0.001	−0.13 to 0.16
10–20	113	−0.01 ± 0.17	−0.03 ± 0.20	0.015	0.017	0.941	<0.001	−0.12 to 0.15
20–30	93	0.01 ± 0.16	0.02 ± 0.18	−0.011	0.196	0.879	<0.001	−0.18 to 0.15
30–40	119	0.02 ± 0.34	0.01 ± 0.36	0.015	0.046	0.974	<0.001	−0.15 to 0.18
40–50	108	0.02 ± 0.24	0.02 ± 0.27	−0.00	0.961	0.946	<0.001	−0.17 to 0.17
>50	122	−0.03 ± 0.44	−0.04 ± 0.48	0.021	0.106	0.955	<0.001	−0.26 to 0.30
Spherical category(diopter)								
<=-2	21	0.07 ± 0.52	0.06 ± 0.49	0.064	0.304	0.848	<0.001	−0.48 to 0.61
−1.99 to −0.5	60	−0.01 ± 0.34	0.00 ± 0.38	−0.012	0.368	0.959	<0.001	−0.23 to 0.20
−0.49 to 0.49	166	−0.03 ± 0.18	−0.04 ± 0.21	0.008	0.227	0.910	<0.001	−0.16 to 0.18
0.5 to 1.99	365	0.02 ± 0.18	0.01 ± 0.20	0.008	0.025	0.935	<0.001	−0.13 to 0.15
>=2	40	−0.01 ± 0.74	−0.03 ± 0.82	0.029	0.122	0.995	<0.001	−0.20 to 0.26

SD: Standard deviation; PCC: Pearson's correlation coefficient; LOA: Limit of agreement.
[a] The *P*-value calculated by pair-t-test.
[b] The *P*-value calculated for Pearson's correlation coefficient (PCC).

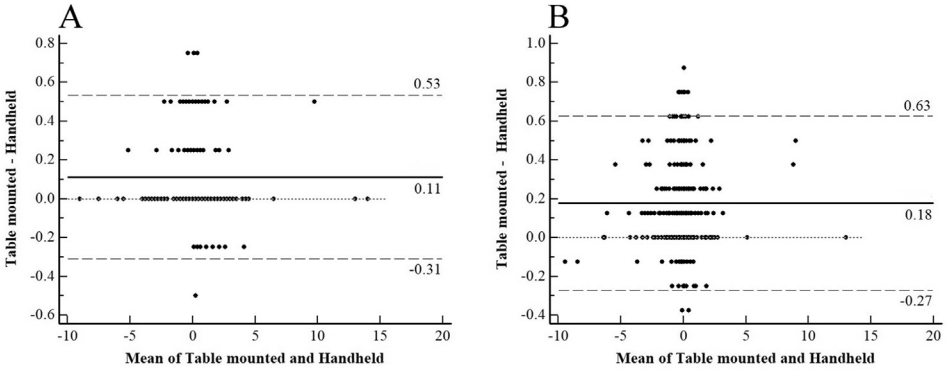

Fig. 2. Agreement between handheld and table-mounted auto-refractometers measurements of the spherical error and spherical equivalent (SE). The middle line indicates the mean difference, and the two dashed side lines show the 95% limits of agreement (LOA).

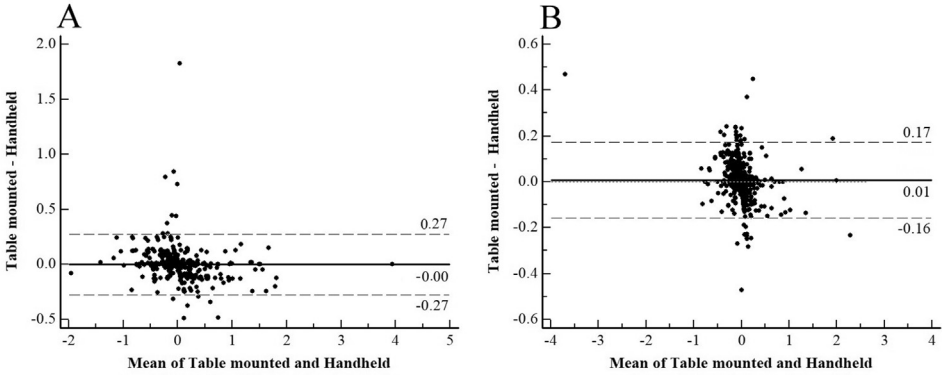

Fig. 3. Agreement between handheld and table-mounted auto-refractometers measurements of the J0 and J45 vectors. The middle line indicates the mean difference, and the two dashed side lines show the 95% limits of agreement (LOA).

reason for the difference could be using a different handheld device since Prabakaran et al. used the Retinomax handheld auto-refractometer.

However, it should be noted that the age range of previous studies was very limited, and only children were included in these studies. For example, the study by Prabakaran et al.[11]

was conducted in children 2–3 years, and the mean age of the participants was 10.03 years in a study by Arici et al.[24] This difference in the age range of different studies may be another reason for lack of consistency in their results. As mentioned earlier, the age range of the subjects was 3–90 years in our study, and the sample size included almost all age ranges from children to the elderly. It seems that the results of our study are more conclusive than previous reports due to its larger sample size and wider age range.

In another study, the SE measured by a handheld auto-refractometer (Retinoimax) was markedly more hyperopic than the SE measured by a Canon table-mounted auto-refractometer (Canon) before cycloplegia.[8]

Previous studies have compared the results of table-mounted auto-refractometers with the results of retinoscopy, Retinomax auto-refractometer, PlusOptix auto-refractometer, and other handheld auto-refractometers in children and young adults.[1,8,11,24,25] No study has been conducted to compare table-mounted and handheld auto-refractometers in older age groups. Measurement of refraction is also required in adults and older people because some people may not be able to sit as a result of old age or disease.

The results of spherical error and SE were very similar in individuals above 30 years of age, and there was more difference in participants below the age of 30 years, which could be due to accommodation,[8] indicating less accommodation control in the handheld device and overestimation of hyperopia in the table-mounted auto-refractometer. Consistent with our findings, Ceyhun also assessed the precision of Nidek ARK-30 handheld auto-refractometer in a population with a mean age of 10.03 ± 2.79 years and concluded that without cycloplegia, there was a myopic trend in the results of refractive errors due to accommodation in children.[14] However, our results may be more reliable considering the larger sample size and the wider age range of the participants.

We studied the difference in the spherical error between different age groups between the two devices and found the greatest difference was related to spherical error more than −2 D, which could be due to the higher possibility of error in myopia in handheld auto-refractometers. This difference is not clinically significant, and similar studies[26–28] have also reported more differences in myopic patients.[1,11,29]

Although there was a significant difference in the oblique vector of astigmatism between the two devices, the difference is not clinically important. Prabakaran also found no significant difference in the cylindrical power between the two devices,[11] and Ceyhun also failed to find a marked difference in J0 and J45 vectors.[24] Since there was a small difference in J45 in our study, its significance could be due to the large sample size and is not therefore clinically important. The small differences observed in age subgroups and spherical error categories were not statistically significant,[26–28] and the correlation of the two devices for J0 and J45 was markedly high. On the other hand, the 95% LOA was narrow for J0 and J45 measurements. Therefore, the results of the two devices could be interchangeably used for refractive assessment. In line with our findings, a similar study also reported a good agreement between a table-mounted and a handheld (Retinomax) auto-refractometer in assessment of astigmatic vectors.[8]

One of the limitations of this study was that the results of retinoscopy were not analyzed. In fact, if the data of these two devices were compared with the results of retinoscopy, more comprehensive information would have been obtained regarding the precision of these devices. It is recommended that the results of this handheld and auto refractometer and retinoscopy be compared in future studies.

In conclusion, although there was a statistically significant difference in J45, J0, SE, and spherical error findings between the two different auto-refractometers in this study, this difference may not be clinically significant. Considering the high correlation between the results of the two devices, narrow LOA, and portability of handheld auto-refractometers, handheld devices may be used instead of table-mounted auto-refractometers for measurement of refractive errors in screening programs, epidemiologic studies, and when a high speed is required, and also in children and disabled people who are not cooperative.

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