Comparison of Refractive Measures of Three Autorefractors in Children and Adolescents

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SIGNIFICANCE: Our study found a good agreement between three autorefractors. Not only will readers benefit as they can now compare data measured with either device in different studies but the three devices can be used in the same study to generate one pool of data, which can be analyzed together.

PURPOSE: The present study aims to evaluate the agreement of three commonly used autorefractors in children and adolescents, and the potential for their interchangeable application in a large-scale study.

METHODS: Participants from seven schools were enrolled using cluster sampling. Refractive errors were measured using the following three autorefractors under cycloplegic conditions in random sequence: Topcon KR-8900, Nidek ARK-510A, and Huvitz HRK-7000A. Refractive errors were compared in terms of spherical equivalent refraction (SER), cylinder power, and the J_0 and J_{45} by repeated-measures analysis of variance (RM-ANOVA) and Bland-Altman 95% limits of agreement (95% LoA).

RESULTS: A total of 2072 participants aged from 4 to 18 years were included. The mean ± SD and 95% LoA of the differences in SER between Topcon and Nidek, Topcon and Huvitz, and Nidek and Huvitz were 0.01 ± 0.24D (–0.46 to 0.48), –0.06 ± 0.31D (–0.66 to 0.54), and –0.07 ± 0.26D (–0.58 to 0.44), and those for the differences in cylinder power were –0.07 ± 0.26D (–0.57 to 0.44), 0.01 ± 0.32D (–0.63 to 0.64), and 0.07 ± 0.28D (–0.48 to 0.62), respectively (RM-ANOVA, $P < .001$). Further, the mean differences in J_0 and J_{45} between each refractor pair ranged from –0.03 to 0.01, and the 95% LoA were –0.78 to 0.74, –0.79 to 0.74, and –0.73 to 0.72 for J_0 and –0.86 to 0.87, –0.86 to 0.88, and –0.83 to 0.84 for J_{45}, respectively.

CONCLUSIONS: Our study will allow for use of these three autorefractors interchangeably in large screening studies.

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Refractive errors, and myopia in particular, have emerged as major public health concerns worldwide, especially in East and Southeast Asia.[1] Holden et al.[2] predicted that by 2050, nearly half of the world's population would have myopia if no effective interventions were identified. Although ordinary refractive errors can be easily corrected with glasses, contact lenses, or refractive surgery, uncorrected refractive errors are the primary cause of visual impairment worldwide (43%) because of the lack of screening and issues of availability and affordability of refractive correction, as recognized by the WHO.[3,4] Thus, there is a need for large-scale vision screening and for a method to accurately assess refractive errors.

Cycloplegic retinoscopy is the gold standard for measuring refractive errors, and noncycloplegic retinoscopy is clinically also commonly used.[5,6] However, retinoscopy is subject to measurement bias and intraobserver/interobserver variations, although experienced clinicians can provide reliable measurements.[7–9] Since the invention of automated refractors, such devices have been increasing in popularity in clinical practice, as well as in epidemiological research, particularly for large-scale vision screening in children.[10–13] Noncycloplegic autorefraction was shown to have a tendency toward minus overcorrection in school-age children resulting in overdiagnosis of myopia,[14,15] whereas cycloplegic autorefraction is potentially more sensitive than subjective refraction and was recommended to be a necessity for precise measurement of refractive errors, especially in hyperopic eyes and in pediatric cases.[16–18]

In some refractive studies, especially large-scale vision screening and longitudinal studies with long follow-up periods, usually more than one type of autorefractor was used.[19–21] The agreement among instruments must be clarified before directly comparing their measurements. However, few studies have been conducted to date assessing the agreement between different refractors. In Asia, autorefractors from Japan (Topcon and Nidek) and Korea (Huvitz) are commonly used. These three brands of table-mounted autorefractors have relatively high market share in China and also are the most commonly used in primary eye care. The present study aimed to compare refractive measurements obtained using KR-8900 (Topcon, Japan), ARK-510A (Nidek, Japan), and HRK-7000A (Huvitz, Korea) after induction of cycloplegia in a large group of children and adolescents ranging in age from 4 to 18 years.

METHODS

Setting and Participants

Children and adolescents aged 4 to 18 years from one kindergarten, two primary schools, and four secondary schools in Song

Jiang District, Shanghai, were enrolled in this study using cluster sampling. All of the children and adolescents were informed of the study protocol, and their parents or legal guardians signed written informed consent forms. The tenets of the Declaration of Helsinki were followed, and the Institutional Review Board of Shanghai General Hospital, Shanghai Jiao Tong University, approved the study. The survey sites were established within the child's education facility.

Research Methods

The children and adolescents were first examined using the visual acuity test with the retroilluminated tumbling E version of the Early Treatment Diabetic Retinopathy Study chart at a distance of 4 m as described in detail by Negrel et al.[22] Based on the following slit-lamp examination, any abnormalities found were recorded. Strabismus was detected by Hirschberg test and alternate prism cover test. Participants were also asked about their history of ocular surgery. Then, the children and adolescents with written informed consent for pupil dilation were subjected to a measurement of intraocular pressure, followed by pupil dilation, if they were considered eligible for cycloplegia. Cycloplegia was achieved by administration of one drop of topical 0.5% proparacaine (Alcaine; Alcon, Fort Worth, TX), followed by two drops of 1% cyclopentolate (Cyclogyl; Alcon), 5 minutes apart in each eye. Pupil size and light reflex were examined at 30 minutes after administration of the last drop of cyclopentolate, and if the pupil was dilated to 6 mm and the light reflex was absent, then cycloplegia was considered established.

The following three types of autorefractors (random sequence) were used to obtain the average of three consecutive refraction measurements for each eye: KR-8900, ARK-510A, and HRK-7000A. In advance to averaging three such measurements per instrument per child, the following criteria were applied to the single measured data for each child, to allow that child's data to enter the agreement part of the study: if any two measurements of one instrument for one specific child varied by more than 0.50 diopters (D), another set of three consecutive measurements were required until the variation between each two measurements within one set was less than 0.50D to avoid poor cooperation of children during their measurements. There were three trained optometrists who performed the autorefraction, and each optometrist solely operated one instrument. Autorefraction was performed in a random sequence by the three optometrists, and they were blind to the data of other optometrists. There was no analysis of consistency between instruments until data collection was complete. The specifications of the three instruments are almost identical, as shown in Table 1. Furthermore, subjective refraction and best-corrected visual acuity were determined in children and adolescents with an uncorrected visual acuity of 20/25 in either eye.

Twenty children were randomly selected to test inter-observer agreement. Two of the three optometrists repeated autorefractions with random sequence using Topcon KR-8900, and they were masked to each other's data. There was no significant difference between different observers for spherical equivalent refraction, cylinder power, and J_0 and J_{45} vector component (P = .437, .132, .202, and .098, respectively, using paired t-test or Wilcoxon rank-sum test for nonparametric data).

Statistical Analyses

A database was created using Epidata 3.1, and all data were doubly entered independently by two trained staff members. Statistical analyses were conducted using IBM SPSS statistics version 20.0 (IBM Co., Armonk, NY).

Children and adolescents with absent cycloplegic refraction data for any of the three autorefractors and those with amblyopia, strabismus, and previous ocular surgery were excluded. As the refractive errors of the two eyes were strongly correlated (Pearson's correlation coefficient = 0.937, 0.939, and 0.930 for Topcon, Nidek, and Huvitz, respectively), only the right eye data were used in statistical analysis.

The refraction data, sphere power (S), cylinder power (C), and axis (θ) measurements were converted into spherical equivalent refraction and Jackson cross-cylinder values (J_0 and J_{45}) as follows: spherical equivalent refraction = $S + C/2$, $J_0 = -(C/2)\cos 2\theta$, and $J_{45} = -(C/2)\sin 2\theta$.[23] Myopia was defined as spherical equivalent refraction –0.5D, hyperopia as spherical equivalent refraction 2.00D, and astigmatism as cylinder power –0.75D in the right eye.

The parameters were presented as the mean (standard deviation, SD) for continuous variables and as rates (proportions) for categorical data. Comparison of the mean values for the different refractors was conducted using repeated-measures analysis of variance (RM-ANOVA) by testing for sphericity. When the sphericity assumption was violated, the Greenhouse-Geisser test was used. The Bonferroni method was used to adjust for comparisons across these post hoc tests. Bland-Altman plots were generated to show the agreement between the autorefractors (Topcon vs. Nidek, Topcon vs. Huvitz, and Nidek vs. Huvitz).[24–26] The prevalence rates of myopia, hyperopia, and astigmatism for different instruments were compared using the χ^2 test to compare the

TABLE 1. Comparison of the specifications of the Topcon, Nidek, and Huvitz autorefractors

Specification	Topcon	Nidek	Huvitz
Sphere range	–25.00 to +22.00D	–30.00 to +25.00D	–25.00 to +22.00D
Cylinder range	–10.00 to +10.00D	–12.00 to +12.00D	–10.00 to +10.00D
Axis range	1° to 180°	0° to 180°	1° to 180°
Minimum power unit	0.12 or 0.25D	0.01, 0.12, or 0.25D	0.12 or 0.25D
Vertex distance	0, 12.0, 13.75 mm	12.0 mm	0, 12.0, 13.5, 15.0 mm
Minimum pupil diameter	2.0 mm	2.0 mm	2.0 mm
Accommodation control	Automatic fogging	Automatic fogging	Automatic fogging
Target	Color picture slide	Color picture slide	Color picture slide
Interpupillary distance measurement	85 mm or less	30 to 85 mm	10 to 85 mm

TABLE 2. Age groups of the children in this study

Age (yr)	N (%)	Male, n (%)
4–5	225 (10.9)	110 (48.9)
6–7	293 (14.1)	144 (49.1)
8–9	329 (15.9)	181 (55)
10–11	268 (12.9)	144 (53.7)
12–13	315 (15.2)	167 (53)
14–15	325 (15.7)	181 (55.7)
16–18	317 (15.3)	118 (37.2)

diagnostic ability of the respective instrument to detect refractive errors. Statistical significance was defined as $P < .05$ (two tailed).

RESULTS

General Characteristics

Among the 2178 children and adolescents who participated in this study, 23 were not eligible for induction of cycloplegia according to the diagnosis of the ophthalmologist, 59 had missing data for at least one of the three autorefractors, 22 were excluded for amblyopia, and another 2 were excluded for strabismus. Ultimately, a total of 2072 children and adolescents aged 4 to 18 years were enrolled in the study, with a mean (SD) age of 10.80 (3.89) years and 50.4% boys. The number of children and adolescents in each age group (grouped in 2-year increments) ranged from 225 to 329 (Table 2). The mean (SD) of spherical equivalent refraction, cylinder power, and the J_0 and J_{45} vector component obtained using the Topcon, Nidek, and Huvitz autorefractors are shown in Table 3. The p values of the repeated-measures ANOVA were <0.01 for the comparison of spherical equivalent refraction, cylinder power, and J_0 among the different refractors, whereas for J_{45}, the P value was .768.

Mean Differences, 95% Limits of Agreement, and Proportions within ±0.50D

As demonstrated in Table 4, the mean differences (SD) and 95% limits of agreement in spherical equivalent refraction between Topcon and Nidek, Topcon and Huvitz, and Nidek and Huvitz were 0.01 (0.24) D (95% limits of agreement –0.46 to 0.48), –0.06 (0.31) D (95% limits of agreement –0.66 to 0.54), and –0.07 (0.26) D (95% limits of agreement –0.58 to 0.44), respectively (Fig. 1). In addition, for cylinder power, the mean differences (SD) and 95% limits of agreement were –0.07 (0.26) D (95% limits of agreement –0.57 to 0.44), 0.01 (0.32) D (95% limits of agreement –0.63 to 0.64), and 0.07 (0.28) D (95% limits of agreement –0.48 to 0.62) (Fig. 2). For J_0 and J_{45}, the mean differences were smaller than those for cylinder power, ranging from –0.03 to 0.01; however, the 95% limits of agreement were greater (Topcon vs. Nidek, Topcon vs. Huvitz, and Nidek vs. Huvitz were –0.78 to 0.74, –0.79 to 0.74, and –0.73 to 0.72 for J_0 and –0.86 to 0.87, –0.86 to 0.88, and –0.83 to 0.84 for J_{45},

TABLE 3. Comparison of mean values of refractive measurements between instruments

	Topcon	Nidek	Huvitz	P Value*	P Value†	P Value‡	P Value§
SER, mean (SD) (range), D	–1.18 (2.59) (–11.875 to 9.125)	–1.19 (2.51) (–11.88 to 9.00)	–1.12 (2.56) (–11.90 to 10.00)	.044	<.001	<.001	<.001
Cylinder power, mean (SD) (range), D	–0.60 (0.61) (–5.00 to 0.00)	–0.53 (0.56) (–4.50 to 0.00)	–0.60 (0.56) (–5.00 to 0.00)	<.001	>.999	<.001	<.001
J_0, mean (SD) (range), D	–0.03 (0.27) (–2.10 to 2.05)	–0.01 (0.26) (–1.61 to 2.16)	–0.003 (0.28) (–2.27 to 1.21)	.026	.002	>.999	.002
J_{45}, mean (SD) (range), D	0.007 (0.33) (–2.40 to 2.40)	0.007 (0.28) (–2.04 to 1.93)	0.001 (0.30) (–1.92 to 1.73)	>.999	>.999	>.999	.768

SER = spherical equivalent refraction; SD = standard deviation.
*Topcon compared with Nidek; †Topcon compared with Huvitz; ‡Nidek compared with Huvitz; §total comparison.

TABLE 4. Differences in mean refractive components between instruments

	SER	Cylindrical Power	J_0	J_{45}
Topcon minus Nidek				
Mean (SD) of difference	0.01 (0.24)	–0.07 (0.26)	–0.02 (0.39)	0.00 (0.44)
95% LoA	–0.46 to 0.48	–0.57 to 0.44	–0.78 to 0.74	–0.86 to 0.87
Within ±0.50/±1.00D, %	98.0/99.6	98.0/99.7	88.4/96.9	84.9/96.2
Topcon minus Huvitz				
Mean (SD) of difference	–0.06 (0.31)	0.01 (0.32)	–0.03 (0.39)	0.01 (0.44)
95% LoA	–0.66 to 0.54	–0.63 to 0.64	–0.79 to 0.74	–0.86 to 0.88
Within ±0.50/±1.00D, %	93.8/99.0	96.2/99.1	86.1/97.0	84.8/96.2
Nidek minus Huvitz				
Mean (SD) of difference	–0.07 (0.26)	0.07 (0.28)	–0.01 (0.37)	0.01 (0.43)
95% LoA	–0.58 to 0.44	–0.48 to 0.62	–0.73 to 0.72	–0.83 to 0.84
Within ±0.50/±1.00D, %	96.5/99.2	97.1/99.2	87.1/97.0	87.6/96.1

SER = spherical equivalent refraction; SD = standard deviation; LoA = limits of agreement.

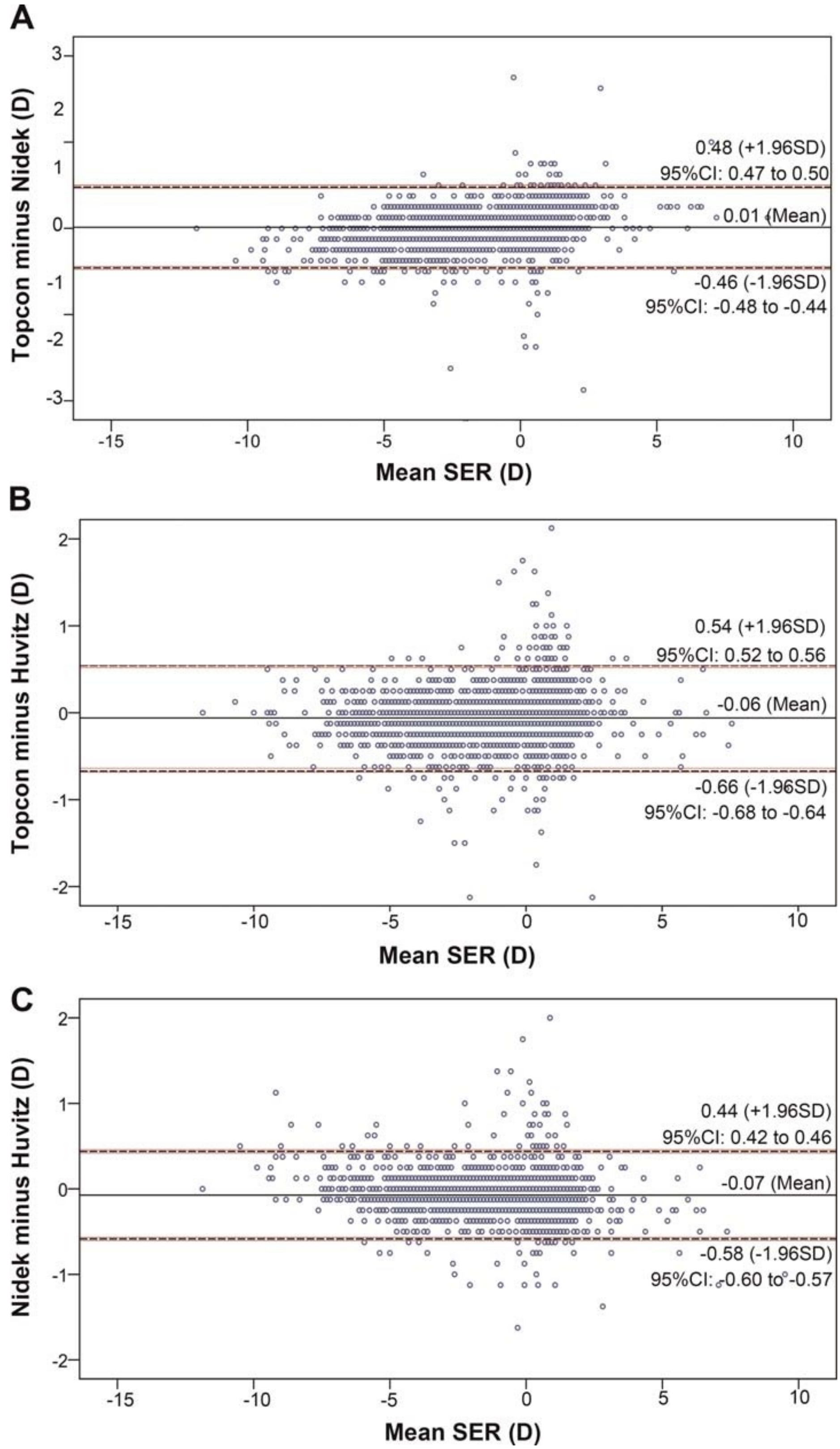

FIGURE 1. Bland-Altman plots of the differences in SER between Topcon and Nidek (A), Topcon and Huvitz (B), and Nidek and Huvitz (C). Solid reference lines indicate the mean and dashed lines depict the corresponding 95% limit of agreement (LoA); solid red lines display the 95% confidence interval (CI) of the LoA.[23,24] SER indicates spherical equivalent refraction.

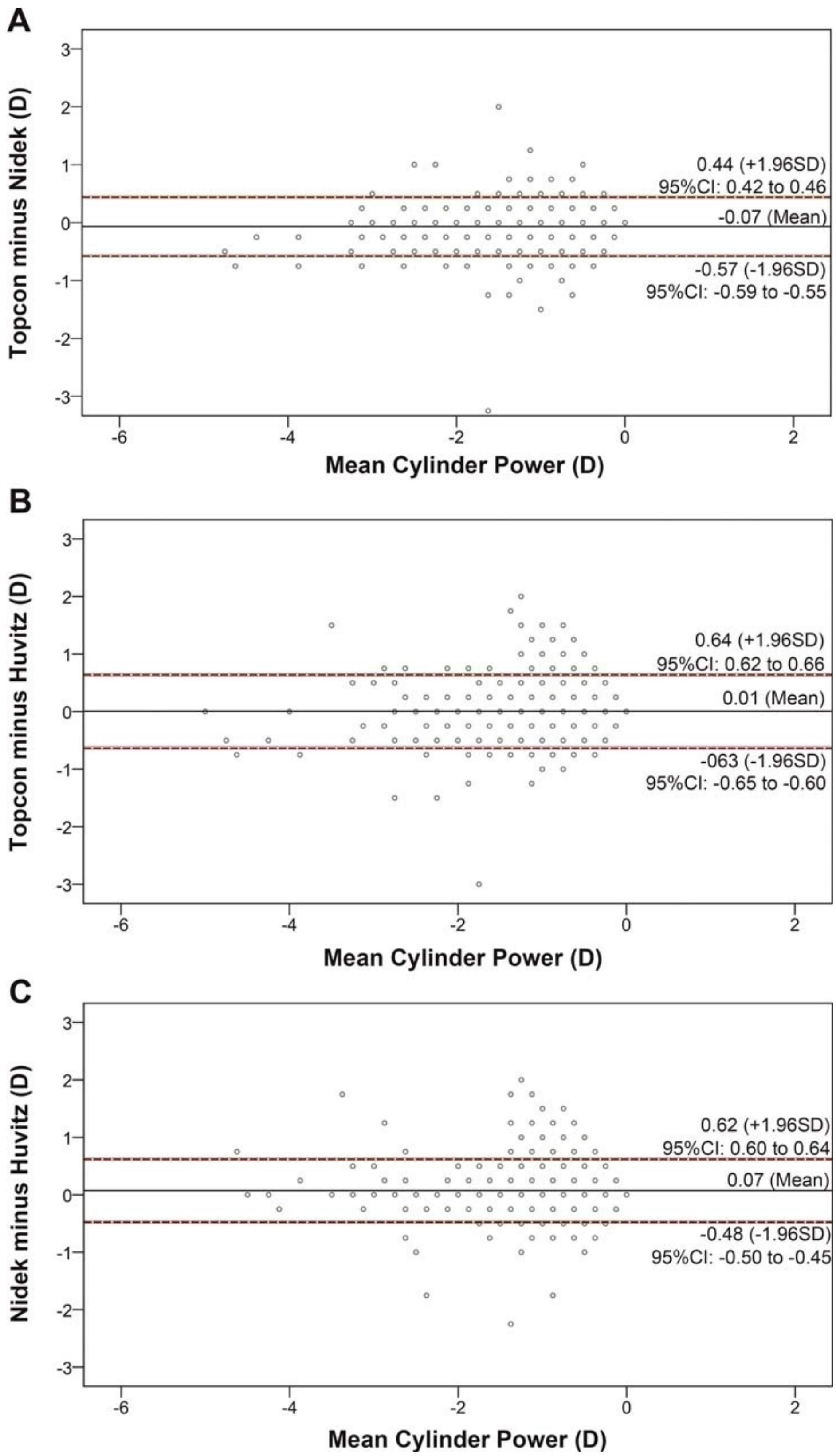

FIGURE 2. Bland-Altman plots of the differences in cylinder power between Topcon and Nidek (A), Topcon and Huvitz (B), and Nidek and Huvitz (C). Solid reference lines indicate the mean and dashed lines depict the corresponding 95% limit of agreement (LoA); solid red lines display the 95% confidence interval (CI) of the LoA.[23,24]

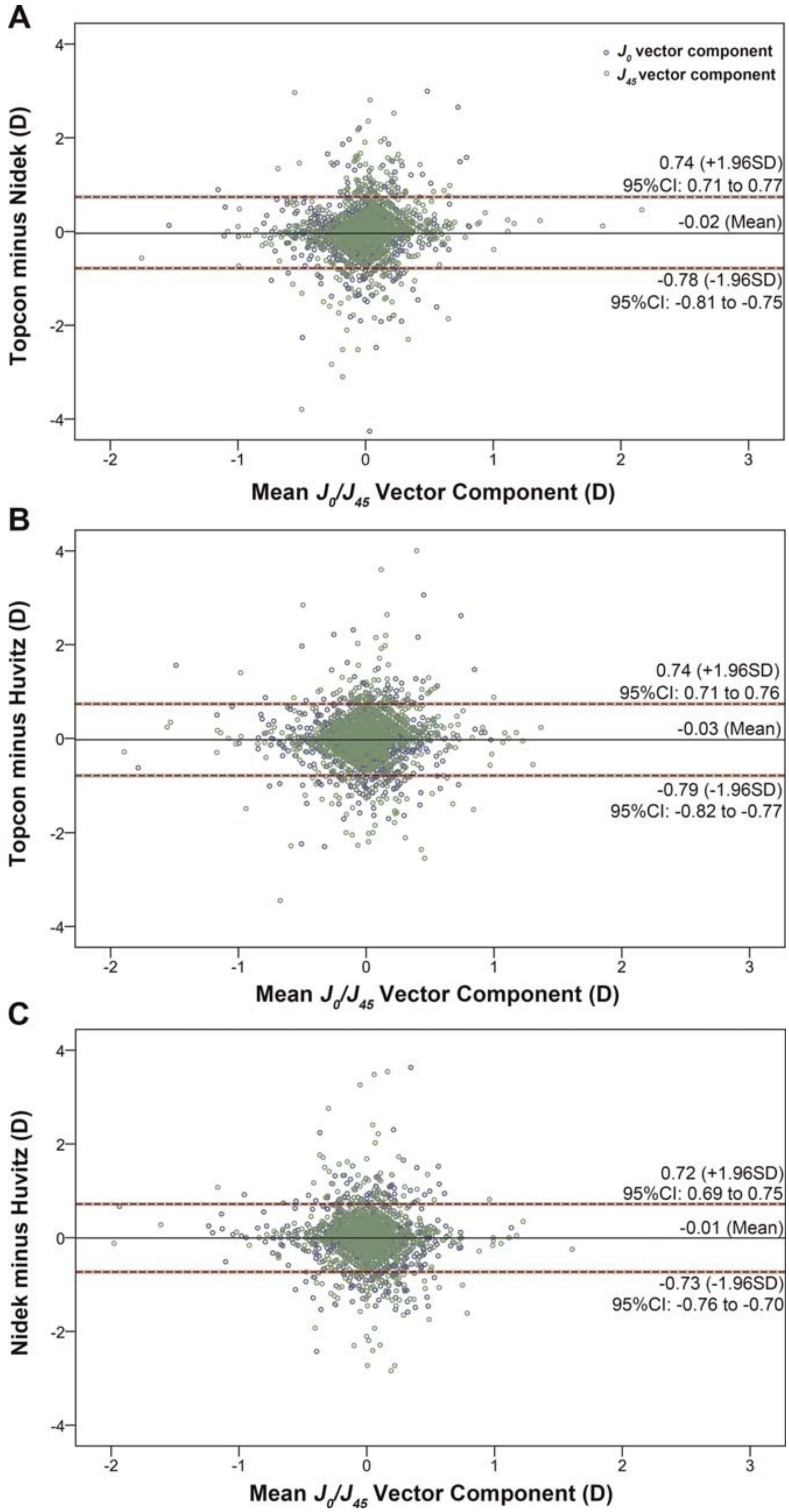

FIGURE 3. Bland-Altman plots of the differences in the J_0 and J_{45} vector components between Topcon and Nidek (A), Topcon and Huvitz (B), and Nidek and Huvitz (C). Solid reference lines indicate the mean of the J_0 vector and dashed lines depict the corresponding 95% limit of agreement (LoA); solid red lines display the 95% confidence interval (CI) of the LoA.[23,24] The mean bias and 95% limits of agreement of the J_{45} vector were similar.

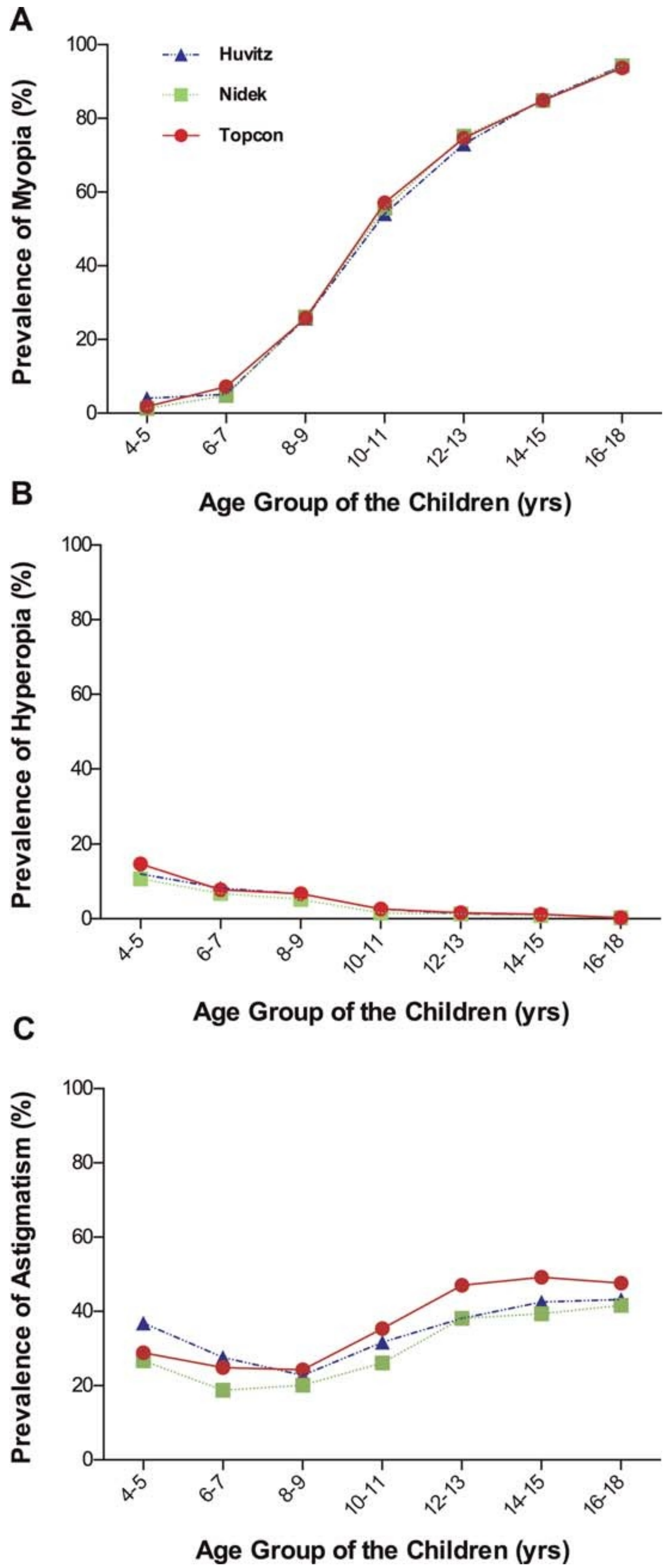

FIGURE 4. Prevalence rates of myopia (A), hyperopia (B), and astigmatism (C) in the different age groups, as measured using the three autorefractors.

respectively) (Fig. 3). The 95% confidence interval of upper and lower limits of agreement for spherical equivalent, cylinder power, and J_0 and J_{45} vector component were demonstrated in Figs. 1 to 3.

The proportions of the absolute differences within ±0.50D in spherical equivalent refraction were 98.0, 93.8, and 96.5% for Topcon vs. Nidek, Topcon vs. Huvitz, and Nidek vs. Huvitz, respectively, and for cylinder power, the proportions were 98.0, 96.2, and 97.1%. For J_0 and J_{45}, the proportions were less than those for spherical equivalent refraction and cylinder power, ranging from 84.8 to 88.4%. Topcon and Nidek showed the greatest agreement within ±0.50D for spherical equivalent refraction, cylinder power, and the J_0 vector component (Table 4).

Agreement in Prevalence Rates

Prevalence rates presented here were used as another measure of comparison, but not to reflect the prevalence rates of the population in our city or the examined ethnicity. The prevalence rates of myopia in the examined population calculated using Topcon, Nidek, and Huvitz were 51.7, 51.4, and 51.2%, respectively, and those of hyperopia were 34.6, 33.2, and 35.1% (χ^2 test, $P > .05$ for all age groups; Fig. 4A and B). However, the differences in the prevalence rates of astigmatism were significant for the age groups of 4–5, 6–7, 12–13, and 14–15 years (28.9, 26.8, and 36.9% for 4–5 years; 24.9, 18.8, and 27.6% for 6–7 years; 47.0, 38.1, and 38.1% for 12–13 years; and 49.2, 39.4, and 42.5% for 14–15 years, obtained by Topcon, Nidek, and Huvitz, respectively; χ^2 test, P = .047, .035, .032, and .035, respectively) (Fig. 4C).

DISCUSSION

This study demonstrated that the differences in spherical equivalent refraction and cylinder power measured using the three autorefractors (Topcon KR-8900, Nidek ARK-510A, and Huvitz HRK-7000A) were acceptable for a large-scale study or for the screening of children and adolescents aged 4 to 18 years. In addition, these autorefractors showed good agreement in analysis of the prevalence rates of myopia and hyperopia, whereas their agreement was less satisfactory in analyses of the axis and the prevalence of astigmatism. Similar performances of Topcon KR-8000 and Nidek ARK-700K have been reported in a previous study conducted by Pesudovs et al.[27] That study reported a difference of 0.14D in spherical equivalent refraction between the two autorefractors, which is greater than the difference of 0.01D calculated in our study. Measurements were performed using the two autorefractors on subjects in two age-, gender-, and spherical equivalent refraction-matched groups, separately, but not repeated measures of subjects within a single group, which might explain the greater difference in spherical equivalent refraction than that observed in the present study.

The proportions of the differences within ±0.50D in spherical equivalent refraction and cylinder power between each pair of autorefractors were at least 96%, with the exception of the difference in spherical equivalent refraction between Topcon and Huvitz, for which the proportion was 93.8%. The 95% limits of agreement of them were close to ±0.50D, demonstrating that the differences among the refractors could be ignored, although they were statistically significant. These results suggest that the differences in spherical equivalent refraction and cylinder power measurements are acceptable for the use of the three autorefractors interchangeably in a large-scale study or for vision screening because of the limit of the instruments' resources or very short work cycles. However, the use of the same instrument or the same brand of instruments for research is still encouraged if resources and time allow.

The agreement for the J_0 and J_{45} vector components measured using the three refractors was relatively poorer than that for spherical equivalent refraction and cylinder power; the proportion of children and adolescents with differences within ±0.5D in these vector components was decreased by approximately 10%. Positive J_0 values represent with-the-rule astigmatism, and negative values correspond to against-the-rule astigmatism, and J_{45} represents oblique astigmatism. Thus, the better agreement of cylinder power and the relatively poorer agreement of the J_0 and J_{45} vector components implied discrepancies in axis detection but not in the power of astigmatism using the three refractors. These findings might have occurred because of the relatively poor repeatability and reliability of the axis measurements performed using the autorefractors, especially among subjects with a cylinder power of −0.75D or more.[28,29]

The diagnostic ability of refractive errors is of the same importance as that of specific refractive measurements in epidemiological studies. In the present study, the prevalence rates of myopia and hyperopia based on spherical equivalent refraction were similar among different age groups, whereas significant differences in the prevalence rate of astigmatism based on cylinder power were detected. Therefore, caution should be taken when using these three autorefractors in the same study when the prevalence of astigmatism is being investigated.

Our study has several limitations. First, the validity and the repeatability of each instrument, which is of great importance to autorefractor performance, were not assessed in this study. However, the present study focused mainly on the consistency between different autorefractors. The reliability and repeatability of the current version of Huvitz[30] and the early versions of Topcon and Nidek[31–34] had been previously published, and the current versions have been widely used in epidemiological studies to assess the prevalence of refractive errors as well as their progression.[35–40] Second, this study only assessed three types of autorefractors; therefore, the findings cannot be applied to other brands of autorefractors or newer technologies based on wavefront-based techniques. Third, our findings may only be applicable to the Chinese children and adolescents aged 4 to 18 years but not those in other age groups or of other ethnicities. Another limitation is the lack of a comparison subjective refraction. However, previous studies had suggested a good agreement between cycloplegic autorefraction and subjective refraction (95% limits of agreement: −0.4 to 2.0 of Topcon KR-8000, −1.18 to 0.71 of Allergan Humphrey, and −0.68 to 0.41 of Nidek AR-1000),[27,41] and the autorefractors compared in the present study were mainly applied in vision screening or progressive study, but not for the purpose of prescribing spectacles.

In conclusion, the differences in spherical equivalent refraction and cylinder power measured using the three autorefractors were clinically acceptable in the children and adolescents aged 4 to 18 years. Thus, it is reasonable to use these instruments interchangeably in the same large-scale study or in screening for the detection of refractive error and determination of the prevalence rates of myopia and hyperopia, as well as the progression of spherical equivalent refraction and cylinder power; however, caution should be taken when using these autorefractors for the assessment of the axis and prevalence of astigmatism.

The current focus of screening for refractive error has therefore gained an important tool. Not only will readers benefit as they can now compare data measured with either device in different studies (if other criteria are comparable) but the three devices can be used in the same study to generate one pool of data, which can be analyzed together.

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