Original Article

Repeatability of ARK-30 in a pediatric population

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Purpose: To determine repeatability and agreement of the ARK-30 handheld autorefractor with retinoscopy under cycloplegic and noncycloplegic conditions in children. **Methods:** Three consecutive autorefractor measurements (with and without cycloplegia) and retinoscopy were performed and compared in 30 randomized eyes of 30 children (mean age of 6.7 ± 2.7 years with spherical equivalent [SE] refraction from –4.01 to +7.38 D) in a cross-section and masked study. Bland–Altman analysis of autorefractor measurements (with and without cycloplegia) and agreement with retinoscopy were calculated with conventional notation (sphere [Sph] and cylinder [Cyl]) and vector notation (SE, J_0, and J_{45} coefficients). **Results:** ARK-30 measurements without cycloplegia were lower than under cycloplegic conditions (Sph: –0.52 ± 2.37 D vs + 0.86 ± 2.60 D, P < 0.01; Cyl: –0.83 ± 0.80 D versus –0.78 ± 0.77 D, P = 0.37; and SE: –0.94 ± 2.19 D vs + 0.47 ± 2.44 D, P < 0.01, respectively) and statistically different (P < 0.03) from retinoscopy (Shp: +0.83 ± 2.66 D; Cyl: –0.71 ± 0.87 D; SE: +0.51 ± 2.49 D). Without statistical differences were in J_0 and J_{45} coefficients. Cyloplegic autorefraction measures were not found to be statistically significantly different to retinoscopy measures. ARK-30 under cycloplegia shows better repeatability with lower limits of agreement (LoA) in Sph (LoA: –0.66 to +0.69 D), and SE (LoA: –0.66 to +0.65 D) than without cycloplegia (LoA: –1.45 to +1.77 D, and –1.38 to +1.74 D, respectively). **Conclusion:** Under noncycloplegic conditions, ARK-30 autorefractor has low repeatability and a tendency toward minus over correction in children. However, repeatability and agreement with retinoscopy under cycloplegic conditions allow use of ARK-30 in children to estimate refraction but not to substitute gold standard retinoscopic refraction.

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Objective refraction, including retinoscopy and autorefraction, plays a crucial role to identify and correct refractive errors in children, helping to prevent and reduce the risk of amblyopia. Autorefraction has demonstrated the ability to give quick, repeatable, and accurate readings of refractive error in children without examiner bias.[1,2] Nevertheless, for some instruments, pseudomyopia caused by accommodation and inadequate autofogging mechanisms have been reported.[3-5] Other factors such as fixation instabilities,[6] small pupils,[7] and media changes[8] can increase autorefractor variability in all subjects regardless of age. Therefore, retinoscopy, with and without cycloplegic is a necessary test in pediatric patients' eye exam.[9,10]

Portable or handheld autorefractors have been proposed to improve pediatric patients' objective refraction and have been compared to table-mounted autorefractors, video-refraction, and retinoscopy.[2,9,11] ARK-30 handheld autorrefractor (Nidek Co. LTD, Aichi, Japan) is a portable autorefractor demonstrating good results after cataract surgery.[12] However, there are no previous reports that support its use in children population.

The aims of this study were (1) evaluate the repeatability of the ARK-30 handheld autorefractor under cycloplegic and noncycloplegic conditions and (2) determine the agreement between this instrument with retinoscopy in a pediatric sample.

Methods

Study population

This was a cross-section and masked study. A baseline eye examination was performed on all subjects comprising visual acuity assessment, objective refraction techniques (with and without cycloplegia), binocular balancing, slit-lamp examination, and direct and indirect ophthalmoscopy. Subjects were excluded if they had significant pathology that could influence objective measurement of refraction such as congenital cataract or corneal leukomas affecting the visual axis. In order to achieve adequate cycloplegia autorefraction measures were conducted 30 min after the instillation the

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last drop of cyclopentolate hydrochloride 1% (Colircusi Cicloplejico, ALCON CUSI, Spain). Two drops in 10 min were administrated in the inferior cul de sac.

Written-informed consent was obtained from parents of each subject after approval of this study by the Human Sciences Ethics Committee of the University of Valladolid. All subjects were treated in accordance with the Declaration of Helsinki.

Refraction measures

The ARK-30 (Nidek Co. LTD, Aichi, Japan) is a portable autorefractor with a measurement range of –20.00 to +22.00 D for sphere and 12.00 D for cylinder. All subjects underwent autorefraction using the normal mode with the fogging mechanism activated to avoid instrument myopia or accommodation and to obtain a result comparable to a 6-m subjective refraction. In this mode, the "autoshot" facility permitted automated serial measurements when the instrument was in focus. Moreover, even ARK-30 autorefractor allows faster refractive power measurements (around 0.2 s); a minimum of child's collaboration that must look to device's target is required to achieve the autorefraction.

One trained optometrist performed three consecutive "autoshot" measurements in normal mode on each eye. The mean of these measurements was used as the final value for comparison to retinoscopy outcome. To avoid bias related with the use of both eyes of the same patient, data of one eye were randomized chosen to conduct the statistical comparisons.

To maintain masking, a different trained optometrist conducted cycloplegic retinoscopy (Heine Beta 200, Heine Optotechnik, Herrsching, Germany) and subjective refraction, when cooperation permitted.

Assessing the variance in the astigmatism poses a problem in the conventional clinical notation (e.g. –3.25 × 20 degrees). Therefore, the sphere, cylinder, and axis components were converted into a vector representation[13] with the coefficients M, J_0, and J_{45} where M was the spherical equivalentlens of power equal to the mean spherical equivalence (M = sphere + [cylinder/2]), J_0 was the Jackson cross-cylinder at axis 0° (J_0= –[cylinder/2] cos[2 × axis]), and J_{45} was the Jackson cross-cylinder at axis 45° (J_{45}= –[cylinder/2] sin[2 × axis]).

Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS for Windows software, version 22.0, SPSS, Inc., Chicago, IL, USA). Normal distribution of variables was assessed using the Kolmogorov–Smirnov test (*P* values < 0.05 indicated that the data were not normally distributed). Results were presented as means ± standard deviation (SD), and 95% confidence interval (CI 95%).

Repeatability is the variation in measurements taken by the same operator with the same instrument on the same subject and under the same conditions, between multiple testings. The repeatability of ARK-30 was evaluated by obtaining three automated refraction measurements under cycloplegic and noncycloplegic conditions. The intraclass correlation coefficient (ICC) was calculated. The differences between each of the three test readings were averaged to determine the mean difference for sphere, cylinder, spherical equivalent, and the coefficients J_0 and J_{45} with and without cycloplegia. Repeated analysis of variance (ANOVA) was used to detect differences between the three measures.

The difference between automated refraction with and without cycloplegia was assessed using Bland–Altman analysis.[14] The degree of agreement between automated refraction (with and without cycloplegia) and cycloplegic retinoscopy was, also, evaluated using Bland–Altman analysis.[14] The differences between two measurements were plotted against the averages. Limits of agreement were calculated (mean ± 1.96 SD). Significant differences were tested with Wilcoxon rank test. For all comparisons, *P* values of <0.05 were considered statistically significant. The relationship between mean value (x) and the difference (y) was determined using linear regression analyses, r^2 correlation coefficient was calculated to test-retest reliability (*P* values of <0.05 were considered statistically significant).

Results

The study comprised 30 randomized eyes (14 OD and 16 OS) of 30 children (18 boys, 12 girls) with a mean age of 6.7 ± 2.7 years (range: 3–13 years) with a mean spherical equivalent refraction (ARK-30 with cycloplegia) of –0.47 ± 2.44 D; (range: –4.01 D to +7.38 D). Table 1 summarizes ARK-30 autorefraction (with and without cycloplegia) and cycloplegic retinoscopy results (sphere, cylinder, spherical equivalent, and J_0 and J_{45} coefficients).

Repeatability of ARK-30 refraction

ARK-30 provided lower repeatable refraction measurements of sphere, cylinder, spherical equivalent, and J_0 and J_{45} coefficients

Table 1: Summary of the ARK-30 refraction without and under cycloplegia and retinoscopy

	Sph (D)	Cyl (D)	SE (D)	J_0 (D)	J_{45} (D)
ARK-30	−0.52±2.37	−0.84±0.80	−0.94±2.19	−0.03±0.28	+0.01±0.51
(without cycloplegia)	(−4.25 to+7.75)	(−3.50 to 0.00)	(−4.50 to+7.06)	(−0.99 to+0.69)	(−1.73 to+1.54)
ARK-30	+0.86±2.60	−0.78±0.78	−0.47±2.44	+0.03±0.32	−0.03±0.45
(with cycloplegia)	(−3.75 to+8.00)	(−3.75 to 0.00)	(−4.01 to+7.38)	(−1.12 to+0.85)	(−1.79 to+1.26)
*P**	*P*<0.01	*P*=0.37	*P*<0.01	*P*=0.70	*P*=0.65
Retinoscopy	+0.85±2.66	−0.71±0.87	−0.51±2.49	−0.13±0.31	−0.14±0.42
(with cycloplegia)	(−3.25 to+9.50)	(−3.25 to 0.00)	(−3.30. to+8.90)	(−1.08 to+0.40)	(−1.08 to+1.21)
*P***	*P*<0.01	*P*=0.03	*P*<0.01	*P*=0.21	*P*=0.22
*P****	*P*=0.46	*P*=0.14	*P*=0.38	*P*=0.22	*P*=0.08

Mean±standard deviation (minimum and maximum) value are presented. **P* comparing ARK-30 without and with cycloplegia. ***P* comparing retinoscopy with ARK-30 without cycloplegia. ****P* comparing retinoscopy with ARK-30 under cycloplegia without cycloplegia than those achieved under cycloplegic conditions [Table 2].

ARK-30 showed a tendency toward negative results when is used under noncycloplegic conditions [Fig. 1] with a mean difference of –1.38 ± 1.19 D, LoA: –3.72 to +0.96 D, ($P < 0.01$); ICC = 0.950; $r^2 = 0.04$, ($P = 0.06$) for sphere; a difference of –0.06 ± 0.36 D, LoA: –0.76 to + 0.64 D, ($P = 0.37$); ICC = 0.974; $r^2 = 0.01$, ($P = 0.47$) for cylinder; a difference of –1.41 ± 1.18 D, LoA: –3.71 to +0.90 D, ($P < 0.01$); ICC = 0.943; $r^2 = 0.05$, ($P = 0.04$) for spherical equivalence; a difference of –0.06 ± 0.46 D, LoA: –0.95 to +0.84 D, ($P = 0.70$); ICC = 0.515; $r^2 = 0.02$, ($P = 0.20$) for J_0 coefficient, and a difference of + 0.04 ± 0.56 D, LoA: –1.05 to +1.13 D, ($P = 0.65$); ICC = –0.147; $r^2 = 0.02$, ($P = 0.19$) for J_{45} coefficient.

Agreement of ARK-30 automated refraction with retinoscopy

The differences between retinoscopy and ARK-30 (without cycloplegia) showed worse agreement and statistically significant differences in sphere (+1.37 ± 1.00 D, $P < 0.01$), cylinder (+0.15 ± 0.32 D, $P = 0.03$), and spherical equivalent (+1.45 ± 0.99 D, $P < 0.01$) [Table 3]. However, J_0 and J_{45} coefficients showed nonstatistically significant differences. There were no apparent trends in the difference variabilities as a function of the mean values. The range of difference was from –0.50 (3.3%) to + 3.25 D (10%) in sphere and from –0.50 D (6.7%) to + 1.00 D (3.3%) in cylinder [Fig. 2].

However, nonstatistically significant differences were found between retinoscopy and ARK-30 conducted under cycloplegia ($P > 0.49$) [Table 3]. The range of difference was

Table 2: Summary of the ARK-30 repeatability refraction without and under cycloplegia

	Mean±SD	LoA (P)	ICC	r^2 (P)
Repeatability of ARK-30 (without cycloplegia)				
Sphere (D)	−0.16±0.82 (P=0.90)	−1.45 to+1.77	0.980	r^2=0.01 (P=0.33)
Cylinder (D)	−0.03±0.29 (P=0.94)	−0.54 to+0.59,	0.978	r^2=0.01 (P=0.35)
Spherical equivalent (D)	+0.18±0.80 (P=0.88)	−1.38 to+1.74	0.977	r^2=0.03 (P=0.12)
J_0 (D)	−0.01±0.30 (P=0.92)	−0.60 to+0.59	0.678	r^2=0.03 (P=0.11)
J_{45} (D)	+0.05±0.74 (P=0.74)	−1.40 to+1.51	0.215	r^2<0.01 (P=0.39)
Repeatability of ARK-30 (under cycloplegia)				
Sphere (D)	−0.01±0.34 (P=0.99)	−0.66 to+0.69	0.997	r^2<0.01 (P=0.52)
Cylinder (D)	−0.03±0.37 (P=0.96)	−0.76 to+0.70	0.958	r^2=0.02 (P=0.16)
Spherical equivalent (D)	−0.01±0.33 (P=1.00)	−0.66 to+0.65	0.997	r^2<0.01 (P=0.73)
J_0 (D)	+0.09±0.48 (P=0.25)	−0.85 to+1.02	0.703	r^2=0.03 (P=0.09)
J_{45} (D)	+0.09±0.60 (P=0.49)	−1.09 to+1.28	0.185	r^2<0.01 (P=0.99)

Mean difference±standard deviation; limits of agreement (LoA), intraclass correlation coefficient (ICC), and r^2 coefficient value are presented

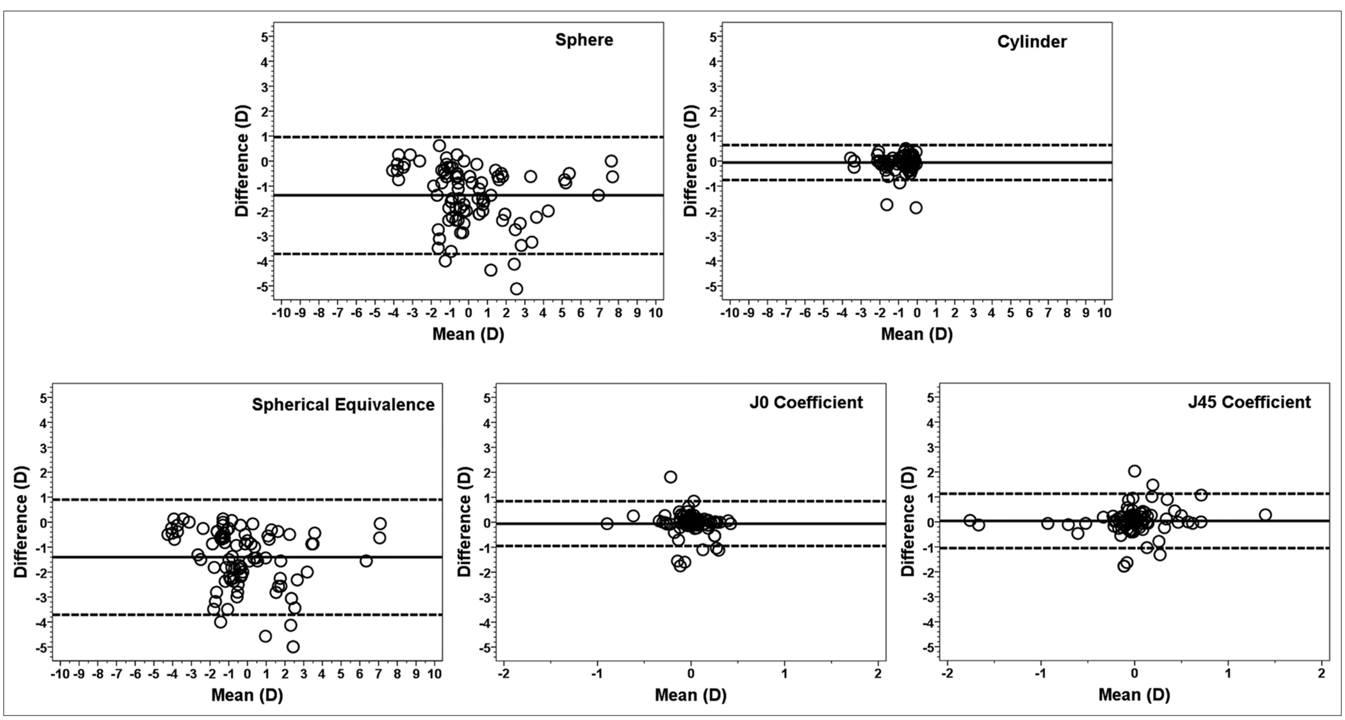

Figure 1: Bland–Altman plot comparing the difference between ARK-30 measurements collected under cycloplegic and under noncycloplegic conditions. Mean difference (continuous line) and limits of agreement (discontinuous line) were plotted to sphere (top-left), cylinder (top-right), spherical equivalence (bottom left), and J_0 (bottom center) and J_{45} (bottom right) refraction coefficients

Table 3: Summary of the agreement between ARK-30 autorefraction and retinoscopy, without and under cycloplegia

	Mean±SD	LoA	ICC	r^2 (P)
Differences between ARK-30 and retinoscopy (without cycloplegia)				
Sphere (D)	+1.37±1.00 (P<0.01)	−0.60 to+3.34	0.958	r^2=0.10 (P=0.09)
Cylinder (D)	+0.15±0.32 (P=0.03)	−0.48 to+0.78	0.961	r^2=0.03 (P=0.19)
Spherical equivalent (D)	+1.45±0.99 (P<0.01)	−0.50 to+3.39	0.953	r^2=0.01 (P=0.07)
J_0 (D)	−0.10±0.33 (P=0.21)	−0.75 to+0.56	0.358	r^2=0.11 (P=0.07)
J_{45} (D)	+0.14±0.55 (P=0.22)	−0.94 to+1.23	0.517	r^2=0.16 (P=0.03)
Differences between ARK-30 and retinoscopy (under cycloplegia)				
Sphere (D)	−0.01±0.86 (P=0.46)	−1.69 to+1.68	0.973	r^2<0.01 (P=0.81)
Cylinder (D)	+0.09±0.35 (P=0.14)	−0.59 to+0.78	0.953	r^2=0.12 (P=0.06)
Spherical equivalent (D)	+0.04±0.86 (P=0.38)	−1.65 to+1.73	0.969	r^2<0.01 (P=0.84)
J_0 (D)	−0.15±0.39 (P=0.22)	−0.91 to+0.60	0.755	r^2=0.40 (P<0.01)
J_{45} (D)	+0.18±0.54 (P=0.08)	−0.87 to+1.23	0.318	r^2=0.16 (P=0.03)

Mean difference±standard deviation; limits of agreement (LoA), intraclass correlation coefficient (ICC) and r^2 coefficient value are presented

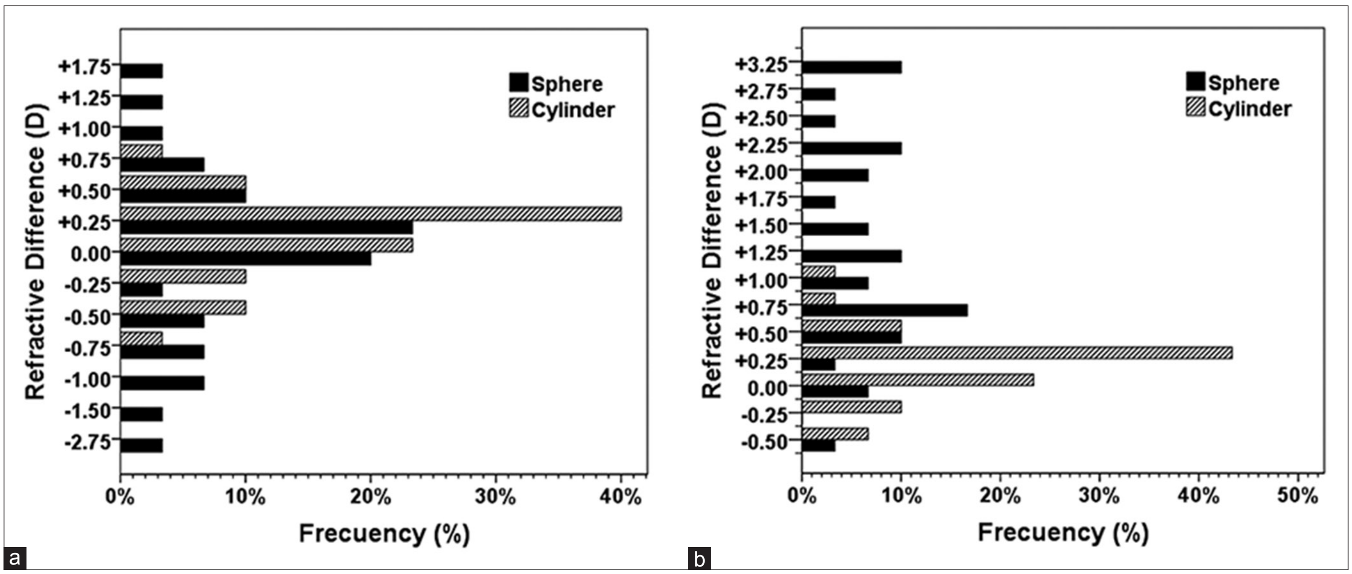

Figure 2: Frequency of difference between the retinoscopy and ARK-30 under (a) and without (b) cycloplegia for sphere and cylinder. Positive differences mean than ARK-30 shows a higher myopic value

from –2.75 (3.3%) to + 1.75 D (3.3%) in sphere and from –0.75 D (3.3%) to +0.75 D (3.3%) in cylinder [Fig. 2]. There were no apparent trends in the difference variabilities as a function of the mean values.

Discussion

Noncycloplegic autorefraction is a popular technique widely used to know the objective refractive status in children, conducted in several situations like vision screening, clinical practice, or in research settings, for example, in epidemiologic studies, clinical trials or others.[10]

The validity and repeatability of autorefraction have been widely studied in different populations: children,[9-11,15-18] youth,[6,19] and adults,[4,5,20-24] using several devices.[25] However, to the best of our knowledge, this is the first report about the clinical application of the portable ARK-30 autorefractor in pediatric population (between 3 and 13 years old).

Our results are consistent with data from previous studies.[3-5,11,20-23] We found high repeatability in sphere, cylinder, spherical equivalent, and J_0 and J_{45} coefficients under cycloplegic and noncycloplegic conditions, with slightly better repeatability (lower limits of agreement [LoA]) when autorefraction was conducted under cycloplegia [Table 2].[9,17]

We found good agreement between ARK-30 results under cycloplegic conditions and cycloplegic retinoscopy. Retinoscopy and subjective refraction are the gold standard in pediatric population assessments;[10,11] however, good trained practitioner is required to achieve reliable retinoscopy results.[24] We found autorefractor values for sphere and spherical equivalent more negative (mean of 1.37 ± 1.00 D [P < 0.01] and 1.45 ± 0.99 D [P < 0.01], respectively [Table 3]) than cycloplegic retinoscopy (hyperopic underestimation or tendency toward myopic overcorrection), similar to previous reports.[9,10,11,19] Differences are minimized when autorefraction was conducted under cycloplegia in sphere and spherical equivalent results (–0.01 ± 0.86 D [P = 0.46] and + 0.04 ± 0.86 D [P = 0.38], respectively [Table 3]). Our results agree with previous reports that suggest than autorefractors without cycloplegia do not avoid accommodation; showing over-negative refractive outcome.[10,11,15,17,19] Harvey *et al*.[9] concluded that autorefraction (Nikon Retinomax) is reproducible and reliable in young children under cycloplegia as our results supports.[10]

Our results improve previous reports of other handheld autorefractometers in children. Suryakumar and Bobier[15] found a larger difference in comparison to retinoscopy refraction with a difference of + 0.37 ± 0.45 D under cycloplegic conditions and a difference of –1.15 ± 1.47 D without cycloplegia, in a child population (3–5 years) using three different devices (Retinomax K plus; Welch Allyn SureSight, and Power Refractor). Wesemann and Dick[17] reported a negative overcorrection higher of 2.0 D in almost one in four children between the age of 2 and 12 years when cycloplegia was not used, similar to the results of the present study. However, under cycloplegia we did not find any case with a negative overcorrection higher of 1.75 D [Fig. 2].

Other studies, using different models of autorefractors, showed the same tendency of the autorefraction to underestimate refractive error relative to retinoscopy and subjective refraction.[4,5,21] Farook *et al*.[4] find 0.75 D over minus result with –2.20 to + 0.70 limits of agreement of Retinomax handheld autorefractor, compared with subjective refraction in an adults population (between 21 and 40 years). Zadnik *et al*.[24] and Rosenfield *et al*.[26] concluded than autorefractor (Canon R-1 autorefraction) is a valuable tool in adult refractive testing, having good correlation with values obtained after subjective refraction.

Autorefraction is not an accepted substitute for prescribing spectacles,[27] because refraction and prescribing are different concepts,[12] so autorefraction should not be perceived as substitute for the gold standard retinoscopic refraction. Binocular balancing, measurement of oculomotor coordination and accommodation assessment, are some aspects covered with subjective refraction that autorefraction cannot evaluate. However, our results suggest that the ARK-30 handheld autorefractor serves as a good tool to approximate children's refractive error. Furthermore, the differences between measures with and without cycloplegia,[28] suggest than noncycloplegic measurements must be interpreted with caution and cycloplegia is highly recommended to achieve reliable autorefraction in children. A subjective measure of refraction, where possible, dependent on age and cooperation, is also important to consider prior to prescribing a spectacle correction in children. The results of this study showed that the ARK-30 is as quick, accurate, and repeatable as other autorefractors currently available under noncycloplegic conditions,[3,21] improving their results under cycloplegia, with the advantages to be a portable device. So, this instrument may be of great useful for refractive assessment in children, especially with cycloplegia.

Our study had some advantages compared to other studies, because we include a repeatability (using three different measurements) and cycloplegic retinoscopy comparison analysis, with a masked design. Moreover, only one experienced observer performed retinoscopy, and thus interobserver bias was controlled and minimized. Second, a trained observer conducted all autorefraction measurements without knowledge of the retinoscopy results (masked design). This methodology reduces bias in data collection and analysis. Finally, our study population involved only children, with a wide range of refractions (sphere from –4.25 to +7.75 D), providing better analysis of the use of ARK-30 in pediatric population. However, the major limitations of this study may be related with a relative small sample size, and the range of refractions included. So, more research with large sample to provide a separate analysis ranking children by age, level of cooperation; and assessing of high refractions could be necessaries, to show if repeatability and agreement with cycloplegic retinoscopy could be influenced by the child age, cooperation, or the amount of refraction.

Conclusion

In conclusion, ARK-30 handheld autorefractor is repeatable to achieve objective refraction in children with more repeatable values under cycloplegic. Autorefraction should not be perceived as substitute for the gold standard retinoscopic refraction because, under noncycloplegic conditions, ARK-30 autorefractor has lower repeatability and a tendency toward minus over correction in children resulting in over diagnosis of myopia, suggesting that noncycloplegic measurements must be interpreted with caution and cycloplegia is highly recommended to achieve repeatable autorefraction results in children.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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