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Nabin Paudel

Technological University Dublin, nabin.paudel@TUDublin.ie

Sameep Adhikari

Drishti Eye Care Centre, Kalanki, Kathmandu, Nepal

Ajit Thakur

Drishti Eye Care Centre, Kalanki, Kathmandu, Nepal

Bhairaja Shrestha

Drishti Eye Care Centre, Kalanki, Kathmandu, Nepal

James Loughman

Technological University Dublin, james.loughman@tudublin.ie

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Clinical Accuracy of the Nidek ARK-1 Autorefractor

Nabin Paudel, PhD,^{1,2*} Sameep Adhikari, BOptom,¹ Ajit Thakur, MOptom,¹ Bhairaja Shrestha, MD,¹ and James Loughman, PhD²

SIGNIFICANCE: Autorefractors are commonly used by eye care practitioners worldwide as a starting point for clinical prescribing and by researchers as an instrument to study development of refractive errors and accommodation. This study demonstrates that the Nidek ARK-1 provides a reasonable and repeatable estimate of refractive error.

PURPOSE: The purposes of this study were (a) to compare refraction measurements of the Nidek ARK-1 (2016 release) autorefractor with that of subjective refraction and retinoscopy performed by an experienced clinician and (b) to determine the intratest and intertest variability of autorefractor measures taken using the ARK-1 autorefractor.

METHODS: Sixty-seven adult patients aged 18 to 69 years underwent retinoscopy, subjective refraction, and ARK-1 autorefractor on a same day by a single clinician. A separate subset of 14 participants was invited for the repeatability and reproducibility study. Both eyes of each participant were included in the analysis.

RESULTS: A statistically significant (but not clinically significant) positive spherical difference was observed between the ARK-1 and subjective refraction ($P = .003$). Spherical equivalent refractive errors were statistically similar between the ARK-1 and subjective refraction ($P = .20$). A statistically and clinically significant difference was observed in the cylindrical component between the ARK and subjective refraction ($P < .01$). No statistically significant difference was observed between the ARK and subjective refraction in both the horizontal (J_0 ; $P = .08$) and oblique cylindrical vector (J_{45} ; $P = .96$). Bland-Altman analysis revealed that the 95% limits of agreement were widest between the ARK and subjective refraction in all of the refractive components (-0.60 to 0.89 diopter for spherical component, -0.80 to 0.69 diopter for spherical equivalent, and -0.98 to 0.30 diopter for cylindrical component). The intertest and intratest variability of the ARK-1 was small.

CONCLUSIONS: The Nidek ARK-1 autorefractor is a useful clinical tool that provides a reasonable and repeatable estimation of refractive error in adults.

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Author Affiliations:

¹Drishti Eye Care Centre, Kalanki, Kathmandu, Nepal

²Centre for Eye Research Ireland, Technological University Dublin, Dublin, Ireland

*nabin.paudel@dit.ie

Autorefraction has been an integral procedure in optometric practice for many years. It is commonly used as a starting point for subjective refraction in clinical practice^{1,2} and to study accommodation status³ and the development of refractive errors in research.⁴ Most of the commercially available autorefractors are designed as a closed-view apparatus whereby a fixation target is located within the system and a combination of lenses is incorporated to relax accommodation. This arrangement does not represent a natural viewing environment and can therefore lead to the stimulation of accommodation due to proximity of the surrounding or awareness of being in an enclosed surrounding known as proximal accommodation.^{5,6} This accommodation interferes with the true measurement of refractive error of the eyes and hence leads to inaccuracies in the results. A variety of autorefractors are available, each based on one of a number of different design principles. New models of autorefractor are released regularly, generally incorporating upgraded design or operational features to overcome measurement challenges such as minimizing the influence of accommodation and eye movements. From a clinical and research perspective, devices that provide rapid measurements, incorporate features to optimize measurement accuracy and reliability, provide natural unobstructed binocular viewing, and are less influenced by factors such as accommodation and eye movements are desirable.⁷

Many previous studies have compared the performance of autorefractors with that of subjective refraction and retinoscopy.^{8–12}

Although some level of disagreement is to be expected between different methods, the levels of agreement are variable. Because different autorefractors work on different design principles, it is necessary to compare the performance of each newly released instrument with other models¹³ and also with traditional refraction methods such as retinoscopy and subjective refraction. The level of agreement between different methods and the accuracy and the validity of the instrument will determine the confidence of the clinician or the researcher to trust the results obtained with the instrument, whether be it for clinical prescribing or for research purposes.

The Nidek ARK-1 (Nidek Technologies, Gamagori, Japan) is an autorefr/keratometer platform based on the Scheiner disc principle.¹⁴ It combines pupillography, keratometry, and autorefractor. The ARK-1 is a relatively new addition to the autorefractor market (released in 2016). It uses a large pupil zone imaging method and has measurement ranges of -30 to $+25$ diopter sphere, up to 12 diopter cylinder, and 0 to 180° axis. The autorefractor incorporates a super luminescent diode that provides a clear and sharp image compared with older designs and a highly sensitive charge-coupled device that is stated to allow the autorefractor to perform measurement in densely cataractous eyes.¹⁵

The purpose of this study was twofold. First, the study was designed to compare the autorefractor performance of the Nidek ARK-1 autorefractor with the routinely used standard refraction protocol—retinoscopy and subjective refraction—performed by an experienced

eye care professional in noncyclopleged adult eyes. Second, the intratest and intertest variability of autorefraction measures applied to the autorefraction function of the ARK-1 was determined.

METHODS

This was a cross-sectional study whereby 67 patients attending the Drishti Eye Care Center, a tertiary-level eye care center in Kathmandu, Nepal, were enrolled. The research was approved by the ethical committee of the Nepal Health Research Council, and the study was conducted in accordance with the tenets of the Declaration of Helsinki. Verbal and written informed consents were obtained from each participant before being enrolled into the study. Subjects were included only if they were free of ocular pathology. All of the refraction procedures were performed under noncycloplegic conditions. Retinoscopy was performed first, followed by subjective refraction. Either the retinoscopy finding or the patient's previous prescription (if available) was used as the starting point for subjective refraction. Subjective refraction was conducted with a trial frame with vertex distance kept to a minimum. Cylindrical power and axis were refined using a 0.25-diopter Jackson cross cylinder. Refraction of each eye was performed monocularly followed by binocular balancing using the alternate occlusion method. The highest plus sphere and the lowest minus cylindrical power that provided the best acuity and comfortable vision were considered as the end point. Subjective refraction was recorded to the closest 0.25 diopter sphere, 0.25 diopter cylinder, and 2.5°. To minimize the risk of bias, autorefraction was conducted by the same examiner (NP) but after subjective refraction was completed. The autorefractor was calibrated daily according to the manufacturer's guidelines using a schematic model eye (-5.00 diopter sphere). Participants were instructed to look at the internal fixation target (balloon). Three measurements of each eye were taken over an approximate 6-second time frame, and the readings were manually averaged by the clinician. Intratest and intertest variability of the ARK-1 was determined in a separate group of 14 individuals using two methods, determining the standard deviation of seven consecutive readings (intratest) and retesting the same eye within a duration of 2 weeks (intertest).

Data Analysis

Assuming an effect size of 0.4, our sample size calculations (G*Power¹⁶) indicate that 67 eyes are sufficient for a power of 90% with a two-sided paired *t* test, adopting a significance value of 5%.

Both eyes of each participant were included in the data analysis. There was no significant variation in the measured refractive error

between eyes (intra-class correlation between two eyes close to 1 for all measures). Statistical analyses therefore were computed using averaged data from both eyes as suggested by Armstrong.¹⁷

Refraction measurements were compared in the form of mean sphere, cylinder, and spherical equivalent. Spherical equivalent was calculated by adding half of the cylindrical power to the spherical component. Measurements were also subjected to vector analysis for comparison. Vector analysis is an established method for evaluating refractive error data, as it considers magnitude and direction of the cylinder of astigmatism for statistical calculation of refractive errors.¹⁸ Vector analysis was conducted using the formulas suggested by Thibos et al.¹⁸ represented as follows, whereby J_0 represents the horizontal cylindrical vector and J_{45} represents the oblique cylindrical vector.

$$J_0 = -(\text{cylinder}/2)\cos(2 \times \text{axis})$$

$$J_{45} = -(\text{cylinder}/2)\sin(2 \times \text{axis})$$

Bland-Altman plots¹⁹ of the sphere, cylinder, spherical equivalent, and J_0 and J_{45} were used to demonstrate the limits of agreement between retinoscopy, subjective refraction, and autorefraction values, whereas mean differences were assessed using a paired-samples *t* test. SPSS v.21 statistical software was used for data analysis (SPSS, Chicago, IL). MedCalc statistical software was used to plot the Bland-Altman charts.²⁰

RESULTS

One hundred thirty-four eyes of 67 participants (54% male) were assessed. Mean ± SD age of the participants was 32 ± 13 years (range, 18 to 69 years). Subjectively assessed mean spherical equivalent refractive errors ranged from +3.00 to -6.25 diopter sphere. The maximal astigmatism was 3.00 diopter cylinder. Of the eyes with astigmatism (n = 87), 56% were against the rule, 35% were with the rule, and the rest were oblique. Twenty-eight eyes of 14 participants with a mean age of 26 ± 6 years were subjected to the repeatability and reproducibility analysis. Subjectively assessed spherical equivalent refractive error for this analysis ranged between +0.50 and -1.50 diopter sphere. The maximal astigmatism was -1.50 diopter cylinder.

Spherical Component Analysis

The Nidek ARK-1 statistically significantly underestimated the spherical component as compared with subjective refraction and retinoscopy (Table 1; Figs. 1 and 2). The 95% limits of agreement in the spherical component between the ARK and retinoscopy, the

TABLE 1. Mean difference and significance in various refractive components between ARK-1, retinoscopy, and subjective refraction

| Refractive components | Mean ± SD difference (95% CI) and significance | | | | | |
|--------------------------|--|--------|-------------------------------|--------|-------------------------------|--------|
| | ARK vs. RET | P | ARK vs. SUB | P | RET vs. SUB | P |
| Spherical component | 0.09 ± 0.35 (0.00 to 0.18) | .03* | 0.14 ± 0.38 (0.05 to 0.23) | .003* | 0.04 ± 0.25 (-0.01 to 0.25) | .16 |
| Cylindrical component | -0.15 ± 0.26 (-0.21 to -0.08) | <.001* | -0.33 ± 0.32 (-0.41 to -0.25) | <.001* | -0.18 ± 0.31 (-0.26 to -0.10) | <.001* |
| Spherical equivalent (M) | 0.00 ± 0.33 (-0.07 to 0.08) | .95 | -0.05 ± 0.38 (-0.15 to 0.03) | .20 | -0.06 ± 0.27 (-0.12 to 0.00) | .06 |
| J_0 | 0.02 ± 0.16 (-0.02 to 0.06) | .29 | 0.05 ± 0.25 (0.00 to 0.12) | .08 | 0.03 ± 0.23 (-0.02 to 0.09) | .20 |
| J_{45} | 0.00 ± 0.22 (-0.06 to 0.05) | .86 | 0.00 ± 0.22 (-0.05 to 0.05) | .96 | 0.00 ± 0.06 (0.00 to 0.02) | .42 |

ARK = autorefractor; CI = confidence interval; M = spherical equivalent; RET = retinoscopy; SUB = subjective refraction.

*Statistical significance.

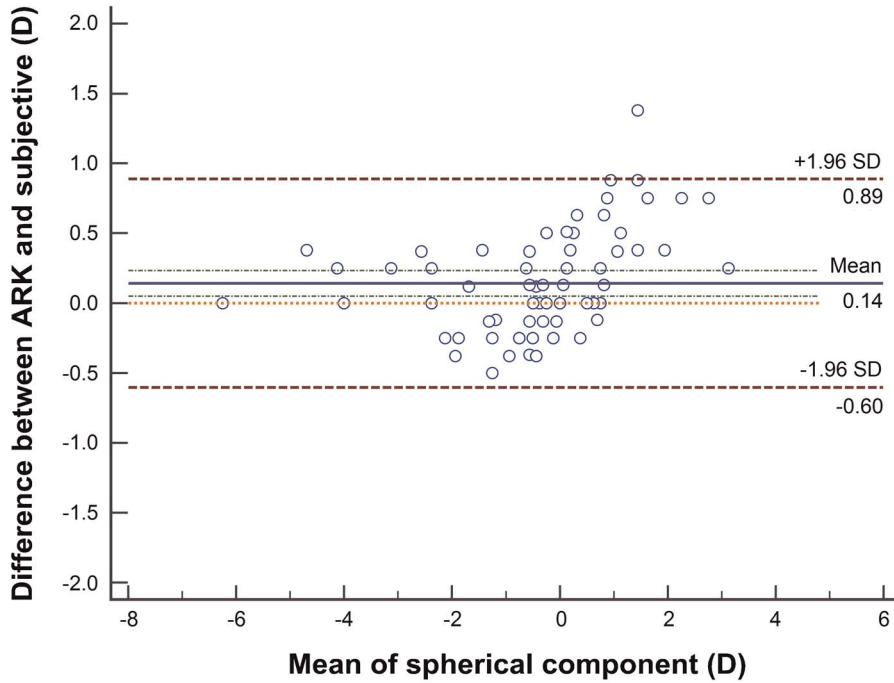


FIGURE 1. Bland-Altman plots of the spherical component between autorefraction and subjective refraction. For all the Bland-Altman plots, the solid blue lines represent the observed mean agreement between methods, dashed green lines above and below the blue line represent 95% CI of the observed mean, dashed brown lines represent 95% limits of agreement, and dashed orange horizontal lines represent perfect mean agreement between methods. ARK = autorefractor; CI = confidence interval.

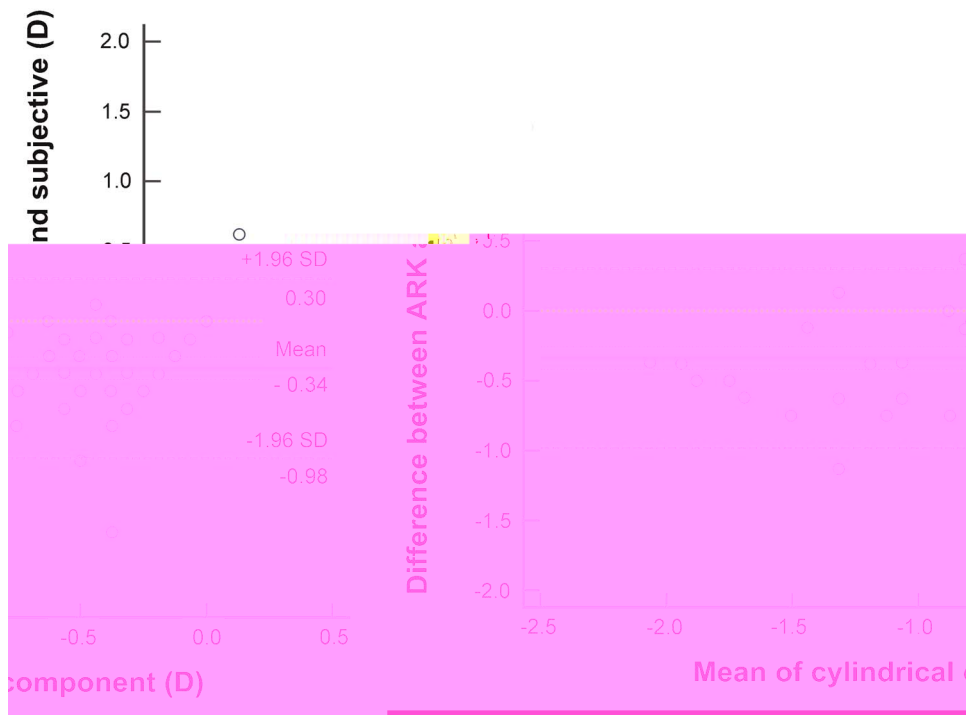


FIGURE 2. Bland-Altman plots of the spherical equivalent between autorefraction and subjective refraction.

ARK and subjective refraction, and retinoscopy and subjective refraction were -0.60 to 0.80 , -0.60 to 0.89 , and -0.46 to 0.55 diopter, respectively (Fig. 1).

Spherical Equivalent Analysis

No significant differences were observed in spherical equivalent findings between any of the three methods (Table 1). The 95% limits of agreement between the ARK and retinoscopy, the ARK and subjective refraction, and retinoscopy and subjective refraction were -0.65 to $+0.65$, -0.80 to $+0.69$ (Fig. 2), and -0.59 to $+0.47$ diopter.

Cylindrical Component Analysis

The ARK statistically significantly overestimated the cylindrical component compared with both retinoscopy and subjective refraction, with the largest difference observed between the ARK and subjective refraction (0.33 diopter cylinder; Table 1; Figs. 3, 4). The 95% limits of agreement between the ARK and retinoscopy, the ARK and subjective refraction, and retinoscopy and subjective refraction were -0.67 to 0.37 , -0.98 to 0.30 (Fig. 3), and -0.80 to 0.43 diopter, respectively.

Vector Analysis

The mean horizontal cylindrical vector (J_0) differences between the ARK and retinoscopy, retinoscopy and subjective refraction, and the ARK and subjective refraction were not statistically significant (Table 1). The ARK measurements were slightly more negative than retinoscopy and subjective refraction. The 95% limits of agreement between the ARK and retinoscopy, the ARK and subjective refraction, and retinoscopy and subjective refraction were -0.30 to 0.34 , -0.47 to 0.58 (Fig. 4), and -0.43 to 0.58 diopter, respectively. Although the ARK readings were slightly biased toward negative cylinder,

the mean differences in the oblique cylindrical vector (J_{45}) between the ARK, retinoscopy, and subjective refraction were not statistically significant (Table 1). The 95% limits of agreement between the ARK and retinoscopy, the ARK and subjective refraction, and retinoscopy and subjective refraction were -0.44 to $+0.44$, -0.44 to $+0.44$ (Fig. 5), and -0.12 to $+0.13$ diopter.

Variability

The intratest and intertest variability of the ARK-1 was small (Table 2).

DISCUSSION

In general, the levels of agreement between autorefracton and subjective refraction measurements were in accordance with previous studies. Certainly, the spherical component and mean spherical equivalent measurement differences between the ARK and subjective refraction are similar to those observed for other models of autorefracton such as Shin-Nippon 500, Nidek AR-1000, Allergan Humphrey 570, Allergan Humphrey 500, and Canon RK-1 autorefracton.^{7,8,11,12,21,22} Retinoscopy and subjective refraction exhibited the highest levels of agreement across all cutoff values herein. More importantly, however, the agreement was least between the ARK and subjective refraction measurements, which are the most relevant clinical parameters when determining the level of confidence a clinician should afford to a new autorefracton device. Our findings indicate that this autorefracton differs by more than 0.25 diopter for close to one in every two measurements and more than 0.50 diopter for one in five (Table 3). Although these findings are not surprising given the various factors that affect both types of measurements, they are clinically important and should be considered in routine clinical practice.

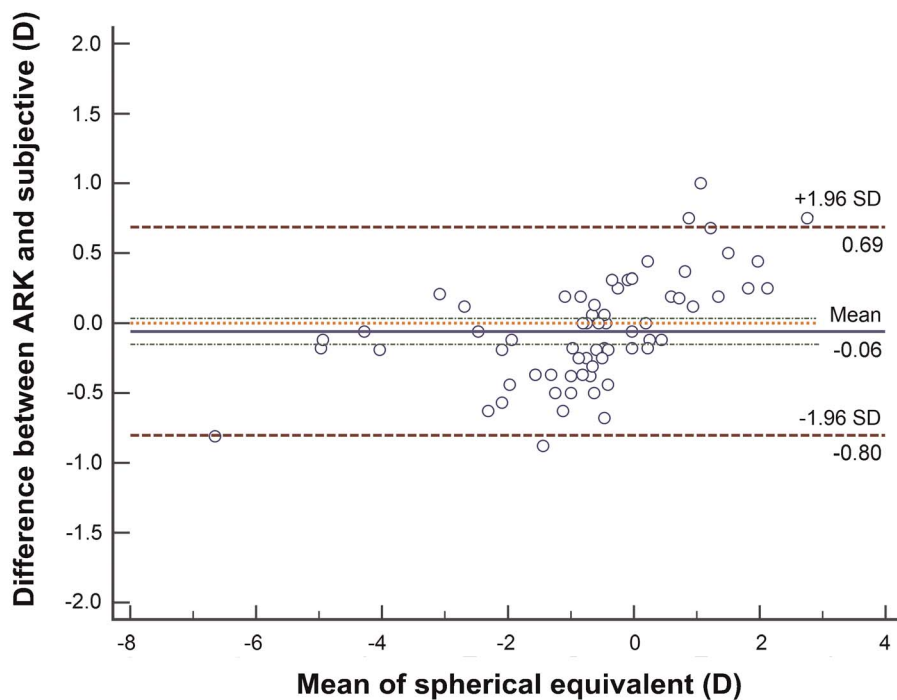


FIGURE 3. Bland-Altman plots of the cylinder between autorefracton and subjective refraction.

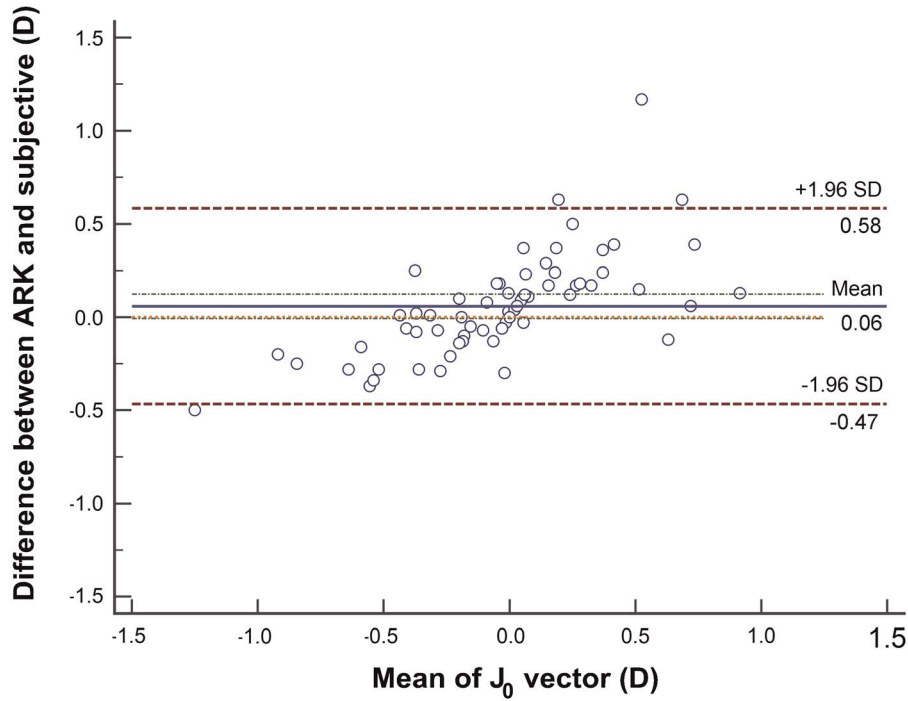


FIGURE 4. Bland-Altman plots of the J_0 vector between autorefracton and subjective refracton.

The positive bias of the spherical component refractive error with the ARK as compared with subjective refracton was statistically significant but not clinically significant (it is a common practice for clinicians to prescribe in 0.25-diopter steps). The direction of bias

(positive bias) found herein is similar to that found with the Shin-Nippon autorefracton, an autorefracton with binocular viewing design to allow for minimal influence of accommodation on refractive measurements.⁹ This finding could imply that the accommodation

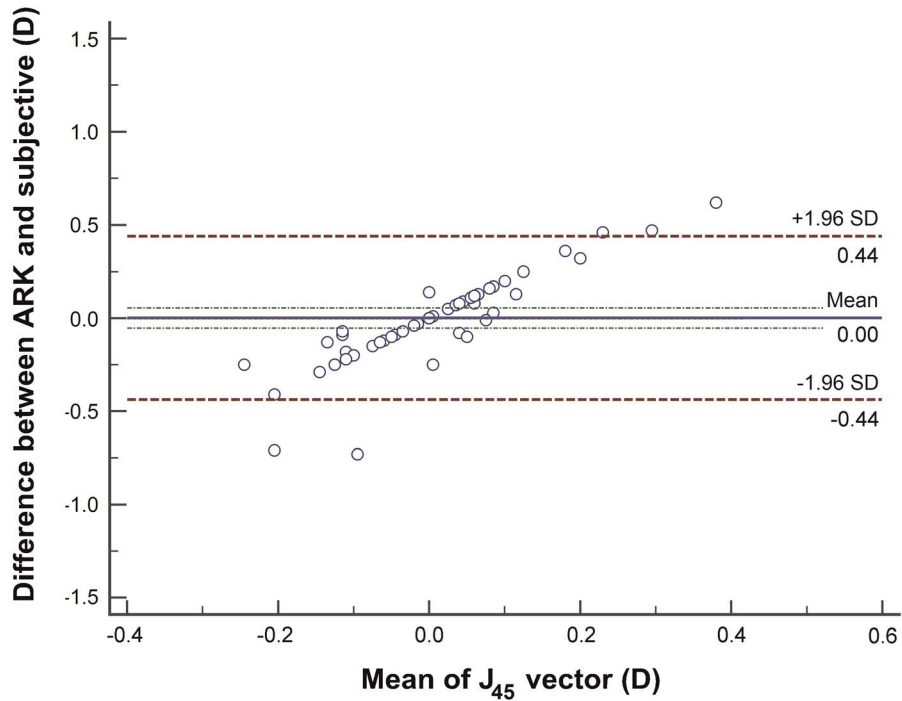


FIGURE 5. Bland-Altman plots of the J_{45} vector between autorefracton and subjective refracton.

TABLE 2. Intratest (repeatability) and intertest variability (reproducibility) of the ARK-1 in 28 eyes of 14 individuals

| Refractive components | Intrate variability DS or DC | Intertest variability | | |
|-----------------------|---------------------------------|-------------------------------|------|-----|
| | | Mean difference (DS or DC) | SD | P |
| Sphere | 0.15 | 0.03 | 0.33 | .57 |
| Cylinder | 0.10 | -0.03 | 0.27 | .49 |
| Spherical equivalent | 0.13 | 0.01 | 0.30 | .75 |
| J_0 | 0.06 | 0.02 | 0.16 | .49 |
| J_{45} | 0.05 | 0.007 | 0.09 | .64 |

DC = diopter cylinder; DS = diopter sphere.

control mechanism (fogging) incorporated within the ARK-1 compares relatively favorably with binocular viewing design autorefractors. The magnitude of positive bias in the spherical component between ARK and subjective refraction observed herein is also broadly similar to that reported with other devices (0.15 to 0.18),^{7,9} being slightly higher than some (0.005 to 0.04 diopter sphere),²³ but lower in terms of mean spherical equivalent for other studies (0.15 to 0.16 diopter sphere).⁹ Because cycloplegia was not used in this study, the positive slopes of the bias in the Bland-Altman plots for sphere and spherical equivalent measurement between the methods (Figs. 1, 2) could be due to the fogging mechanism of the instrument or an accommodative effect in younger hyperopic participants during subjective refraction or a combination of both. However, because hyperopes comprised only 22% of study participants and were almost exclusively older than 40 years (97%), a strong accommodative effect is unlikely.

It must be noted, however, that, although the mean differences of refractive components between the tests seem to be small, their agreement must be interpreted with caution. For instance, if we consider the spherical equivalent comparison between the ARK and subjective refraction, we observe a nonsignificant mean difference of 0.04 diopter sphere. If we look at the Bland-Altman plot (Fig. 1), however, the wide limits of agreement could be clinically important (95% limits of agreement, -0.80 to +0.69 diopter). In fact, the limits of agreement between the ARK and subjective refraction are the widest compared with other test pairs. The nonsignificant difference between the mean spherical equivalent values is potentially due to the nature of the bias in the ARK measurements wherein the hyperopic and cylindrical values are overestimated, which then cancel each other out. Similar finding is also observed in the spherical component measures between the ARK and subjective refraction (Table 1, Fig. 3). The limits of agreement between the ARK and subjective refraction in the spherical and spherical equivalent measurements, however, were similar to some of the previous designs of autorefractors¹¹ but considerably higher than others.^{7,8}

With regard to the cylindrical component, the positive bias between autorefractor and subjective refraction (-0.33 diopter cylinder) was considerably higher than in previous studies (0.002 to 0.05 diopter cylinder).^{8,21,22} The bias between retinoscopy and subjective refraction was also high compared with earlier studies.^{1,10} Both the autorefractor and retinoscopy measurements for the J_0 and J_{45} components, meanwhile, were less positively biased compared with subjective refraction measurements relative to those obtained in previous studies with different models of autorefractor,^{8,22} whereas the percentage of cylindrical component differences between ARK and subjective refraction that fell within ± 0.25 and ± 0.50 diopter cylinder was considerably lower (74 to 87% for ± 0.25 diopter cylinder and 90 to 97% for ± 0.50 diopter cylinder in previous studies^{21,22}; Table 3).

The levels of intertest and intratest variability of the ARK-1 are in agreement with previous validation studies on Shin-Nippon SRW-5000,⁸ the Hoya AR-570,¹⁰ and the Nikon NRK8000.²⁴

The reasons underlying the observed variation in findings between different methods could be many. Previous researchers have suggested that the presence of higher-order aberrations can lead to significant differences in measurements between different methods.²⁵ In addition, the three refraction methods pose different accommodative demands to the patients that influence the refraction measurement, hence possibly explaining some inconsistencies in the results. Moreover, the cognitive demand involved in subjective refraction, unlike in either of the other two refraction methods, can at least in part contribute to the differences. Likewise, the discrepancy in the measurements in our study compared with other studies could relate to the different principles used in different models of autorefractors. For instance, the ARK-1 uses the two-pin-hole Schiener disc principle, whereas other autorefractors such as Canon use the ray deflection method, Topcon uses the image size principle, Humphrey autorefractor uses the knife edge principle, Shin-Nippon (Grand Seiko) uses the image reflection method, and the Nidek OPD Scan II uses the retinoscopy principle.^{14,26} Moreover, different models of autorefractors have different mechanisms to control accommodation such as positioning of the fixation target (internal vs. external) and viewing condition (monocular vs. binocular).

All of the refractive components obtained via retinoscopy were closer to subjective refraction than with the autorefraction results. In addition, the range of limits of agreement between the retinoscopy and subjective refraction was narrower than that between the ARK and subjective refraction. This suggests that retinoscopy when performed by an experienced clinician can be the method of choice for the starting point of subjective refraction. This finding is in accordance with an earlier study.¹ However, the small intratest and intertest variability of the ARK-1 may signify that this instrument can be used in various other purposes such as for studies observing the change in refractive errors in myopia control studies,

TABLE 3. Proportion of the difference in refractive components between the three methods

| Refractive components | ARK and SUB (%) | | | ARK and RET (%) | | | RET and SUB (%) | | |
|-----------------------|-----------------|------------|------------|-----------------|------------|------------|-----------------|------------|------------|
| | ± 0.25 | ± 0.50 | ± 1.00 | ± 0.25 | ± 0.50 | ± 1.00 | ± 0.25 | ± 0.50 | ± 1.00 |
| Sphere | 60 | 86 | 98 | 64 | 92 | 98 | 80 | 97 | 100 |
| Spherical equivalent | 56 | 85 | 98 | 63 | 91 | 98 | 74 | 94 | 100 |
| Cylinder | 46 | 77 | 97 | 73 | 92 | 100 | 72 | 86 | 100 |

ARK = autorefractor; RET = retinoscopy; SUB = subjective refraction.

screening children for refractive errors, and ensuring findings obtained with retinoscopy in highly irregular/aberrated eyes.

It must be acknowledged that this study is not without limitations. First, we agree with previous authors that considering subjective refraction as a reference may have limitations,^{22,27} as there may be a variation in measurements if subjective refraction is conducted by one or more clinicians.¹⁰ Therefore, we considered subjective refraction by a single practitioner to minimize clinician bias, as also implemented by other studies.^{22,28} Second, given the potential of ARK-1 to measure spherical refractive error within the range of -30 to +25 diopters and cylindrical error of up to 12 diopters, the narrow range of refractive errors included in our study limits any interpretation of the utility of ARK-1 in patients with high refractive errors. Previous studies have demonstrated higher variability of autorefractor measurement with high refractive error measurements,⁷ although it should be noted that epidemiological studies indicate that between 85 and 90% of population refractive errors lie within the measurement range reported herein, so the results are applicable

for most of likely clinic attendees.^{29,30} Third, the researcher had knowledge of the participant's previous prescription, which may have introduced some bias in the subjective refraction. The researcher made sure, however, to follow a consistent routine for each participant, with the end point defined by the criteria to achieve the best possible acuity and comfortable vision with the new prescription. A standardized method of subjective refraction including alternate occlusion for binocular balancing was therefore conducted on all participants irrespective of the knowledge of the participants' previous prescription. Finally, this study involved the use of a single ARK-1 instrument, so the findings cannot be assumed to reflect performance limits of all ARK-1 instruments.

In conclusion, Nidek ARK-1 could be a valuable addition to any optometric or ophthalmic practice as an instrument for approximating refractive errors and tracking the progression of refractive development in adults. Some caution should be exercised while interpreting its results, which, as with all autorefractors, should not be used as a replacement for traditional prescribing routines.

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