



Comparison of Adult Refractive Disorder Measurements Using HandyRef-K, Retinomax, Plusoptix, and Table-top Autorefractometer Devices

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Abstract

Objectives: This study was conducted to compare refractive error measurements recorded using the Nidek HandyRef-K handheld autorefractometer (HDY; Nidek Co. Ltd., Tokyo, Japan), Plusoptix A09 photorefractor (PO; Plusoptix GmbH, Nuremberg, Germany), Retinomax K-plus 3 (RTX; Right Mfg. Co. Ltd., Tokyo, Japan), and a table-mounted autorefractometer/keratometer (TTR; URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea).

Methods: Patients aged ≥18 years underwent measurement of refraction without cycloplegia using 4 devices and the spherical power (SP), cylindrical power (CP), and spherical equivalent (SE) values were analyzed and compared.

Results: A total of 181 eyes of 181 patients were enrolled in the study. The mean age of the patients was 33.08 ± 0.95 years (range: 18-79 years). There was a significantly significant difference in the SP, CP, and SE values determined by the devices (p<0.001). The SP and SE values of the RTX and the HDY were similar, while the other device results were different (Wilcoxon signed-rank test, p=0.004). The CP values of the PO and the TTR, the HDY and the TTR were also comparable.

Conclusion: The HDY, RTX, and the PO are suitable for screening in clinical practice, but the findings strongly suggest that they should be used with caution.

Keywords: Adult population, HandyRef-K, Plusoptix, Retinomax K-plus 3

Introduction

The subjective refraction technique provides the best corrected visual acuity and is the gold standard of optometry. However, it is well known that retinoscopy is easily influenced by the physiological state of the patient and the experience level of the examiner (1). In recent years, automatic

refractors have become valuable tools, as a result the busy clinical schedule of ophthalmologists as well as the increasing faith of patients in sophisticated mechanical devices (2). There are currently several models and techniques available and the options continue to improve. For example, photoscreening is a useful form of vision screening for children since it requires less time than a traditional method (3).

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Photorefractometers require minimal patient cooperation and provide the means for a fast and easy clinical evaluation. Handheld autorefractometers are particularly helpful for measuring the refractive values of infants and small children, in addition to adults who have difficulty complying with protocols for table-mounted devices. Each device and method has advantages and disadvantages.

One advantage of handheld autorefractokeratometers is that they can be used to measure refractive errors and determine keratometric values in the supine position. However, the existing analysis of the accuracy of different devices is limited.

The present study was designed to compare the refractive error measurements of the Nidek HandyRef-K handheld autorefractometer (HDY; Nidek Co. Ltd., Tokyo, Japan), the Plusoptix A09 photorefractor (PO; Plusoptix GmbH, Nuremberg, Germany), the Retinomax K-plus 3 autorefractometer/keratometer (RTX; Right Mfg. Co. Ltd., Tokyo, Japan), and a table-mounted autorefractometer/keratometer (TTR; URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea).

Methods

Study Design

This comparative cross-sectional study was conducted at Istanbul Training and Research Hospital. Sequential patients who presented at the ophthalmology department between January and April 2016 were invited to participate. Written, informed consent was obtained from all of the patients prior to the examinations. The study was approved by the medical ethics committee of Bakırköy Dr. Sadi Konuk Training and Research Hospital (KAEK 2017/170) and adhered to the tenets of the Declaration of Helsinki.

Patients

The main criteria for exclusion were the presence of a systemic disease affecting the eyes or an ocular pathology other than a refractive error. Patients who had disorders that could affect the measurements, such as cataracts, pterygium, vitreous opacity, strabismus, or nystagmus, and those with previous ocular surgery or trauma were excluded. Patients who were unable to complete any of the 4 device measurements were also excluded. Patients ≥18 years of age without any anterior or posterior segment pathology other than refractive errors were included in the study.

A detailed eye examination, including an orthoptic evaluation, central fixation, cover-uncover test, and anterior and posterior segment evaluation with slit-lamp biomicroscopy, was performed for each patient. The refractive error of each eye was measured using the HDY, RTX, PO, and the TTR without cycloplegia by a single, experienced physician (ZS) in a semi-lighted room. The average of 3 measurements with each device was used for comparison.

Retinomax K-plus 3

Measurements with the RTX device were performed at a distance of about 5 cm from the patient, according to the manufacturer's instructions. The RTX is an autorefractor and keratometer that uses a fogging mechanism to avoid or minimize the effect of accommodation. Eight measurements are evaluated and a single representative value is provided. The spherical range is -18 to +22 diopters (D) in 0.25 D increments and the cylindrical range is 12 D.

Plusoptix A09

Binocular measurements were performed with the PO device under dim lighting conditions I meter in front of the patient, as recommended by the manufacturer. The spherical measurement range is -7.0 to +5.0 D in 0.25 D increments, and the cylindrical range is -7.0 to +5.0 D in 0.25 D increments. A minimum pupil diameter of 3.0 mm is required.

HandyRef-K

The HDY device was used at a distance of about 46 mm from the patient, according to the instruction manual. The spherical range is -20 D to +20 D and the cylindrical range is 0 to +12 D. The minimum pupil size required for measurement is 2.0 mm.

The spherical power (SP), cylindrical power (CP), cylindrical axis (CA), and spherical equivalent (SE) values obtained using all of the devices were statistically compared. The following formula was used to calculate the SE in D: SE(D) = Sphere(D) + [Cylinder(D)/2]

Patient Groups According to Refractive Error

Patients with refractive errors of > -3 D were assigned to Group I, refractive errors between -1 and -3 D were categorized as Group 2, refractive errors between -1 and +1 D were classified as Group 3, refractive errors between +1 and +3 D made up Group 4, and Group 5 comprised those with refractive errors of > +3 D.

Statistical Analysis

All of the statistical analyses were performed using MedCalc Statistical Software version 12.7.7 (MedCalc Software by, Ostend, Belgium) The descriptive statistics were reported as the mean and SD or minimum-maximum for continuous data, and the number of cases and percentages were used for nominal variables. The Wilcoxon signed-rank test was used for comparisons of dependent variables between 2 groups and the Friedman test was used for comparisons of more than 2 groups. A value of p<0.0125 was considered to indicate statistical significance for binary comparisons. Bland-Altman plots were used to compare the agreement of the device measurements. A value of p<0.05 was accepted as statistically significant.

Results

In all, 181 right eyes of 181 adult patients were enrolled. The mean age of the patients was 33.08 ± 0.95 years (range: 18-79 years); 52 of the patients (28.7%) were male and 129 of the patients (71.3%) were female.

Table I shows the mean (±SD) SP, CP, CA, and SE measurements of the study population recorded with each method. There were statistically significant differences in the SP, CP, and SE measurements (Friedman test, p<0.001). No statistically significant difference was observed in the CA values (Friedman test, p=0.265).

Binary comparisons of the SP, CP and SE values are provided in Table 2. Statistically significant differences in the SP

values were observed between the results of the RTX and the PO, the RTX and the TTR, the PO and the HDY, the PO and the TTR, and the HDY and the TTR (Wilcoxon signed-rank test, p<0.001). There was no statistically significant difference between the RTX and the HDY findings (Wilcoxon signed-rank test, p=0.004).

The CP measurements revealed statistically significant differences between the RTX and the PO, the RTX and the HDY, the RTX and the TTR, and the PO and the HDY (Wilcoxon signed-rank test, p<0.001). There were no statistically significant differences between the HDY and the TTR (Wilcoxon signed-rank test, p=0.435).

The findings of each patient group are illustrated in Figures I and 2.

Table 1. The mean (±SD) spherical and cylindrical power, cylindrical axis, and spherical equivalent measurements obtained with the Plusoptix A09 photorefractor, the Retinomax K-plus 3 autorefractor/keratometer, the HandyRef-K autorefractokeratometer, and a table-top autorefractometer

	Plusoptix A09	Retinomax K-plus 3	HandyRef-K	Table-top autorefractometer	p*
Spherical power mean±SD (min-max)	0.36+1.2 (-5.5-3.5)	-0.51+1.2 (-4.5-4.7)	-0.37+1.1 (-4.25-4)	-0.08+1.12 (-4.25-4.5)	<0.001
Cylindrical power mean±SD (min-max)	-0.53+0.57 (-3.7-0)	-0.45+0.5 (-3.5-0)	-0.64+0.67 (-5-0)	-0.61+0.6 (-4.4-0)	<0.001
Axis value mean±SD (min-max)	113.2+53.2 (1-180)	113.9+50.2 (1-180)	113.3+51.4 (5-180)	111.3+48.9 (10-180)	0.265
Spherical equivalent mean±SD (min-max)	0.09+1,24 (-5.63-3)	-0.74+1.2 (-4.5-4.5)	-0.70+1.1 (-4.2-3.9)	-0.38+1.1 (-4.3-4.3)	<0.001

^{*} Friedman test; HandyRef-K: Nidek Co. Ltd., Tokyo, Japan; Plusoptix A09: Plusoptix GmbH, Nuremberg, Germany; Retinomax K-plus 3: Right Mfg. Co. Ltd., Tokyo, Japan; Table-top autorefractometer: URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea.

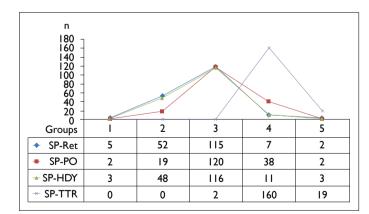


Figure 1. Distribution of spherical power values according to refractive error and device.

SP-HDY: Spherical power of HandyRef; SP-PO: Spherical power of Plusoptix; SP-Ret: Spherical power of Retinomax; SP-TTR: Spherical power of table-top autorefractometer. Refractive error groups: Group 1: > -3 diopters (D), Group 2: between -I and -3 D, Group 3: between -I and +1 D, Group 4"between +I and +3 D, Group 5: > +3 D. HandyRef-K: Nidek Co. Ltd., Tokyo, Japan; Plusoptix A09: Plusoptix GmbH, Nuremberg, Germany; Retinomax K-plus 3: Right Mfg. Co. Ltd., Tokyo, Japan; Table-top autorefractometer: URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea.

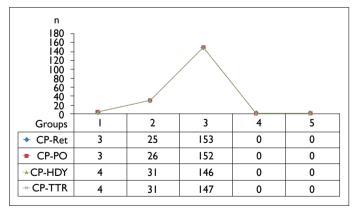


Figure 2. Distribution of cylindrical power values according to refractive error and device.

CP-HDY: Cylindrical power of HandyRef; CP-PO: Cylindrical power of Plusoptix; CP-Ret: Cylindrical power of Retinomax; CP-TTR: Cylindrical power of table-top autorefractometer. Refractive error groups: Group 1:>-3 diopters (D), Group 2: between -1 and -3 D, Group 3: between -1 and +1 D, Group 4"between +1 and +3 D, Group 5:>+3 D. HandyRef-K: Nidek Co. Ltd., Tokyo, Japan; Plusoptix A09: Plusoptix GmbH, Nuremberg, Germany; Retinomax K-plus 3: Right Mfg. Co. Ltd., Tokyo, Japan; Table-top autorefractometer: URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea.

Comparison of the SE measurements revealed statistically significant differences between the RTX and the PO, the RTX and the TTR, the PO and the TTR, the HDY and the TTR, and the HDY and the PO (Wilcoxon signed-rank test, p<0.001). There was no statistically significant difference between the RTX and the HDY (Wilcoxon signed-rank test, p=0.345).

Only the HDY and the RTX provided similar SP and SE parameter results (Wilcoxon signed-rank test, p=0.004) (Table 2). The CP values of the PO and HDY were similar to those of the TTR.

The 95% limits of agreement calculations for the SP, CP, CA, and SE measurements of the 4 devices are provided in Table 3

Bland-Altman analysis revealed good agreement between the CA measurements of the PO and the TTR (p=0.079), but there was no agreement in the SP, CP, or SE values (p<0.001, p=0.006, p<0.001 respectively). Good agreement was observed between the HDY and the TTR in the CP measurements (p=0.431), but there was no agreement in the SP, CA, or SE values (p<0.001, p=0.016, p<0.001). There was no agreement between the RTX and the TTR in the SP, CP, CA, or SE measurements (p<0.001, p<0.001, p=0.004, p<0.001 respectively). Good agreement was found between the HDY and the RTX in the CA and SE measurements (p=0.421 and p=0.362 respectively) but there was no agreement in the SP or CP values (p=0.002, p<0.0001 respectively). Good agreement was seen between the HDY and the PO in the CA measurements (p=0.916), but there was no agreement in the SP, CP, or SE (p<0.0001, p=0.003, p<0.0001 respectively).

Good agreement was found between the RTX and the PO in the CA measurements (p=0.460), but there was no agreement in the SP, CP, or SE (p<0.0001).

Discussion

This was a descriptive cross-sectional study designed to assess the agreement between 4 methods used to detect refractive errors. To the best of our knowledge, this is the first evaluation of the HDY autorefractometer and the RTX, PO, and TTR in an adult population.

Objective refraction using autorefractometers is an initial step in an optometric examination performed before refractive surgery for adults (4). In routine clinical practice, we use both table-top autorefractometers and subjective refraction to assess refractive errors, and we usually prefer noncycloplegic refraction in adult cases because of the discomfort and inconvenience of cycloplegic eye drops. It has been reported in some studies that cycloplegia is not required in estimates of refractive error in adults of approximately 20 years of age (5).

In this study, a TTR was compared with the HDY, the RTX, and the PO devices. The SE measurements of the HDY were consistent with those of the RTX (p=0.345). The CP results of the HDY were more similar to those measured using the TTR (p=0.435).

Payerols et al. (6) reported that the PO photoscreener underestimated hyperopia (0.73 D) and slightly overestimated myopia (0.05 D), and they concluded that the PO would provide greater accuracy in myopic children (6). Acar et al. (7) noted that because PO measurements can be recorded quickly and easily, it is especially helpful in cases of adults with mental retardation or other factors that may limit compliance (7).

It has been suggested that use of the PO may eliminate the need for cycloplegia in early detection of refractive errors in children (8). Ozdemir et al. (9) reported that PO measurements were incorrect after instillation of cyclopentolate. Additionally, the CP results with or without cycloplegia were higher. However, the non-cycloplegic PO measurements of SE

Table 2. Binary comparisons of spherical power, cylindrical power, and spherical equivalent measurements

p*	Spherical power	Cylindrical power	Spherical equivalent
Plusoptix-Retinomax	<0.001	<0.001	<0.001
HandyRef- Retinomax	0.004	<0.001	0.345
Table-top- Retinomax	<0.001	<0.001	<0.001
HandyRef- Plusoptix	<0.001	<0.001	<0.001
Table-top- Plusoptix	<0.001	0.036	<0.001
Table-top- HandyRef	<0.001	0.435	<0.001

^{*}Wilcoxon signed-rank test; HandyRef-K: Nidek Co. Ltd., Tokyo, Japan; Plusoptix A09: Plusoptix GmbH, Nuremberg, Germany; Retinomax K-plus 3: Right Mfg. Co. Ltd., Tokyo, Japan; Table-top autorefractometer: URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea.

Table 3. Summary of variance between the HandyRef-K-Retinomax, HandyRef-K-Plusoptix, Retinomax-Plusoptix, Table-top autorefractometer-Handyref-K, Table-top autorefractometer-Retinomax, and Table-top autorefractometer-Plusoptix measurements

	Mean	Standard	95% limits of	P *
	difference	deviation	agreement	
HandyRef-Retinomax				
SP	-0.133	0.564	-0.2153-(-0.04992)	0.002
СР	0.187	0.432	0.1231-(0.2499)	p<0.0001
Axis	0.690	9.082	-1.0026-(2.3831)	0.421
SE	-0.039	0.579	-0.1243-(0.04559)	0.362
HandyRef-Plusoptix				
SP	0.746	0.939	0.6082-(0.8835)	p<0.0001
СР	0.102	0.453	0.03573-(0.1687)	0.003
Axis	-0.115	11.583	-2.2739-(2.0439)	0.916
SE	0.797	0.939	0.6593-(0.9346)	p<0.0001
Retinomax- Plusoptix				
SP	0.878	0.986	0.7338-(1.0231)	p<0.0001
СР	-0.084	0.282	-0.1256-(-0.04295)	p= 0.0001
Axis	-0.805	11.543	-2.9569-(1.3463)	p= 0.460
SE	0.836	0.971	0.6940-(0.9787)	p<0.0001
Table-top- HandyRef				
SP	-0.30	0.56	-0.3833-(-0.2190)	p<0.001
СР	-0.02	0.49D	-0.09934-(0.04254)	p= 0.431
Axis	2	8.7	0.3814-(3.6186)	p= 0.016
SE	-0.32	0.59	-0.4020-(-0.2287)	p<0.001
Table-top-Retinomax				
SP	-0.43	0.59	0.5196 -(-0.3479)	p<0.001 *
СР	0.16	0.30	0.1144-(0.2017)	p<0.001
Axis	2.69	9.6	0.930-(4.4776)	p= 0.004
SE	-0.35	0.593	-0.4417-(-0.2677)	p<0.001
Autorefractometer-PlusOptix A09				
SP	0.45	0.77	0.3314-(0.5580)	p<0.001
CP	0.07	0.36	0.02164-(0.1260)	p= 0.006
Axis	1.9	11.30	-0.2226-(3.9925)	p= 0.079
SE	-0.48	0.74	0.3722-(0.5910)	p<0.001

^{*} Bland-Altman analysis; CP: Cylindrical power; SE: Spherical equivalent; SP: Spherical power; HandyRef-K: Nidek Co. Ltd., Tokyo, Japan; Plusoptix A09: Plusoptix GmbH, Nuremberg, Germany; Retinomax K-plus 3: Right Mfg. Co. Ltd., Tokyo, Japan; Table-top autorefractometer: URK 800, Unicos Co. Ltd., Daejeon, Republic of Korea.

and SP were similar to cycloplegic refraction measurements in preschool and non-verbal children. In our study, good agreement in CP measurements was observed between the PO and the TTR in an adult group (p=0.036). The light and the sound features of the PO make measurement easier than TTR in patients with cooperative difficulty(10).

The RTX is a monocular refractor that uses a fogging technique. This device has been found to be a reliable instrument in several comparisons with other autorefractors and TTR (11-13). It is portable and easy to use, and is frequently used to provide vision screening for preschool children (14). Our study group of adults had a mean age of 33.08+0.95

years (range: 18-79 years). The SP was found to be more myopic in the RTX measurements. The CP values of the HDY and the RTX were not correlated. However, the CP measured with the RTX was less myopic than that of the other devices. The PO results were more compatible. Other studies evaluating the accuracy of both the RTX and the PO have reported consistent with retinoscopy (8,15). Bui Quoc et al. (16) reported moderate correlation in the SE results and strong correlation in astigmatism power findings between the RTX and the PO. We did not find a correlation between the RTX and the PO measurements. This may have been a result of using noncycloplegic measurements. Patient accommodation can lead to more myopic values when using the RTX without cycloplegia, and more hyperopic values with the PO may be related to the fact that measurements are taken from a distance of I meter, eliminating the factor of accommodation. The PO can detect strabismus, refractive errors, and even media opacity, potentially eliminating the need for a dilated fundus examination in some patients (17).

It has been demonstrated in the literature that the non-cycloplegic values obtained with the PO are more hyperopic and closer to the values obtained with cycloplegia than the noncycloplegic values obtained with the RTX (18-20). This can be an advantage; some families do not want to authorize cycloplegia, and allergy sufferers or those who want to avoid the side effects of the drops may prefer this method. On the other hand, the PO measurements may not be adequate in small or large pupils; the RTX or the HDY may be preferable in these cases.

Our group measurements revealed a difference in the SP measurements using TTR and those of the other devices, as well as the CP measurements, but without statistical significance. Yilmaz et al. (8) found that the spherical and cylindrical results of the PO and the RTX were similar.

The fact that retinoscopy and cycloplegia were not used may be considered a limitation of this study; however, refractive evaluation is generally performed using noncycloplegic measurements.

We analyzed noncycloplegic refraction in an adult population. Many patients who present for refractive error evaluation do not wish to endure the effects of cycloplegic eye drop instillation, such as blurry near vision and photophobia, particularly when they must return to work or routine daily activities.

The accuracy of the PO and the RTX has been well established (8, 9, 15). We elected to include the HDY device as well, but further studies comparing the HDY with retinoscopy would also be valuable.

Strengths of this study include a large number of patients and a first evaluation of the accuracy of the HDY autorefractometer among adults.

In conclusion, the HDY and the RTX yielded comparable SP and SE results, but the CP values did not correlate. The lack of correlation between the PO and other devices, especially in CP, suggests that these handheld vision screening devices cannot be used interchangeably. They are suitable for use in clinical practice, particularly because they are an easier and faster method of refractive error evaluation, but we strongly recommend that they should be used with great caution.

Disclosures

Ethics Committee Approval: The study was approved by the medical ethics committee of Bakırköy Dr. Sadi Konuk Training and Research Hospital (KAEK 2017/170) and adhered to the tenets of the Declaration of Helsinki.

Peer-review: Externally peer-reviewed. **Conflict of Interest:** None declared.

Authorship Contributions: Involved in design and conduct of the study (ZS, EE, IP); preparation and review of the study (ZS, BKY, SB); data collection (ZS, EE, AV, TO); and statistical analysis (ZS); and all contributors confirmed the final version of the manuscript.

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