Comparison of 2Win and plusoptiX A12R refractometers with Retinomax handheld autorefractor keratometer

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PURPOSE To test the accuracy and validity of the 2Win and the plusoptiX A12R refractometers in detecting amblyopia risk factors.

METHODS Children were screened using both devices, using two sets of referral criteria each, and underwent complete ophthalmic examination, including cycloplegic refraction. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Median values for the pairs of refractometers were compared using the Wilcoxon signed-rank sum test for sphere, cylinder, and power vectors J0 and J45 for axis (both eyes).

RESULTS A total of 284 eyes of 142 children (mean age, 37.9 ± 19.8 months) were included. Comparison of mean cycloplegic and manifest refractometer measurements provided statistically significant differences in both eyes. For sphere, the means were lower and for cylinder, higher for both devices, and both correlated well with the gold standard for astigmatic power vectors J0 and J45. Using referral criteria 1, the sensitivity, specificity, PPV and NPV, and inconclusive results were 67.4%, 83.7%, 87.9%, 59.4%, and 4.9%, respectively, for the 2Win, with sensitivity of 13% in the hyperopia group; 73.1%, 95.9%, 96.6%, 69.1%, and 10.6%, respectively, for the plusoptiX A12R, with a sensitivity of 33.3% in the hyperopia group. Using criteria 2, the values were 98.8%, 38.8%, 73.9%, and 95.0% (2Win) and 94.9%, 65.3%, 81.3%, and 88.9% (plusoptiX A12R).

CONCLUSIONS In manifest conditions, the accuracy of the 2Win and plusoptiX A12R refractometers is low in hyperopia and astigmatism, but the devices are well correlated with each other, and both have high specificity; sensitivity is low in hyperopia, resulting in the underestimation of hyperopic refractive error. The optional Plusoptix sensitive referral criteria seems to be appropriate for the A12R. The 2Win provided fewer inconclusive results and was preferred for use with younger and developmentally delayed children. (J AAPOS 2019;23: 276.e1-5)

Photoscreeners and autorefractors are used to estimate the refractive status of pediatric patients using automated software; these instruments are designed to detect risk factors for amblyopia rather than amblyopia itself or structural ocular abnormalities.[1,2] Updated guidelines regarding amblyopia risk factors were published by the AAPOS Vision Screening Committee in 2013. These recommendations were made with the expectation that vision screening will be performed several times during a child's formative years and reflect the need for high specificity in younger children and high sensitivity in older children.[3]

Photoscreening and autorefraction are now recognized as appropriate methods for the vision screening of children 3-5 years of age as well as uncooperative older children. The American Academy of Pediatrics has issued a policy statement supporting the use of these technologies for preschool vision screening.[4,5] According to the US Preventive Services Task Force, the best practice instrument-based screening method is photoscreening and autorefraction.[6]

The current study aimed to test the accuracy and validity of the 2Win refractometer (Adaptica, Padua, Italy) and the plusoptiX A12R autorefractor (Plusoptix, Nuremberg, Germany) for the detection of amblyopia risk factors, comparing them with cycloplegic refraction data obtained using the Retinomax K-Plus 2 (Righton, Tokyo, Japan) handheld autorefractor keratometer as the gold standard.[7,8]

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Subjects and Methods

This study was approved by the Rovereto Hospital Ethics Committee and was conducted in accordance with the Declaration of Helsinki. The parents or guardians of all the children provided informed consent prior to their inclusion in the study. We prospectively included consecutive eyes of children examined at the Orthoptic Service and Pediatric Ophthalmology & Strabismus Clinic Rovereto Hospital. Inclusion criteria were consultation for refractive error screening or monitoring of amblyopia. Children with manifest strabismus and children unable to perform cycloplegic autorefraction with Retinomax K-Plus 2 were excluded.

Refraction

Two refractometers—the plusoptiX A12R Mobile Binocular Autorefractor 6.1.11.0 version and the 2Win Adaptica Binocular Mobile Refractometer and Vision Analyzer 4.1_161003 version—were used by 2 different orthoptists in manifest conditions; the Retinomax K-Plus 2 handheld autorefractor keratometer (cycloplegic refraction) was used by a pediatric ophthalmologist. Operation of both the plusoptiX A12R and the 2Win refractometers is straightforward, and examination may be performed by an orthoptist or a trained nurse. Both refractometers have a spherical and cylindrical range of −7.0 to +5.0 D with 0.25 D increments. The refractive values, pupil size, and gaze are displayed; AAPOS 2013 pass-fail criteria for refractive and nonrefractive amblyopia risk factors are provided on a separate screen window (for the 2Win refractometer only). The Retinomax K-Plus 2 is used with its front support to stabilize the measurements, which are taken in autorefractometry mode with maximum reliability index (quality control value >7).

Study Protocol

All children underwent manifest refraction measurements using both refractometers. Two sets of referral criteria were used for both devices. Referral criteria 1 was established according to the manufacturer Adaptica and AAPOS 2013 vision screening pass/fail criteria. Referral criteria 2 was established according to the manufacturer Plusoptix (sensitive curve).

Measurements with the Retinomax K-Plus 2 were obtained after instillation of cyclopentolate 1% or 0.5%, according to the following protocol: 1 drop in both eyes at 0 and 10 minutes, and then refraction measured 30 minutes after the first drop. A complete ophthalmological examination was then performed. The guidelines for refractive correction in infants and young children (AAO PPP 2017 Pediatric Eye Evaluations)[9] were used as failure criteria.

Mean and standard deviation were obtained for each cycloplegic measurement, each refractometer, and each eye. We correlated amount of cylinder, amount of sphere, and astigmatic power vectors J0 and J45.[10] Medians obtained for the pairs of refractometers were compared using the Wilcoxon signed-rank sum test for the right and left eyes independently; Pearson correlation coefficients were calculated to test the correlation between the pairs of refractometers for each cycloplegic measurement, always keeping the two eyes separate.

Validity measurements (sensitivity, specificity, positive and negative predictive values) were provided, in accordance with referral 1 and referral 2 criteria, to assess the diagnostic agreement between the 2Win and Retinomax K-Plus 2 and between the plusoptiX A12R and Retinomax K-Plus 2 in terms of hyperopia, myopia, astigmatism, and anisometropia. The inconclusive result rates were also calculated for the 2Win and plusoptiX A12R refractometers. All statistical analyses were performed using SAS 9.1.3 (SAS Institute Inc, Cary, NC). A P value of ≤ 0.05 was considered statistically significant.

Results

Data on 284 eyes of 142 children (mean age, 37.9 ± 19.8 months [standard deviation]) were collected. Thirty-two of 142 children (22.5%) presented with visual inattention of varying degrees due to prematurity, illness, or delayed neuropsychomotor development. The mean measurements with the Retinomax K-Plus 2 (cycloplegic refraction) for left and right eye of the 142 subjects were as follows: right eye, sphere 1.89 ± 3.07, cylinder 0.73 ± 1.35, astigmatic vector J0 0.46 ± 0.58, and astigmatic vector J45 0.01 ± 0.33; left eye, sphere 1.93 ± 3.24, cylinder 0.77 ± 1.49, astigmatic vector J0 0.55 ± 0.61, and astigmatic vector J45 0.02 ± 0.36.

Accuracy

Comparison of the mean cycloplegic measurements with the pairs of refractometers provided statistically significant differences for the right and left eyes: compared with the Retinomax K-Plus 2, both manifest refractometers presented lower means for sphere measurements; both, and especially the 2Win, presented higher means for cylinder measurements; and both presented a good correlation with the gold standard for astigmatic power vectors J0 and J45. Despite the significant differences, Pearson correlation coefficients were always >0.60, with good correlation between the 2Win and plusoptiX A12R manifest refractometers (eSupplement 1A, available at jaapos.org; Figure 1).

Validity

For refractive errors, the Retinomax K-Plus 2 examination yielded 90 positives and 52 negatives. The positive children were as follows: hyperopia 48 (33.8%), myopia 8 (5.6%), astigmatism 84 (59.1%), and anisometropia 24 (16.9%).

The sensitivity, specificity, positive and negative predictive values, and inconclusive results (%) for the 2Win and plusoptiX A12R refractometers are provided in eSupplement 1B (referral criteria 1). Our results for the 2Win showed good specificity for all refractive errors together, good sensitivity, and good PPV and NPV for myopia, astigmatism, and anisometropia, but very poor sensitivity for hyperopia. The inconclusive result rate was low (4.9%). The plusoptiX A12R demonstrated very good specificity for all refractive errors together, and

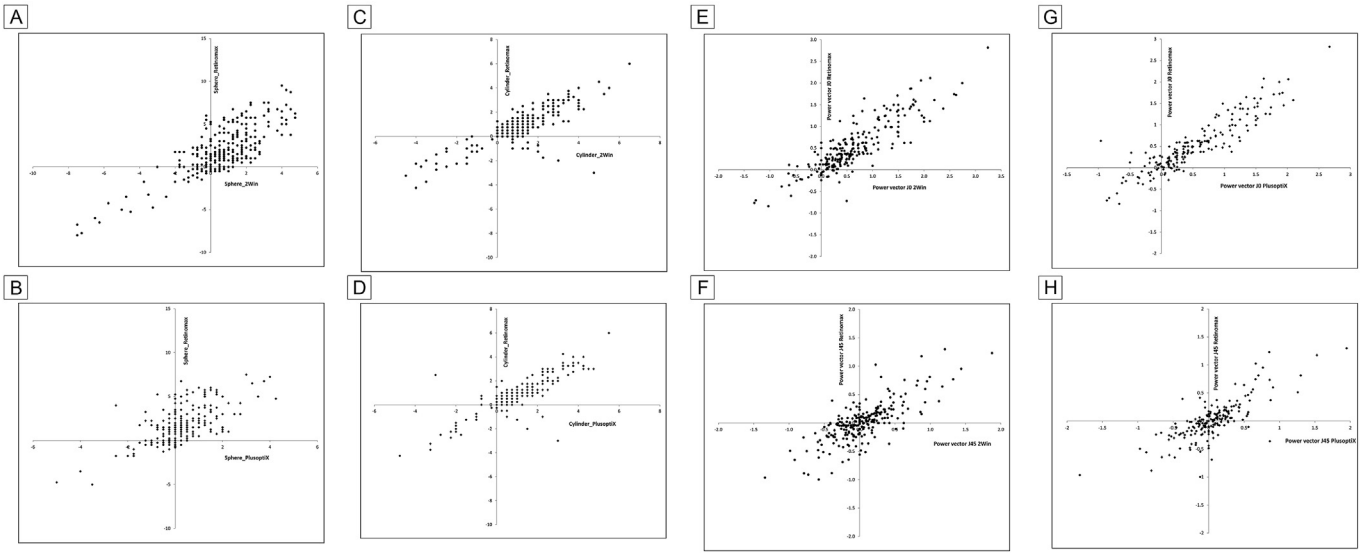

FIG 1. Amount of sphere: 2Win compared to Retinomax (A) and Plusoptix compared to Retinomax (B). Amount of cylinder: 2Win compared to Retinomax (C) and Plusoptix compared to Retinomax (D). Power vector J0: 2Win compared to Retinomax (E). Power vector J45: 2Win compared to Retinomax (F). Power vector J0: Plusoptix compared to Retinomax (G). Power vector J45: Plusoptix compared to Retinomax (H).

good sensitivity and PPV and NPV for myopia, astigmatism, and anisometropia; however, it had poor sensitivity for hyperopia. The inconclusive result rate was higher than for the 2Win device (10.6%).

The sensitivity, specificity, PPV and NPVs, and inconclusive results (%) for the 2Win and plusoptiX A12R refractometers are provided in eSupplement 1C (referral criteria 2). Our results for the 2Win showed good sensitivity for all refractive errors together but poor specificity for astigmatism and poor PPV for all refractive errors except myopia. The plusoptiX A12R also had very good sensitivity for all refractive errors together but poor PPV for anisometropia and myopia.

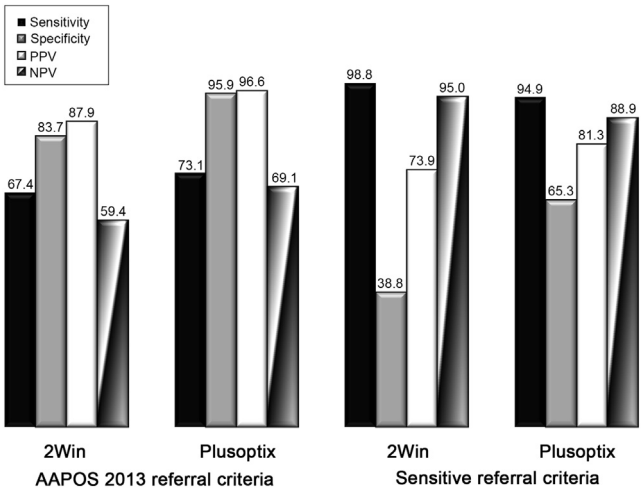

FIG 2. Validity rates obtained with the 2Win and the plusoptiX A12R using AAPOS 2013 and sensitive referral criteria. *NPV*, negative predictive value; *PPV*, positive predictive value.

The validity rates obtained with the 2Win and plusoptiX A12R refractometers using referral criteria 1 and 2 are summarized in Figure 2.

Discussion

Amblyopia risk factors (ARFs), which may be detected earlier than amblyopia itself,[11] include significant refractive errors, strabismus, and media opacities, conditions that interfere with clear retinal image formation. The AAPOS Vision Screening Committee consensus and aged-based criteria for ARFs detection using photoscreening were published in 2013. With respect to refractive errors, these criteria were predicated on refractive status. Photo-video screening instruments are fast, easy, and safe tools that require minimal cooperation from the child being tested; they provide an estimate of manifest refractive status and have been developed in an effort to improve the accuracy of vision screening while reducing costs in terms of time and personnel.[12]

Both devices tested in this study have a relatively simple user interfaces. In terms of the power supply, battery life, and recharging issues, the two devices performed similarly. Anecdotally, our orthoptists found it simpler to learn to use the plusoptiX A12R than the 2Win. The former was felt to be more intuitive and has fewer programs and apps. The 2Win was preferred for measurements on very small children and those with short attention spans and developmental delay.

Our results confirm the well-documented video refractometers' underestimation of hyperopia in manifest conditions (compared to cycloplegic automated data); the AAPOS guidelines, on the other hand, suggest manifest conditions to better differentiate compensating hyperopic

children who are at low risk of amblyopia. We observed an overestimation of astigmatism (mixed and hyperopic, not myopic) with both devices, especially with the 2Win. Both refractometers presented a good correlation with gold-standard for astigmatic power vectors J0 and J45.

In our study cohort, in using referral criteria 1, both refractometers had high specificity and lower sensitivity, in accordance with the low age of our sample and the refractive error. Williams and colleagues[13] (no data provided regarding the age of the sample studied) recently reported that the specificity of the plusoptiX A12R was lower than that observed in our study, whereas sensitivity was higher. The specificity of the 2Win, on the other hand, was better in our study than was reported previously by Kirk and colleagues,[14] and sensitivity was lower.

Sensitivity was low in the hyperopia group for both devices.[15] This may be due to the more accommodative and attractive target used (colored lights) for the 2Win especially (although the accommodative target can be switched off by the screener). We also observed that normal/high accommodation in the hyperopic group was less amblyogenic than hypo-accommodation, and a trial with +3.00 sphere lenses in both eyes (provided with the plusoptiX A12R only) was useful for remeasuring the hyperopia to better detect the refractive error and the accommodative range. The anisometropic refractive error, especially hyperopic anisometropia, was less well identified by both refractometers, which is probably due to the powerful pediatric accommodation and the asymmetrical accommodation in this type of ametropia.[16]

In the more sensitive curve of referral criteria 2 (recommended by the manufacturer), plusoptiX A12R version 6.1.11.0 showed good sensitivity but had a poor PPV for myopia and anisometropia and poorer overall specificity. In order to improve this latter parameter, more recent versions of the software propose (to pediatricians and in the S models only) five different curves (referral criteria) that the user may choose from as appropriate.

In the 2Win version 4.1_161003, the more sensitive curve (not recommended by the manufacturer) appeared to be less suitable; although the refractometer showed excellent sensitivity, its specificity was poor, and it had a low PPV for anisometropia. The reference curve provided by Adaptica would appear to be more suitable, although a selection of curves that can be employed by the examiner would also, in this case, make it possible to better clarify the potential of this device. Finally, lower inconclusive results were found with the 2Win device, probably because of the more attractive target and a better estimation of myopia.[14-17]

In conclusion, in manifest conditions, the accuracy of the 2Win and plusoptiX A12R is low in hyperopia and astigmatism; however, a good correlation between the two devices was observed. According to AAPOS 2013 vision screening pass/fail criteria, both refractometers have high specificity; sensitivity is low in hyperopia, resulting in the underestimation of hyperopic refractive error. The optional Plusoptix sensitive referral criteria seems to be appropriate for the A12R. The 2Win was preferred for measurements on younger children and those with developmental delay, as it provided fewer inconclusive results.

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