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Comparison of cycloplegic refraction between Grand Seiko autorefractor and Retinomax autorefractor in the Vision in Preschoolers–Hyperopia in Preschoolers (VIP-HIP) Study

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Abstract

PURPOSE—To evaluate the agreement of cycloplegic refractive error measures between the Grand Seiko and Retinomax autorefractors in 4- and 5-year-old children.

METHODS—Cycloplegic refractive error of children was measured using the Grand Seiko and Retinomax during a comprehensive eye examination. Accommodative error was measured using the Grand Seiko. The differences in sphere, cylinder, spherical equivalent (SE) and intereye vector dioptric distance (VDD) between autorefractors were assessed using the Bland-Altman plot and 95% limits of agreement (95% LoA).

RESULTS—A total of 702 examinations were included. Compared to the Retinomax, the Grand Seiko provided statistically significantly larger values of sphere (mean difference, 0.34 D; 95% LoA, −0.46 to 1.14 D), SE (mean, 0.25 D; 95% LoA, −0.55 to 1.05 D), VDD (mean, 0.19 D; 95% LoA, −0.67 to 1.05 D), and more cylinder (mean, −0.18 D; 95% LoA, −0.91 to 0.55 D). The Grand Seiko measured ≥0.5 D than Retinomax in 43.1% of eyes for sphere and 29.8% of eyes for SE. In multivariate analysis, eyes with SE of >4 D (based on the average of two autorefractors) had larger differences in sphere (mean, 0.66 D vs 0.35 D; $P < 0.0001$) and SE (0.57 D vs 0.26 D; $P < 0.0001$) than eyes with SE of ≤4 D.

CONCLUSIONS—Under cycloplegia, the Grand Seiko provided higher measures of sphere, more cylinder, and higher SE than the Retinomax. Higher refractive error was associated with larger differences in sphere and SE between the Grand Seiko and Retinomax. (J AAPOS 2017;21: 219–223)

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Significant refractive error is the most prevalent vision disorder in children[1, 2] and is a strong risk factor for amblyopia and strabismus.[3] Moderate hyperopia in 4- and 5-year-olds was recently found to be associated with deficits in preschool early literacy.[4] Autorefractors have been widely used to assess the refractive error status of children in vision screening, clinical practice, and research settings because of their high repeatability and their ability to be successfully administered by trained lay individuals as well as nurses and eye care professionals.[5–8] The Retinomax (Righton, Tokyo, Japan) and Grand Seiko (Grand Seiko Co Ltd, Hiroshima, Japan) autorefractors are two commonly used devices for assessing refractive error in preschool children, each with different optical systems. The handheld Retinomax autorefractor uses an internal fixation target in conjunction with built-in automatic fogging mechanisms to minimize accommodation during measurement. This closed-view environment limits the device to measurement of distance refractive error only and may induce instrument myopia.[9] The Grand Seiko is a tabletop autorefractor that uses open-view, binocular viewing of external fixation targets to control accommodation.

Although the repeatability and accuracy of these devices for measuring refractive error has been established in children and adults,[5–7, 10–15] prior research has not assessed their agreement in young children under cycloplegia. Choong and colleauges[10] compared measurements from Grand Seiko and Retinomax autorefractors on 117 primary school children 7–12 years of age in Malaysia. However, these results from school-age children may not be generalizable to younger children, because reliable measurements from autorefractors require cooperation for stable fixation.[15] Also, the agreement of measurements between refractors may be related to the refractive error status of an eye,[11] and the refractive error in preschool children tends to be more hyperopic than in school-age children, particularly compared to Asian myopic children. Because these instruments are commonly used, evaluating their agreement for measuring cycloplegic refractive error in young children is important for vision screening, clinical care, and vision research. The purpose of this study was to evaluate the agreement between the Retinomax and Grand Seiko autorefractors for measuring refractive error under cycloplegia in 4- and 5-year-old children.

Subjects and Methods

This is a secondary analysis of data from children examined for eligibility in the Vision in Preschoolers–Hyperopia in Preschoolers (VIP-HIP) Study, a multicenter, multidisciplinary, cross-sectional study conducted over a 3-year period, from 2011 to 2014. The details of the VIP-HIP Study have been published elsewhere.[4, 16] Only details of the study procedure related to this paper are described herein.

Subjects and Inclusion Criteria

Children 4- and 5 years old attending preschool or kindergarten who were potentially eligible for the VIP-HIP study based on a screening test of dry refraction were invited to undergo eligibility testing. Although participation in the VIP-HIP study was limited to those who met the VIP-HIP criteria for hyperopia (≥3.0 to ≥6.0 D in most hyperopic meridian of at least 1 eye, astigmatism ≥1.5 D, and anisometropia ≥1.0 D) or emmetropia (hyperopia

≥1.0 D; astigmatism, anisometropia, and myopia <1.0 D) and who did not have amblyopia or strabismus,[4] this secondary analysis included all children who took part in the eligibility examination for VIP-HIP and completed testing on both Retinomax and Grand Seiko, regardless of magnitude of refractive error or presence of amblyopia or strabismus. The children were recruited from communities around Salus University Pennsylvania College of Optometry (Philadelphia, PA), Ohio State University College of Optometry (Columbus, Ohio), and New England College of Optometry (Boston, MA). Institutional review board approval and written parental informed consent were obtained prior to performing any study procedures.

Procedures

Eligibility eye examinations were performed by study-certified licensed eye care professionals experienced in working with young children. Testing included monocular distance visual acuity (ATS protocol)[17] in order to identify children suspected of having amblyopia (corrected visual acuity worse than 20/40 or ≥2 lines worse than the contralateral eye) and cover testing at distance and near in order to identify children with strabismus. Prior to cycloplegia, accommodative error in the right eye was measured with the Grand Seiko (Binocular WR-5100K or WAM-5500, Grand Seiko Co. Ltd, Hiroshima, Japan) while children viewed a naturalistic target (a detailed sticker of popular cartoon characters) at 33 cm. Cycloplegic autorefraction in both eyes was performed 30–45 minutes after administration of 2 drops of 1% cyclopentolate. In the VIP-HIP study, cycloplegic autorefraction using the Grand Seiko autorefractor was an optional study procedure, while cycloplegic autorefraction using the Retinomax autorefractor (Righton, Tokyo, Japan) was required for all children. When testing with the Grand Seiko autorefractor was performed, it immediately preceded testing with the Retinomax autorefractor. Subjective refraction was not performed in these children due to their young age and limited attention span. Calibration of each autorefractor was checked at least monthly using a model eye provided by the manufacturer.

Statistical Analysis

We used the Bland-Altman plot to evaluate the agreement in refractive error measurements (sphere, cylinder, spherical equivalent) between the Grand Seiko and Retinomax autorefractors.[18] Spherical equivalent (SE) was calculated as the sphere + (cylinder/2). The refractive error measurements from the two autorefractors and their differences (Grand Seiko – Retinomax) were summarized using mean standard deviation (SD) and 95% limits of agreement (95% LoA), calculated as the mean difference ± 1.96 × SD of the difference. We evaluated the factors, including age, sex, race, SE (using the mean SE value from the Grand Seiko and Retinomax), accommodative error as measured by the Grand Seiko, and the presence of strabismus or suspected amblyopia for their association with the difference in refractive error measurements between autorefractors. These factors were first evaluated using univariate analyses then by multivariate linear regression models by including all the statistically significant factors from univariate analyses. In analyses of refractive error measurement that included both eyes of a child, the intereye correlation was accounted for by using the generalized estimating equation approach.[19]

In addition, we summarized the difference in the refractive error between eyes of a child by using the intereye vector dioptric distance (VDD).[20] To calculate the intereye VDD, we first converted the clinical notation of refractive error (S, C × β, where Sis sphere, *C* is cylinder, and β is axis) into the rectangular Fourier form [M, J0, J45]. *M* is the spherical equivalent; *J0* is the power at axis 0°/180° [J0 = (−C/2)cos2β]; and J45 is the power at 45°/135° [J45 = (−C/2)sin2β]. VDD between the two eyes of a child was then calculated as VDD = sqrt(2) × sqrt[$(M_0\text{-}M_1)^2 + (J0_0\text{-}J0_1)^2 + (J45_0\text{-}J45_1)^2$], where the subscript 0 represents the left eye, and 1 represents the right eye. VDD provides a full description of the difference in refractive error between the two eyes of a child. We assessed the agreement of VDD between the Grand Seiko and Retinomax autorefractors.

All the statistical analyses were performed in SAS v9.4 (SAS Institute Inc, Cary, NC), and two-sided *P* of <0.05 was considered to be statistically significant.

Results

Of 858 children who completed eligibility testing for the VIP-HIP study, 702 (81.8%) children (1,404 eyes) were tested with both the Grand Seiko and the Retinomax autorefractors and were included in the statistical analysis of agreement. The characteristics of the 702 children (53% female) included in the analysis are reported in eTable 1. Age ranged from 45 to 72 months, with a mean age and standard deviation of 58 ±5.6 months (median, 58 months; IQR, 54–62 months). Of the 702, 27% were Hispanic, and 69% were African American. The majority of children (95%) were enrolled from a Head Start program. Thirty-one children (4.4%) had suspected amblyopia, and 8 (1.1%) had strabismus at distance or near. The mean spherical equivalent from cycloplegic Retinomax was 1.68 ± 1.53 D, with a range of −2.00 to 7.00 (median, 1.50 D; IQR, 0.50–2.75).

Agreement of Refractive Error between Autorefractors

Cycloplegic refractive error measurements between the autorefractors are provided in eTable 2; Bland-Altman plots, in eFigures 1–4. On average, the Grand Seiko measured larger values of sphere than the Retinomax (mean, 2.33 vs 1.99 D; $P < 0.0001$), with a mean difference of 0.34 D (95% LoA, −0.46 to 1.14 D). The Grand Seiko provided larger sphere than the Retinomax by 0.5 to 0.74 D in 297 eyes (21.2%), by 0.75 to 0.99 D in 184 (13.1%) eyes and by ≥1 D in 123 eyes (8.8%); their difference was within ≥0.25 D in only 268 eyes (19.1%). See eTable 3. The magnitude of cylinder from the Grand Seiko was greater than the Retinomax (−0.75 vs −0.57 D, $P < 0.0001$), with a mean difference of −0.18 D (95% LoA, −0.91 to 0.55 D). The mean difference in spherical equivalent was 0.25 D (95% LoA, −0.55 to 1.05 D), and the Grand Seiko had larger spherical equivalent than the Retinomax by 0.5–0.74 D in 233 eyes (16.6%), by 0.75 to 0.99 D in 113 (8.1%) eyes, and by ≥1 D in 72 eyes (5%); their spherical equivalent difference was within ±0.25 D in only 456 eyes (32.5%). See eTable 3. The mean difference in VDD was 0.19 D (95% LoA, −0.67 to 1.05 D).

Factors Associated with Difference in Refractive Error between Autorefractors

In univariate analysis, neither child age nor sex was significantly associated with the differences in refractive error measurements between autorefractors (eTable 3). African

American children had a smaller mean difference between autorefractors than other children in sphere (0.32 vs 0.39 D, $P = 0.02$) and in spherical equivalent (0.23 vs 0.30 D, $P = 0.01$). The degree of refractive error was significantly associated with refractive error differences between the autorefractors (eTable 4). Eyes with larger refractive error tended to have larger differences in sphere (Pearson correlation coefficient, $\rho = 0.17$; $P < 0.0001$ [eFigure 1]) and spherical equivalent ($\rho = 0.23$, $P < 0.0001$ [eFigure 3]). Compared to eyes with spherical equivalent of ≤4 D (based on the average of measurements from the two autorefractors), eyes with spherical equivalent of > 4 D had larger differences in sphere (mean, 0.67 D vs 0.31 D; $P < 0.0001$) and spherical equivalent (mean 0.60 D vs 0.21 D, $P < 0.0001$ [eTable 4, eFigure 3]).

In right eyes (n = 693) with accommodative error measured using the Grand Seiko, greater accommodative error was significantly associated with larger difference in refractive error measurements between autorefractors for sphere ($\rho = 0.20$, $P < 0.0001$ [eFigure 5]), spherical equivalent ($\rho = 0.30$, $P < 0.0001$) and VDD ($\rho = 0.10$, $P = 0.009$) but not for cylinder ($\rho = -0.01$, $P = 0.80$). In the eyes with accommodative error of > 1.35 D (cutpoint determined based on 95% percentile in emmetropic subjects) compared to eyes with accommodative error of ≤1.35 D, the mean difference between the autorefractors was significantly larger for sphere (0.54 vs 0.36 D, $P = 0.0003$), spherical equivalent (0.44 vs 0.27 D, $P = 0.0008$), and VDD (0.29 vs 0.18 D, $P = 0.046$). See eTable 4.

The eyes of children with strabismus or suspected amblyopia had larger mean differences between the Grand Seiko and Retinomax in spherical equivalent (0.42 vs 0.24 D, $P = 0.02$) than the eyes without strabismus and suspected amblyopia (eTable 4).

In multivariate models that included the significant factors from univariate analysis (race, refractive error, accommodative error, presence of strabismus or suspected amblyopia), only spherical equivalent remained significantly associated with the differences in refractive error measurements between the two autorefractors (eTable 5). Compared to eyes with spherical equivalent of ≤4 D, eyes with spherical equivalent of > 4 D had larger differences in sphere (mean, 0.66 vs 0.35 D; $P < 0.0001$) and spherical equivalent (mean 0.57 vs 0.26 D, $P < 0.0001$).

Discussion

In this secondary analysis of VIP-HIP study data we evaluated the agreement of cycloplegic refractive error measurements between two commonly used autorefractors, the Grand Seiko and the Retinomax. Overall, our study found small, statistically significant differences in cycloplegic refraction between autorefractors, with the Grand Seiko measuring larger values of sphere (mean, 0.34 D larger) and spherical equivalent (mean, 0.25 D larger) than the Retinomax. We also found that in eyes with hyperopia of > 4 D, the cycloplegic refractive error measurements from the Grand Seiko were larger than those from the Retinomax by a mean of 0.66 D in sphere and 0.57 D in spherical equivalent. Because the differences were greater in the children with higher accommodative error, which was associated higher magnitudes of hyperopia,[16] and accommodative error did not remain significant in multivariate analysis, it does not appear that these differences are attributable to differences in accommodation. Our results showed a difference of > 0.50 D in 43% of eyes for sphere and 30% of eyes for spherical equivalent. Based on prior studies of variability of retinoscopy measurements among differing examiners, which concluded that a refractive difference of > 0.5 D should be considered significant,[21, 22] these differences in refractive error between autorefractors are clinically significant.

Since its introduction in 1995, the Retinomax has been widely used for assessing refractive error, particularly for children in both clinical care and research settings. Several studies found that the Retinomax had high repeatability and good agreement with cycloplegic retinoscopy.[5, 13, 15, 23] In fact, the cycloplegic Retinomax has been used for comparison to measure refractive error in large epidemiological pediatric eye disease studies, including the Multi-Ethnic Pediatric Eye Disease Study and Baltimore Pediatric Eye Disease Study.[24, 25] However, Wesemann and colleagues[15] found that Retinomax measurements in children under cycloplegia provided slightly more "plus" (by a mean of 0.25–0.50 D in spherical equivalent) than subjective refraction or retinoscopy in children and adults. Cordonnier and colleagues[11] reported that the Retinomax used on children under cycloplegia had decreased accuracy in cases of higher ametropia (sphere >3.5 D or myopia >3 D) than cycloplegic retinoscopy, in particular with respect to cylinder power.

The Grand Seiko (Shin-Nippon SRW-5000) was first used in the mid-1990s for research on accommodation and refractive error. It has since undergone a number of developments to improve its clinical and research utility and has been used widely in optometry and vision science.[26] Several clinical evaluations of the Grand Seiko (WAM-5500, WR-5100K) found that its measurements were very similar to those from a subjective refraction (mean difference within 0.15 D) over a wide range of refractive error (−15 to 6.5 D) in adults.[12, 14, 27, 28]Choong and colleagues[10] found that the Grand Seiko WR-5100K provided similar measurement of SE as a subjective refraction (−0.44 D vs −0.37 D, $P = 0.21$) in 7- to 12-year-olds (N = 117).

Although the repeatability and accuracy of these devices for measuring refractive error has been established in children and adults,[5–7, 10–15] prior research has not assessed their agreement in young children. Choong and colleagues[10] showed a mean sphere difference of 0.24 D (−0.07 D from the Grand Seiko vs −0.31 D from the Retinomax), a mean cylinder difference of −0.27 D (−0.73 D vs −0.46 D), and a mean SE difference of 0.10 D (−0.44 D vs −0.54 D) under cycloplegic conditions. Although we studied 4- and 5-year-olds, who are likely to be hyperopic (with mean SE of 1.68 D from cycloplegic Retinomax) and had a much larger sample size (N = 702 children), the differences between the Retinomax and the Grand Seiko from our study (0.34 D in sphere, −0.18 D in cylinder, and 0.25 D in spherical equivalent) are in the same direction and similar magnitude as the differences in the study by Choong and colleagues[10] (with mean SE of −0.54 D from cycloplegic Retinomax).

The present study found that the Grand Seiko measured (under cycloplegia) higher sphere, greater cylinder, and higher spherical equivalent than the Retinomax. It is possible that these differences in cycloplegic refractive error measures between autorefractors in these 4- and 5-year-olds may be partly due to spherical aberration in the peripheral portion of the cyclopleged pupil[29, 30] if one autorefractor is better at excluding the more peripheral portion of the reflex. However, our study did not collect data on pupil size at the time of the cycloplegic measurement. As described above, cycloplegic Retinomax measurement has been compared to retinoscopy; however, cycloplegic Grand Seiko versus retinoscopy has not been studied.

This study is based on data from the VIP-HIP and provides the largest sample size to date for assessing the agreement between the Grand Seiko and Retinomax autorefractors and the only study for comparing measures of cycloplegic refractive error in young children. In spite of its large sample size, this study has several limitations. First, the order of measuring cycloplegic refractive error using the Retinomax and Grand Seiko was not randomized, because VIP-HIP was not designed to compare these two autorefractors. Instead, cycloplegic refractive error was always measured first by the Grand Seiko and immediately afterward by the Retinomax; thus a systemic bias could have been introduced. However, we believe that the short time interval for measuring refractive error using these objective autorefractors would not introduce substantial bias from either the effect of cycloplegia or because of subject fatigue. Second, the study did not have the refractive error measurements from cycloplegic retinoscopy, the gold standard for measuring refractive error; thus we could not make definite inferences on which device provides more accurate measurements of refractive error. However, repeatability and accuracy of these devices for measuring refractive error has been previously established in children and adults.[5–7, 10–15] Finally, the children examined were limited to those believed to be candidates for the VIP-HIP study based on screening results consistent with emmetropia or moderate hyperopia (3–6 D); therefore, children with severe myopia or astigmatism were under-represented, limiting the generalization of our study findings to the general population of children.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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