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ORIGINAL ARTICL

Impact of Confidence Number on the Screening **Accuracy of the Retinomax Autorefractor**

THE VISION IN PRESCHOOLERS STUDY GROUP

ABSTRACT

Purpose. To assess the impact of Retinomax reading confidence number on screening accuracy and to determine whether repeated testing to achieve a higher confidence number improves screening accuracy in preschool children.

Methods. Lay and nurse screeners trained in the use of the Retinomax Autorefractor screened 1452 children enrolled in the Vision in Preschoolers (VIP) Phase II Study. All children also received a comprehensive eye examination. Using statistical comparison of correlated proportions, we compared sensitivity and specificity for detecting any VIP-targeted condition and conditions grouped by severity and by type (amblyopia, strabismus, significant refractive error, and unexplained decreased visual acuity) among three groups of children who had confidence numbers below, at or above the manufacturer's suggested confidence number of 8. The reading with the highest confidence number for each eye was used in the analysis. Each child's confidence number group was defined based on the lower confidence number of the pair of readings for the two eyes. Among the 771 (53.1%) children who had repeated testing either by lay or nurse screeners because of a low confidence number (<8) for one or both eyes in the initial testing, the same analyses were also conducted to compare results between the initial reading with confidence number <8 and repeated test reading with the highest confidence number in the same child. These analyses were based on the failure criteria associated with 90% specificity for detecting any VIP condition in VIP Phase II. We also examined the association between ocular conditions and confidence number. Hochberg procedure was used to adjust the p value for multiple comparisons.

Results. A lower confidence number category was associated with higher sensitivity (0.78, 0.65, and 0.61 for $\lt 8$, 8, $\gt 8$, respectively, $p = 0.04$) but much lower specificity (0.64, 0.89, and 0.93, $p < 0.0001$) of detecting any VIP-targeted condition. Through repeated testing, 87% of readings that initially had a confidence number below 8 reached 8 or above, and the increased confidence number that resulted from repeated testing was associated with significantly higher specificity (0.81 vs. 0.86, $p = 0.002$) and a nonsignificant change (by -0.04 to 0.03) in sensitivities. Children with any VIP-targeted condition, significant refractive error, hyperopia, astigmatism, or myopia were more likely to have a low confidence number.

Conclusions. A higher confidence number obtained during Retinomax Autorefractor screening is associated with better screening accuracy. Repeated testing to reach the manufacturer's recommended minimum value is worthwhile in preschool vision screening with the Retinomax. Failure to achieve manufacturer's recommended minimum value through repeated testing should be a factor considered in referring children for a comprehensive eye examination. (Optom Vis Sci 2007;84:181-188)

Key Words: confidence number, Retinomax Autorefractor, screening accuracy, preschool vision screening

he Retinomax Autorefractor has been identified as a useful tool for screening refractive error in preschool children.¹⁻⁷ This handheld autorefractor can be used by individuals with minimal ophthalmic experience² and the process of measurement is quick and simple. During the measurement of an eye, the Retinomax provides up to eight measured values of refractive error (including sphere, cylinder, and axis) and then determines a single best representative reading (based on the measured values) along with a confidence number for the representative reading. The con-

fidence number ranges from E to 10, with higher confidence number indicating better reliability of the reading for the eye. When the confidence number is below the manufacturer's recommended minimum value of 8, the manufacturer states that care is required in the use of the measurement results and that the screening should be repeated.⁸ When the Retinomax is used with preschool-aged children, the confidence number of the initial reading is often below the manufacturer's recommended minimum value of 8. For example, in the Vision in Preschoolers (VIP) Phase II study, about 21% (20.1% by lay screen-

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ers, and 22.3% by nurse screeners) of eyes had a confidence number below 8 in the first attempt using Retinomax, and required repeated testing.² In the screening setting, especially when screening preschool children, repeated testing to achieve a higher confidence number may be time-consuming. Therefore, it is important to know whether it is worthwhile to perform repeated testing to achieve a higher confidence number when the first reading is below the manufacturer's recommended minimum value.

To date, there are no reports concerning the impact of confidence number on the screening accuracy of the Retinomax, nor concerning whether repeated testing to achieve a higher confidence number is worthwhile. The purpose of the present article is to address the impact of confidence number of a reading on the screening accuracy (sensitivity and specificity) of the Retinomax. Specifically, we examine whether repeated testing can help achieve higher confidence number and determine whether a higher confidence number achieved during retesting improves screening accuracy. Additionally, we examine whether certain ocular conditions are associated with obtaining a low confidence number with the Retinomax.

METHODS

Details of the VIP Phase II Study design have been published previously,² and are thus described only briefly here.

Participants

Three- and four-year-old children (as of September 1, 2003) who were participants in Head Start were invited to enroll into the VIP Phase II Study through five VIP clinical centers (Berkeley, CA; Boston, MA; Columbus, OH; Philadelphia, PA; Tahlequah, OK). Among the 1452 children who completed the comprehensive eye examination [Gold Standard Eye Examinations (GSE)], 1437 children completed the screening of Retinomax by both lay and nurse screeners and 1451 children completed the screening by either lay or nurse screeners (seven children each completed screening by lay screeners only and by nurse screeners only). The research was approved by the institutional review board of each clinical center and written informed consent was obtained from parents before testing of each child.

Comprehensive Eye Examination

The comprehensive eye examination was conducted in the VIP vans⁹ by optometrists and ophthalmologists who were experienced in providing care to children. Screeners and GSE examiners were masked to each others' results. As part of comprehensive examination, monocular distance visual acuity (VA) assessment using the Electronic Visual Acuity system,¹ cover testing at distance and near, and cycloplegic retinoscopy was conducted to determine whether a child had any of the four VIP rargeted conditions (amblyopia, strabismus, significant refractive error, and unexplained reduced VA). Unilateral amblyopia is defined as three-line (presumed amblyopia) or two-line (suspected amblyopia) interocular acuity difference accompanied by strabismus or anisometropia or both. Reduced VA was defined as VA worse than 20/50 in 3-year olds and worse than 20/40 in 4-year olds. Bilateral ambiyopia was defined as reduced VA and an amblyogenic factor in each eye (astigmatism >2.5 D, hyper-

opia >5.0 D, or myopia >8.0 D). GSE results were also used to determine the severity of the conditions, categorized into three hierarchical groups (Group 1, 2, and 3).¹ Group 1 is considered to be most severe, very important to detect, and should be treated early. Group 1 includes bilateral amblyopia, presumed unilateral amblyopia with worse eye VA of 20/64 or worse, constant strabismus, hyperopia ≥5.0 D, astigmatism \geq 2.5 D, myopia \geq 6.0 D, or severe anisometropia (interocular difference >2 D in hyperopia, >3 D in astigmatism, or >6 D in myopia). Group 2 includes suspected unilateral amblyopia, presumed unilateral amblyopia with worse eye VA better than 20/64, intermittent strabismus, hyperopia of >3.25 and $<$ 5.0 D and interocular difference in spherical equivalent (SE) ≥0.5D, astigmatism of >1.5 and <2.5 D, myopia of \geq 4.0 and <6.0 D. Group 3 includes bilateral or unilateral reduced VA, hyperopia of \geq 3.25 and \leq 5.0 D and interocular difference in SE $<$ 0.5 D, or myopia of $>$ 2.0 and <4.0 D.

Retinomax Autorefractor Screening

The Retinomax Autorefractor (Nikon Retinomax K+, Nikon Inc, Tokyo, now manufactured by Righton Ophthalmic Instruments, Tokyo) is a hand-held instrument that measures refractive error monocularly along two meridia. Measurements can be made in auto measurement mode, continuous measurement mode, or quick mode. In the auto measurement mode, used in the present study, the screener places the instrument's headrest on the child's forehead, encourages the child to fixate the internal target, and focuses the mire in the center of the right pupil while up to eight measured values are taken automatically by the autorefractor. The screener then repeats the process for the left eye. Based on the eight measured values, the instrument calculates a single representative reading for each eye and a confidence number for the representative reading. The instrument's printout shows the eight individual measured values of refractive error, the single representative reading and the confidence number. The confidence number, which indicates variability of measured values, ranges from 1 to 10, with larger confidence numbers indicating better reliability. If there are less than three valid measured values, the confidence number cannot be calculated for a reading and "E" (Error) is shown instead of a confidence number. The manufacturer's recommended minimum confidence number is 8. In the VIP Study, up to three readings per eye were permitted when an initial confidence number below 8 was obtained; even if the confidence number from all three readings was <8, no further repeated testing was performed. The reading was repeated only on the eye(s) with confidence number <8.

Data Analysis

We examined the impact of confidence number of Retinomax readings on accuracy by two different approaches.

For the first (highest confidence number) approach, the reading associated with the highest confidence number for each eye was determined. Based on these two readings (reading with the highest confidence number for the right eye and reading with the highest confidence number for the left eye), each child was then classified into one of three groups (confidence number ≤ 8 , 8, ≥ 8) on the basis of the lower of the confidence numbers of these two readings. The failure criteria associated with 90% specificity in VIP Phase II were used to classify

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each child as Retinomax screening pass/failure.² For each of three groups of children, we calculated the overall sensitivity and specificity as well as the sensitivity for detecting conditions grouped by severity [Group 1 (most severe), 2, 3 (least severe)] and by type (amblyopia, strabismus, significant refractive error, and unexplained decreased VA). Statistical comparisons for sensitivity and specificity among the three groups of children with increasing confidence number were made using a test for linear trend in proportions.

To determine how the confidence number affects the screening sensitivity and specificity, we examined the relation between several ocular conditions as determined from GSE and confidence number by comparing the proportions of children with each ocular condition among three confidence number groups. The ocular conditions examined were (i) any VIP-targeted condition (amblyopia, strabismus, significant refractive error, or unexplained reduced VA), (ii) the three hierarchical groups of conditions based on severity (Groups 1, 2, and 3), (iii) each of the four individual VIP-targeted conditions, (iv) hyperopia, (v) astigmatism, and (vi) myopia.

Second, because 771 children had at least two repeated readings by either the lay or the nurse screeners because of a low confidence number for one or both eyes on the initial reading, we were able to conduct a within-subjects comparison between results with low confidence number from initial reading vs. highest confidence numbers from the repeated testing in the same individual. This second (initial vs. highest) analysis allowed us to address the question: "Does repeated testing to achieve a higher confidence number improve sensitivity or specificity?"

To demonstrate how the above described analyses were performed exactly, we present an example of a child, whose confidence number pair (OD, OS) from initial resting was (4, 5) and whose confidence number pairs from two repeated restings were (6, 3) and (5, 8) (we permitted a maximum of three readings per eye). The highest confidence number for OD is 6, and for OS it is 8, and the lower confidence number of this highest confidence number pair (6, 8) is 6. Thus this child is assigned to the group of confidence number of <8. The readings associated with highest confidence number pair (6, 8) were used in defining screening pass/failure for this child in the first (highest confidence number) analysis approach. In the second (initial vs. highest) analysis approach, the comparison was made between the readings associated with confidence number pair of $(4, 5)$ of initial testing vs. highest confidence number pair of (6, 8) from repeated testing. When the confidence number from a repeated testing is the same as that of initial resting or that of other repeated testing, the first reading associared with such confidence number is used in the first approach analysis. For example, consider the case in which the confidence number pair (OD, OS) from initial testing was (6, 3) with (4, 5) and (6, 5) in two consecutive repeated testings. The reading associated with the confidence number of 6 in OD from initial testing, and the reading associated with the confidence number of 5 in OS from the first reresting were used in first (highest confidence number) analysis approach. In the second (initial vs. highest) analysis approach, the comparison was made between the reading associated with confidence number of (6, 3) from initial testing, and reading associated with confidence number of 6 in OD from second retesting, and confidence number of 5 in OS from the first retesting.

The above analyses were initially performed separately for measurements made by lay screeners and measurements made by nurse screeners. However, because no substantial differences were found

between results for lay screeners vs. nurse screeners, we combined the data from lay and nurse screeners to increase staristical power and to improve the clarity of presentation. In this combined statistical analysis, the correlation between readings from lay and nurse screeners in the same child was adjusted by using the Generalized Estimating Equations (GEE).¹⁰

Because multiple tests were performed for the comparison of sensitivity of detecting hierarchically grouped conditions, and each of VIP targeted conditions, we used the Hochberg procedure (a less conservative and more powerful procedure than Bonferroni method) to adjust the p values from multiple comparisons, and to control the overall type I error (0.05, two-sided).¹¹ This procedure was executed by PROC MULTTEST in SAS/STAT 9.1 (SAS Institute, Cary, NC).

RESULTS

Distribution of Confidence Number

Using the confidence number from initial resting on each eye of a child, the lower confidence number ranged from E to 10, and initial resting did not provide a reliable measure of refraction (confidence number <8) in 34% readings (Table 1). However, through retesting on those eyes with confidence number <8 on initial resting, the Retinomax Autorefractor provided a reliable measure (confidence number \geq 8) of refraction in 95.4% of readings either from the initial resting or from retesting (Table 1, right column). Of note, even with retesting, 16 readings (eight from lay and eight from nurse screeners, respectively) were marked as "Error (E)," yet these readings did provide values for sphere, cylinder and axis.

Comparisons of Screening Accuracy among Three **Groups of Confidence Number**

Using the failure criteria that provided 90% specificity,² the comparisons of sensitivity and specificity for children with confidence numbers grouped by the lower confidence number between the two highest confidence numbers obtained for the left and right eyes of a child are shown in Table 2. The sensitivity for the detection of any VIP-targeted condition was higher with lower confidence number (0.78 for confidence number <8, 0.65 for confidence number of 8, and 0.61 for confidence number $>$ 8; adjusted p = 0.04, linear trend test). However, the specificity was higher with higher confidence number (0.64 for confidence number <8, 0.89 for confidence number of 8, and 0.93 for confidence number >8 ; adjusted $p < 0.0001$, linear trend test).

Sensitivity for detecting each hierarchically grouped condition and individual VIP rargeted conditions was also highest in children with confidence number \leq 8, and lowest in children with confidence number >8. However, the difference was not significant after adjustment for multiple comparisons (Table 2).

Ocular Conditions Associated with **Confidence Number**

The prevalence of one or more of the VIP-targeted conditions was higher among children with lower confidence number (<8) as measured by either lay or nurse screeners (Table 3; $p < 0.0001$). The prevalence of VIP-rargeted conditions, whether considered by each severity level or each disorder type, was highest when the confidence

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TABLE 1.

Distribution of confidence numbers of Retinomax Autorefractor readings by lay and nurse screeners on 1451 children (Number of readings = 2888, 1444 each based on testing by lay screeners and by nurse screeners)

TABLE 2.

Comparison of sensitivity and specificity for the Retinomax Autorefractor^a among three confidence number groups based on the lower confidence number between eyes for each child

Using the failure criteria at 90% specificity determined from Phase II of VIP.

bLower confidence number of two readings from each child: (1) the reading with the highest confidence number from the child's right eye and (2) the reading with the highest confidence number from the child's left eye.

From linear trend test, with correlation of measures from same child adjusted by GEE.

^dAdjusted by the Hochberg procedure.

number was <8 in all cases; however, the differences between groups based on the lower confidence number were statistically significant only for Group 1 and Group 2 conditions (adjusted $p = 0.03$) and significant refractive error (adjusted $p < 0.0001$).

dren with confidence numbers of ≥8. As shown in Fig. 1C, the percentage of children with astigmatism is much higher in children with confidence number <8 than confidence number of $≥8$ (26.6% vs. 13.9%, p = 0.001).

Further evaluation of the association of confidence number with the prevalence of refractive error was performed. The confidence number of Retinomax Autorefractor readings was positively associated with the presence of hyperopia and myopia (Fig. 1A and B). Children with confidence number <8 as measured either by lay or nurse screeners were more likely to be myopic ($p = 0.003$) and hyperopic ($p = 0.06$) than were chil-

Impact of Confidence Number on Screening **Accuracy: Results from Repeated Testing**

Repeated testing was performed by lay screeners (475 cases) or nurse screeners (490 cases) in 771 children because the confidence number from the initial reading did not reach the manufacturer's

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TABLE 3.

Comparison of prevalence of ocular conditions between two confidence number groups of children based on the lower confidence number for a child

Values inside parentheses indicate percentages.

a Lower confidence number of two readings from each child: (1) the reading with the highest confidence number from the child's right eye and (2) the reading with the highest confidence number from the child's left eye.

^bFrom Fisher's exact test.

"Adjusted by the Hochberg procedure.

FIGURE 1.

Confidence number vs. child's refraction. Confidence number groups were defined based on the lower number of two readings from each child: (1) the reading with the highest confidence number from the child's right eye and (2) the reading with the highest confidence number from the child's left eye. Confidence number <8 group includes children whose confidence number was <8 for testing conducted by either lay or nurse screeners, and ≥8 group includes children whose confidence number was ≥ 8 both for testing conducted by lay screeners and testing conducted by nurse screeners. Refraction was determined based on the cycloplegic retinoscopy, conducted as part of a comprehensive eye examination. Confidence number is marginally associated with hyperopia ($p = 0.06$) (A), significantly associate with myopia ($p = 0.003$) (B), and astigmatism ($p < 0.0001$) (C).

recommended value in one or both eyes of the child. Of note, because of the violation of protocol, repeated testing was not performed in seven children, although their initial reading had a confidence number <8. Among these 771 children, 194 (25.2%) children required retesting by both lay and nurse screeners, 281 (36.5%) required retesting by lay screeners only, and 296 (38.4%) required retesting by nurse screeners only. Testing could be repeated up to two additional times for a maximum total of three readings per eye per child. The confidence number of the repeated test was approximately 2 units better than initial testing, and 840 (87%) retesting readings reached the manufacturer's recommended minimum value of 8 (data not shown).

Children whose readings did not reach the minimum value of 8 by either lay or nurse screeners were more likely than the remaining children in the retested group to have a VIP-targeted condition (50.4% vs. 34.9%, adjusted $\rm p =$ 0.007) and significant refractive error $(46.2\% \text{ vs. } 28.4\%, \text{ adjusted p} = 0.001)$ (Table 4).

Using the 90% specificity failure criteria, sensitivities (based on repeated testing) for detecting any VIP-targeted condition, the hierarchically grouped conditions, and the four VIP-targeted conditions did not change substantially (by -0.04 to 0.03, p $>$ 0.05); however, the specificity significantly improved by 0.05 (0.81 vs. 0.86, $p = 0.002$) (Table 5).

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TABLE 4.

Comparison of prevalence of ocular conditions between two groups of children based on the lower confidence number for a child in retesting

Values inside parentheses indicate percentages.

a Lower confidence number of two readings from each child: (1) the reading with the highest confidence number from the child's right eye and (2) the reading with the highest confidence number from the child's left eye.

^bFisher's Exact test.

"Adjusted by the Hochberg procedure.

TABLE 5.

Comparison of sensitivity and specificity^a between readings with confidence number <8 in initial testing vs. confidence number based on the lower of (1) the highest confidence number reading from the right eye and (2) the highest confidence number from the left eye, based on repeated testing in 767 children in whom >1 Retinomax readings were taken in one or both eyes by lay or nurse screeners

^aUsing the failure criteria at 90% specificity determined from Phase II of VIP.

bReading is the lower confidence number of two readings from each child: 1) the reading with the highest confidence number from the child's right eye and 2) the reading with the highest confidence number from the child's left eye, based on the repeated testing. From the chi-square test with correlation between measures from same children adjusted by GEE.

DISCUSSION

This is the first study to examine the impact of confidence number on the screening accuracy of the Retinomax Autorefractor. A measure of refraction with the recommended confidence number of 8 or greater was obtained in 95.4% of readings from either initial testing or retesting of 1451 children. Methods used in the VIP study to maximize the number of readings with the recommended confidence number were encouragement of the child, training of the screeners and strict adherence to the Retinomax operation instructions. The results indicate that higher confidence numbers are associated with significantly higher specificity, and decreased sensitivity. The increase in specificity between confidence numbers \leq 8 (0.64) and confidence numbers \geq 8 (0.93) is far more than the decrease in sensitivity (e.g., 0.78 vs. 0.61 for any VIP-targeted condition). This fact, coupled with the much higher proportion of children without vision disorders than with vision disorders implies that higher confidence numbers result in an increased accuracy in screening. The increase in specificity resulting from the use of readings with higher confidence numbers would substantially decrease over-referrals without much decrease in the identification of children with any VIP-targeted condition.

Repeated testing with the Retinomax improved confidence number to the manufacturer's recommended value (≥8) in 87% of

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cases. In addition, the higher confidence number achieved by repeared testing significantly increased the accuracy (specificity) of screenings through a significant decrease in over-referrals. This suggests that repeated testing to reach the manufacturer's recommended minimum value is worthwhile in screening. Furthermore, the results suggest that children in whom a reading of the recommended confidence level cannot be achieved after repeated testing should be referred for a comprehensive eye exam. In the group of 117 children in whom the manufacturer's recommended confidence value was not reached even in retesting in this study, 50.4% had at least one VIP-targeted condition and 46.2% had a significant refractive error. The increased prevalence of ocular conditions in children with readings of low confidence number may be due to an inability of the instrument to obtain a sufficient number of valid readings in these children or the inability of these children to cooperate with the screener (perhaps leading to improper alignment or focus).

The Retinomax Operation Manual states that refractive error measurement by Retinomax may be impossible or inaccurate if a child has ocular pathology, such as cataract, abnormal retina, or opaq ue condition of the cornea, crystalline lens or vitreous body, or if pupil has a diameter of 2.5 mm or less.⁸ Our results indicate that several other ocular conditions including astigmatism, myopia, high hyperopia, and significant refractive error in general, are associared with lower confidence numbers. Furthermore, over half of the children with confidence numbers below the manufacturer's recommended value were found to have one or more of the VIP-targeted conditions. Therefore, this association suggests that a repeated low confidence number itself should be a factor to be considered in referring children for a comprehensive eye examination.

Although these findings are drawn from the screening setting, they might also be applied to the clinical setting. The clinician taking a Retinomax reading should be aware of the importance of the confidence number; when initial reading is below manufacturer's recommended minimum value, the clinician should perform repeated testing to make sure that a reliable reading is obtained.

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Reproducibility and accuracy of measurements with a hand held autorefractor in children

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Abstract

*Aim***—To determine reproducibility and accuracy of the Nikon Retinomax autorefractor when used with children who were made cycloplegic.**

*Methods***—Autorefraction and retinoscopy or subjectively refined retinoscopy (where, under the patient's direction, the refraction was varied until the best visual acuity was achieved) were performed on the right eye of 47 children, age 11–93 months. Autorefraction was performed using the Nikon Retinomax, which provides up to eight measured values of refractive error and one representative measurement of refractive error.**

*Results***—Autorefractor measurements were successfully obtained from 7/9 children age 3 years or younger, and from all older children. Vector methods were used** to calculate differences. Retinomax **reproducibility averaged 0.43 D. Unbiased Retinomax and retinoscopy measure**ments differed by an average of 0.82 D. **Unbiased Retinomax and subjectively re**fined retinoscopy differed by an average of **1.03 D.**

*Conclusions***—Reproducibility of Retinomax measured values in children is comparable with reproducibility of retinoscopy, subjective refraction, and autorefraction measurements in adults. AgreementbetweenRetinomax andretinoscopy and agreement between Retinomax and subjective refinement in children is comparable with agreement between autorefraction and subjective refraction in adults. The study indicates that the Retinomax is a useful instrument for measuring refractive errors in young children.**

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High refractive error (for example, anisometropia, astigmatism, hyperopia) in early childhood can lead to amblyopia. $1-4$ There is evidence that amblyopia can be prevented if children at risk receive optical correction at an early age.⁵⁻⁸ Thus, it may be valuable to identify and correct children for high refractive error as early as possible.

The traditional method for detecting refractive errors in preschool age children involves cycloplegic or non-cycloplegic retinoscopy. Although skilled retinoscopists can provide reliable and valid measures of refractive error in children,³ ⁹ retinoscopy is subject to interobserver variation.^{10 11} For this reason, retinoscopy measurements are not an appropriate 'gold standard' for evaluating measurements of refractive error. Recently, there has been an emphasis on the development of measurement tools that are free of operator bias, can be used by lay individuals, and provide a 'gold standard' for retinoscopy measurements. One such tool is the Nikon Retinomax autorefractor (Nikon, Melville, NY, USA), a hand held instrument that measures refractive error. To date, there are no reports of the efficacy, validity, or reliability of the Retinomax for the measurement of refractive error in children.

The aim of this study was to determine if the Retinomax can be used successfully with children under cycloplegic conditions, to examine the reproducibility of the Retinomax in measuring refractive error in children, and to assess the agreement between the Retinomax and retinoscopy and the agreement between the Retinomax and subjective refinement. For each eye, the Retinomax provides up to eight measured values, and one representative measurement of refractive error. We evaluated reproducibility of Retinomax measurements through analysis of Retinomax measured values of refractive error. We evaluated measurement agreement by comparing Retinomax representative measurements with retinoscopy and subjective refinement measurements.

Methods

MATERIALS

Retinomax autorefractor

The Nikon Retinomax is a hand held instrument for measuring refractive error. The instrument is designed for easy use by individuals with minimal ophthalmic experience. The Retinomax provides up to eight measured values of refractive error (including sphere, cylinder, and axis) and then determines a single best representative measure based on the measured values. The algorithm used by the manufacturer for determination of the representative measurement is not published.

SUBJECTS

Subjects were 47 consecutive patients, under the age of 8 years, seen in the paediatric ophthalmology clinic at the University of Arizona. None of the subjects had amblyopia or other cause of decreased visual acuity that precluded fixation with the right eye, and none exhibited any ocular pathology other than refractive error. This study was approved by the University of Arizona Institutional Review

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Board (IRB). Written informed consent was obtained from parents of all children, and verbal assent was obtained from older children.

PROCEDURE

In order to achieve cycloplegia, each child was first given proxymetacaine (proparacaine) 0.5%, followed 30 seconds later by a single drop of cyclopentolate 1% instilled in the inferior cul de sac. The child was held with the eyelid open and the pooled drop in contact with the cornea for approximately 1 second, and then the upper eyelid was lifted, allowing the pooled drop to collect under the upper eyelid. Twenty to 30 minutes later, dynamic retinoscopy was performed to determine adequacy of cycloplegia. Dynamic retinoscopy was performed by observing the retinoscopic reflex while the child was viewing a distant television monitor displaying a cartoon, stopping the cartoon, and then directing the child to attend to a finger puppet held alongside the retinoscope. Evidence of inadequate cycloplegia was a shift in the retinoscopic reflex as viewing distance changed. In no instance was it necessary to instil additional drops.

A certified ophthalmic technician (LKW) then attempted to obtain a Retinomax measurement from the right and left eyes of each subject. Older children were asked to remain still and to fixate on the Retinomax internal fixation target as the examiner held the Retinomax in perpendicular alignment. For younger children, a parent held the child while the examiner aligned the Retinomax. Once fixation was achieved, the examiner attempted a measurement. For children who initially demonstrated little interest in the fixation target, a modified technique was used. Firstly, a small finger puppet was used to attract the child's attention. Then, all room lights were turned off and the Retinomax was immediately positioned in front of the child. Thus, the only visual stimulus present, the fixation target of the Retinomax, attracted the child's attention, and the measurement was made. The Retinomax provided a printout for each eye that included several measured values of refractive error and a single representative measurement of refractive error. For the right eye, we obtained two measured values for one subject, three measured values for one subject, six measured values for four subjects, and eight measured values for all other subjects.

Immediately after autorefraction, an ophthalmologist (JMM) performed retinoscopy followed by subjective refinement, when possible. Subjective refinement was achieved by varying the refraction under the patient's direction until best visual acuity was achieved. The ophthalmologist was masked to the results of the autorefraction at the time retinoscopy with or without subjective refinement was performed. For subjects with whom subjective refinement was performed, the ophthalmologist recorded a single best estimate of refractive error for each eye. For subjects who were assessed with retinoscopy, the ophthalmologist recorded the phoropter reading at neutralisation.

DATA ANALYSES

In order to avoid violations of independence of measurements that arise when data from both eyes of subjects are included in analyses, only data from the right eye of each subject were included. The data relevant to the following analyses were each subject's Retinomax measured values, Retinomax representative measurement, and retinoscopy or subjectively refined measurement of refractive error.

Analysis of the reproducibility and accuracy of refractive error data is complicated by the interaction of sphere, cylinder, and axis measurements. Small axis variations of large cylinder powers can produce the same dioptric blur as large axis variations of small cylinder power. That is, variation of either sphere or cylinder power can produce variation in the net dioptric power. Analysis of the variation of astigmatic power is best accomplished with the vector method described by Long¹² and modified by Harris.¹³ Using this method, each observation of sphere, cylinder, and axis is converted into a single point in dioptric three dimensional space. The advantage of this method is that the deviation for each measurement can be derived in units of dioptres that are related simultaneously to the sphere, cylinder, and axis of the measurements. Repeated observations result in a cluster of points occurring in this three dimensional space. For each subject, the Retinomax measured values of refractive error (usually eight measured values per subject), the Retinomax representative measurement, and the retinoscopy or subjective refinement measurement of refractive error were converted to a value representing a point in dioptric three dimensional space using the method of Harris¹³

REPRODUCIBILITY

Reproducibility of Retinomax measurements was evaluated through the analysis of the Retinomax measured values provided for each subject. The mean of the measured values was calculated according to the method of $Harris¹³$ for each subject, and the vector dioptric distance between each estimate and the mean of that subject's measured values was calculated. This yielded a dioptric error value for each estimate of refractive error. The mean of the dioptric errors was calculated for each subject, and the grand mean dioptric error was calculated for all subjects, for subjects who underwent retinoscopy, and for subjects who permitted subjective refinement. For each group and for subjects overall, Spearman correlation was used to evaluate the relation between reproducibility of measurements (dioptric error) and subject age, amount of spherical power, and amount of astigmatism. Spherical power and astigmatism values for correlations were obtained from subjects' retinoscopy or subjective refinement measurements.

MEASUREMENT BIAS

Since individual retinoscopists, refractionists, and the Retinomax may have a consistent measurement bias, we determined the bias

between retinoscopy and Retinomax representative measurements, and the bias between subjective refinement and Retinomax representative measurements. For subjects who underwent retinoscopy, each subject's Retinomax representative measurement (sphere, cylinder, axis) was subtracted from his/her retinoscopy measurement—that is, the phoropter reading at neutralisation, using vector methods. For subjects who permitted subjective refinement, each subject's Retinomax representative measurement was subtracted from his or her subjectively refined retinoscopy measurement using vector methods. For each group (retinoscopy/subjective refinement), the overall mean of these values was calculated to determine the amount and direction of measurement bias.

While we assume the best subjective refinement under cycloplegia represents an unbiased estimate of the subject's refractive error, we cannot make that assumption for retinoscopy. In retinoscopy, there is large variation between retinoscopists in both spherical measurement accuracy (arising from working distance variation from the typical two thirds of a metre) and cylinder (arising from off axis measurement). Therefore, the measurement bias between retinoscopy and Retinomax measurements represents an 'ideal retinoscopy lens' that, when held before the subject, would best correct for retinoscopy working distance and off axis alignment, as well as any systematic errors that might be present within the Retinomax.

MEASUREMENT AGREEMENT

We evaluated the agreement between Retinomax representative measurements and retinoscopy measurements at neutralisation, and agreement between Retinomax representative measurements and subjective refinement. In order to correct for systematic measurement bias, the mean bias for retinoscopy was subtracted from retinoscopy measurements, and the mean bias for subjective refinement was subtracted from subjective refinement measurements (see Measurement bias, above). This correction yielded a means of comparing the Retinomax with retinoscopy and subjective refinement free of systematic bias. The corrected retinoscopy and subjective refinement measurements were used in analyses of measurement agreement.

For each group, the absolute magnitude of vector dioptric difference between each subject's Retinomax representative measurement and that subject's retinoscopy with or without subjective refinement derived estimate of refractive error was calculated, and the mean of the absolute differences was calculated for retinoscopy and subjective refinement groups. Spearman correlation was used to determine the relation between measure of agreement and subject age, amount of spherical power, and amount of astigmatism for each group. Spherical power and astigmatism values for correlations were obtained from subjects' retinoscopy or subjective refinement measurements.

Use of absolute values in the calculation of deviation resulted in positive mean dioptric deviations. If absolute values had not been used, the mean dioptric difference between the Retinomax and Retinoscopy measurements and between the Retinomax and subjective refinement measurements would have been zero, since we subtracted off the bias between methods of measurement before calculating mean dioptric deviation. Thus, the mean dioptric deviation represents the average difference in any vector direction between measurements obtained by two methods (Retinomax and retinoscopy or Retinomax and subjective refinement).

Results

SUCCESS IN OBTAINING MEASUREMENTS

The ophthalmic technician was successful in obtaining Retinomax measurements from seven of nine subjects who were age 3 years or younger, and from all 38 older subjects. The two subjects from whom we could not obtain measurements were 11 and 14 months old. Obtaining measurements from children less than 3 years of age was more difficult, as they tended to try to turn away from the instrument.

The ophthalmologist was successful in completing retinoscopy in 25 subjects, and subjectively refined retinoscopy in 22 subjects. Overall, we obtained Retinomax and retinoscopy measurements in 23 children (retinoscopy group, mean age 4.1 (SD 1.5) years), Retinomax and subjective refinement measurements in 22 children (subjective refinement group, mean age 6.6 (SD 1.0) years), and only retinoscopy measurements in two children (mean age 1 year). Subjects in the retinoscopy group were significantly younger than subjects in the subjective refinement group $(t(43)$ = 6.54 , $p \leq 0.0001$).

SUMMARY OF RESULTS FROM INDIVIDUAL SUBJECTS

In Tables 1 and 2, we provide the data from individual subjects. Table 1 summarises retinoscopy measurements at neutralisation, Retinomax measurements, bias measurements (retinoscopy—Retinomax measurements, using vector methods), and the vector dioptric $difference¹³$ (VDD, the dioptric difference, averaged across all vector directions, taking into account sphere, cylinder and axis) for subjects in the retinoscopy group. Table 2 summarises subjective refinement measurements, Retinomax measurements, bias measurements (subjective refinement − Retinomax measurements, using vector methods), and the VDD¹³ for subjects in the subjective refinement group.

REPRODUCIBILITY

The dioptric deviations of each subject's Retinomax measured values of refractive error from the mean of each subject's Retinomax measured values are shown in Figure 1. As seen in Figure 1, one subject had an extreme outlier measured value of refractive error. This measured value was not included in the calculation of reproducibility for that subject. Based

Table 1 Retinoscopy subjects

	Retinoscopy at neutralisation		Retinomax representative			Bias				
Subject	Sph	Cyl	Axis	Sph	Cyl	Axis	Sph	Cyl	Axis	VDD
1	2.25	0.50	90	0.75	0.25	78	1.48	0.29	100	0.57
\overline{c}	3.00	0.00	26	1.50	0.50	99	1.00	0.50	9	0.41
3	2.50	0.00		0.25	0.25	112	2.00	0.25	22	1.27
4	1.75	0.75	100	0.75	0.50	93	0.98	0.29	112	0.23
5	3.50	0.00	96	2.75	0.50	103	0.25	0.50	13	1.12
6	2.00	0.00	97	1.00	0.00	96	1.00	0.00		0.35
$\overline{7}$	4.00	1.25	90	3.50	1.75	92	-0.01	0.51	$\overline{7}$	1.46
8	3.00	0.50	90	0.25	0.25	112	2.69	0.36	76	2.32
9	2.75	0.00	90	0.00	0.50	84	2.25	0.50	174	1.83
10	3.00	0.00	64	1.75	0.50	14	0.75	0.50	104	0.45
11	5.25	1.25	70	3.25	1.50	80	1.61	0.54	16	0.99
12	2.75	0.25	95	1.50	0.25	90	1.23	0.04	137	0.09
13	0.50	1.50	90	-0.50	0.50	109	0.93	1.15	82	0.82
14	2.50	0.50	90	2.00	0.25	81	0.49	0.27	98	0.88
15	-0.25	2.25	90	-0.50	1.75	103	-0.01	1.02	66	1.20
16	0.50	2.25	90	-1.00	2.50	84	1.10	0.56	145	0.44
17	2.25	0.75	85	1.25	0.75	80	0.93	0.13	128	0.36
18	3.00	1.00	95	1.75	0.75	97	1.25	0.26	89	0.22
19	2.00	2.25	85	2.25	1.25	92	-0.29	1.08	77	1.55
20	0.75	0.00		-0.75	0.50	105	1.00	0.50	15	0.40
21	2.50	1.00	85	1.25	0.75	92	1.21	0.33	68	0.24
22	0.75	0.00	101	-0.75	0.50	115	1.00	0.50	25	0.36
23	0.75	4.25	90	0.50	3.50	80	-0.14	1.54	116	1.29
								Mean VDD		0.82
								SD		0.58

Sph = sphere; Cyl = cylinder; Bias = retinoscopy measurement − Retinomax measurement, computed using vector methods¹³; VDD $=$ vector dioptric difference¹³ (absolute value of the vector dioptric deviation between Retinomax representative and retinoscopy measurements, taking into account sphere, cylinder, and axis, calculated *after* mean bias was subtracted from retinoscopy measurements).

Sph = sphere; Cyl = cylinder; Bias = subjective refinement measurement − Retinomax measurement, computed using vector meth- ods^{13} ; VDD = vector dioptric difference¹³ (absolute value of the vector dioptric deviation between Retinomax representative and subjective refinement measurements, taking into account sphere, cylinder, and axis, calculated *after* mean bias was subtracted from subjective refinement measurements).

on comparisons of the subject's measured values and the subject's final representative measurement, it was clear that the Retinomax eliminated the outlier in selecting the representative measurement.

Measurements of reproducibility were obtained by calculating a mean deviation score for each subject. The grand mean of the deviation values across all subjects was 0.43 D (SD 0.47). There was a significant correlation between reproducibility and age $(r_s = -0.36,$ p<0.02); with older subjects, mean deviation scores were lower (that is, reproducibility of measurements was better). Reproducibility

was not significantly related to the amount of spherical error or amount of cylinder.

We also evaluated Retinomax reproducibility for the retinoscopy and subjective refinement groups separately. For subjects who underwent retinoscopy, the mean deviation value was 0.49 D (SD 0.40). There was a significant correlation between reproducibility and age for the retinoscopy group $(r_s = -0.49, p<0.02)$; with older subjects, mean deviation scores were lower (that is, reproducibility of measurements was better). Reproducibility in the retinoscopy group was not significantly related to the amount of spherical error or amount of

Figure 1 Individual subjects' Retinomax measured values plotted by age of subject. Circles represent the vector dioptric diVerence between each Retinomax estimate of a subject's refractive error and the average dioptric value13 of that subject's measured values. The Retinomax representative measurement of refractive error is not the mean of the individual measured values, as outliers are discarded.

cylinder. For subjects who were able to complete subjective refinement, the mean deviation value was 0.37 D (SD 0.52). Reproducibility in the subjective refinement group was not significantly related to subject age, spherical power, or amount of cylinder. Reproducibility did not significantly differ between the retinoscopy and subjective refinement groups.

MEASUREMENT BIAS

Retinomax v retinoscopy

The mean bias, calculated by subtracting Retinomax representative measurements from retinoscopy readings at neutralisation using the vector method of Harris,¹³ was $+1.19 +0.11 \times$ 079. This estimate of bias includes any error introduced by the Retinomax, the retinoscopist, and average working distance (usually assumed to be two thirds of a metre, allowing for a −1.5 D retinoscopy lens). If we subtract the traditional 1.5 D correction, bias for the Retinomax in comparison to standard retinoscopy was $-0.31 +0.11 \times 079$.

Retinomax v subjective refinement

The mean bias, calculated by subtracting Retinomax representative measurements from subjective refinement measurements using the vector method of Harris,¹³ was $-0.27 +0.23 \times$ 072. This estimate of bias includes any error introduced by the Retinomax and by subjective refinement.

MEASUREMENT AGREEMENT

Retinomax v retinoscopy

The mean of the absolute values of the dioptric deviations between subjects' Retinomax representative measurements and their retinoscopy measurements was 0.82 D (SD 0.58). The dioptric deviation between Retinomax representative and retinoscopy measurements was not significantly related to subject age, amount of spherical power, or amount of cylinder.

Retinomax v subjective refinement

The mean of the absolute values of the dioptric deviations between subjects' Retinomax representative measurements and their retinoscopy measurements was 1.03 D (SD 0.59). The dioptric deviation between Retinomax representative and retinoscopy measurements was not significantly related to subject age, amount of spherical power, or amount of cylinder.

Agreement between Retinomax and retinoscopy and agreement between Retinomax and subjective refinement did not differ significantly.

Discussion

The Retinomax is a hand held instrument designed to provide a rapid estimate of refractive error. The portability and ease of use of the Retinomax suggest that it might be a useful tool for providing definitive 'gold standard' measurements of refractive error under cycloplegic conditions for use in research studies, and may be useful for screening young children for high refractive errors under noncycloplegic conditions.

We were able to achieve our goal of obtaining Retinomax measurements from all but two subjects between 1 and 8 years of age under cycloplegic conditions. Younger subjects tended to turn away from the Retinomax, as they do with any instrument that is placed close to the face. However, the ophthalmic technician was successful in obtaining Retinomax measurements in seven of nine children less than 3 years old. Retinoscopy was successfully completed in all children, and subjective refinement of the initial retinoscopy reading was successfully completed in 22 children.

The mean vector dioptric difference, taking into account sphere, cylinder, and axis, between the mean of each subject's Retinomax measured values of refractive error and the individual measured values obtained from that subject was 0.43 D (SD 0.47). This reproducibility measure was correlated with subject age; there was better reproducibility of measurements with older subjects. Reproducibility did not differ between retinoscopy and subjective refinement groups. However, reproducibility was correlated with subject age in the retinoscopy group (younger and less cooperative children), but not in the subjective refinement group. These finding suggests that repeated Retinomax measurements or other methods of refraction should be used to determine the precise correction that should be prescribed in younger and less cooperative children, to allow for averaging of values.

It should be noted that the Retinomax provides a single representative measurements (or 'best estimate') based on the measured values of refractive error. Analysis of repeated representative measurements would most likely provide even better reproducibility than we found analysing repeated measured values.

Measurement bias for the Retinomax in comparison with retinoscopy phoropter readings at neutralisation (retinoscopy − Retinomax) was

Table 3 Comparison of reproducibility of retinoscopy measurements¹⁰ with reproducibility of Retinomax measured values

Study	Method	Mean difference [*] (D)	SD(N)	Range(D)	
Sphere					
Safir et al^{10}	Retinoscopy (same retinoscopist)	0.21	0.21(50)	$0 - 0.88$	
Present study	Retinomax (1st two measured values)	0.15	0.19(48)	$0 - 0.75$	
Cylinder					
Safir et al^{10}	Retinoscopy (same retinoscopist)	0.18	0.16(50)	$0 - 0.53$	
Present study	Retinomax (1st two measured values)	0.18	0.17(48)	$0 - 0.75$	

*The *absolute* difference between two measurements was calculated (right eye data recalculated from tables in Safir *et al*¹⁰).

 $+1.19 +0.11 \times 079$. If we subtract the traditional 1.5 D correction from this value, bias for the Retinomax in comparison with standard retinoscopy was $-0.31 +0.11 \times 079$. Measurement bias for the Retinomax in comparison with subjective refinement (subjective refinement − Retinomax) was $-0.27 +0.23 \times 072$. These data suggest that the Retinomax provided an average of approximately 0.25 D less negative/more positive measures of refractive error than retinoscopy and subjective refinement.

The mean vector dioptric difference (averaged across all vector directions, taking into account sphere, cylinder, and axis) between unbiased retinoscopy measurements and their Retinomax representative measurements was 0.82 D (SD 0.58). The mean vector dioptric difference (averaged across all vector directions) between subjective refinement measurements and their Retinomax representative measurements was 1.03 D (SD 0.59). Thus, the accuracy (measurement agreement) of the Retinomax when compared with retinoscopy was similar to the accuracy of the Retinomax when compared with subjective refinement. In addition, the accuracy of the Retinomax, with reference to retinoscopy and subjective refinement, was not significantly related to subject age, spherical power, or amount of cylinder.

COMPARISON WITH PREVIOUS STUDIES: MEASUREMENT REPRODUCIBILITY

Several previous studies have examined reproducibility of measurements of refractive error. In a study conducted by Safir et al,¹⁰ five ophthalmologists performed non-cycloplegic retinoscopy on 10 adult subjects on two separate occasions. The ophthalmologists were masked to the identity of the subjects at the time each retinoscopy was performed. Table 3 compares Safir *et al*⁸¹⁰ reproducibility of non-cycloplegic retinoscopy measurements of sphere and cylinder to reproducibility of the first two Retinomax measured values of sphere and cylinder for each subject in the present study. The results demonstrate little difference between reproducibility of measurements by the same retinoscopist in adult subjects (sphere 0.21 D; cylinder 0.18 D), and reproducibility of Retinomax measured values in children (sphere 0.15 D; cylinder 0.18 D).

Rosenfield and Chiu compared repeatability of non-cycloplegic subjective and objective refraction in 12 adult subjects.¹⁴ Each subject underwent five subjective refractive examinations over a 2 week period. Each examination was followed by objective refraction—that is, autorefraction, with the Canon Autoref R-1. The examiner was unaware of the results of the refractions. For Table 4, we reanalysed our data according to the methods of Rosenfield and $Chiu, ¹⁴$ and compared the reproducibility results from Rosenfield and Chiu with the reproducibility of the first five Retinomax measured values in children. The results indicated poorer repeatability of Retinomax measured values in children, compared with subjective and objective refraction in adults. It should be noted, however, that each of the five objective measurements of refractive error for Rosenfield and Chiu's subjects was calculated as the mean of 25 autorefractor measurements. This method of determining objective refraction measurements may have obscured much of the variability in autorefractor measurements, providing an inappropriate comparison for repeatability of Retinomax measured values. In addition, one of our subjects had an extreme outlier Retinomax measured value, which contributed to the large mean SD for sphere and spherical equivalent (see Fig 1). When the Retinomax data are analysed with-

Table 4 Comparison of reproducibility of subjective and objective * *refraction in adults¹⁴ with reproducibility of Retinomax measured values† in children*

	Method	Study	Subjects	Mean SD(D)	95% limits (D)
Sphere	Subjective refraction	Rosenfield and	Adult $(n=12)$	0.14	$+/-$ 0.27
	Objective refraction	Chiu ¹⁴		0.16	$+/- 0.31$
	Retinomax measured values	Present study	Child $(n=43)$	0.42	$+/- 0.82$
Cylinder	Subjective refraction	Rosenfield and	Adult $(n=12)$	0.08	$+/- 0.16$
	Objective refraction	Chiu ¹⁴		0.19	$+/-$ 0.37
	Retinomax measured values	Present study	Child $(n=43)$	0.24	$+/-$ 0.47
Spherical equivalent	Subjective refraction	Rosenfield and	Adult $(n=12)$	0.15	$+/-$ 0.29
	Objective refraction	Chiu ¹⁴		0.14	$+/-$ 0.27
	Retinomax measured values	Present study	Child $(n=43)$	0.39	$+/-$ 0.76

Mean SD = standard deviation of each subject's five measurements of the right eye was determined, and the mean of the standard deviations was calculated.

95% Limits=1.96 times the mean SD.

*Following each of five subjective refractions, each subject had 25 measurements taken with the Canon R-1 autorefractor. Each of the five measured values of objective refraction were calculated as the mean of 25 measurements.

†The first five Retinomax measured values on each subject were analysed according to the methods of Rosenfield and Chiu.14 Only subjects with at least five measured values were included (43/45).

Table 5 Comparison of reproducibility of retinoscopy, subjective refraction, and autorefraction measurements in adults¹¹ *with reproducibility of Retinomax measured values in children*

Method	Study	Sample (n)	*Mean difference (D)	Standard deviation(D)	95% Confidence interval (D)
Retinoscopy	Zadnik et $al11$	Adults (40)	0.07	0.48	-0.87 to 1.02
Subjective refraction	Zadnik et $al11$	Adults (40)	-0.01	0.48	-0.95 to 0.93
Autorefraction	Zadnik et $al11$	Adults (40)	0.05	0.16	-0.27 to 0.37
Retinomax ⁺	Present study	Children (35)	-0.06	0.21	-0.47 to 0.35

 $*$ Mean of the differences between two measurements in the vertical meridian (right eye only).

†For each subject, the difference (D) between the first two measured values of spherical power in the *vertical* meridian was determined. Subjects with oblique axes of astigmatism (that is, greater than 20° from horizontal or vertical) were not included in these analyses.

Table 6 Agreement between subjective refraction and autorefraction measurements in adults15 and agreement between retinoscopy and Retinomax representative measurements in children

Method	Study	Sample (n)	Mean difference (D) *	Standard deviation (D)	95% Limits of agreement (D) +
(Humphrey 500) – (subjective refraction)	Kinge et al^{15}	Adults (224)	-0.23	0.47	-1.18 to $+0.71$
$(Nidek AR-1000)$ – (subjective refraction)	Kinge <i>et al</i> ¹⁵	Adults (80)	-0.13	0.27	-0.68 to 0.41
$(Retinomax) - (retinoscopy)\ddagger$	Present study	Children (23)	$+0.26$	0.66	-1.06 to 1.58
(Retinomax) – (subiective refinement)	Present study	Children (22)	$+0.07$	0.84	-1.61 to 1.75

 $*$ Mean of the differences between two measurements of spherical equivalent (right eye only).

†Mean ± 2 standard deviations.

‡Standard 1.5 D correction applied to retinoscopy measurements (phoropter at neutralisation) before calculations.

out that subject, the mean SDs are 0.26 for sphere, 0.22 for cylinder, and 0.22 for spherical equivalent. Nevertheless, Rosenfield and Chiu's results also indicated that subjective refraction in adults yielded better reproducibility than Retinomax measured values in children.

Zadnik and colleagues conducted a study examining the reproducibility of cycloplegic retinoscopy, subjective refraction, and autorefraction in 40 adult subjects.¹¹ For Table 5, we reanalysed our data according to the methods of Zadnik *et al*, and compared the results from Zadnik *et al* with the reproducibility of the first two Retinomax measured values in children. The findings were similar to the results of our comparisons with Safir *et al*'s¹⁰ data. There was little difference in reproducibility of Retinomax measured values in children (−0.06 D) and reproducibility of retinoscopy (0.07 D), subjective refraction (−0.01 D), and autorefraction (0.05 D) in adults.

COMPARISON WITH PREVIOUS STUDIES: MEASUREMENT AGREEMENT

In a recent study, Kinge and colleagues¹⁵ evaluated agreement between subjective refraction and autorefraction in adult subjects made cycloplegic. For Table 6, we analysed our data according to the method used by Kinge *et al*. 15 The Retinomax and retinoscopy agreement was comparable with agreement between the Humphrey autorefractor and subjective refraction, and poorer than agreement between the Nidek autorefractor and subjective refraction. The Retinomax and subjective refinement had better agreement (mean difference closer to 0) than both autorefractors (Humphrey and Nidek) and subjective refraction. These analyses suggest that the Retinomax provides agreement with retinoscopy and subjective refinement in young children that is comparable with agreement between other autorefractors (Humphrey and Nidek) and subjective refraction in adults.

Although the magnitude of the mean differences between the three autorefractors and subjective refraction/retinoscopy were similar (ranging from 0.07 D to 0.26 D), the sign of the mean differences differed. That is, the Retinomax provided more positive/less negative measurements, in comparison with retinoscopy and subjective refinement, and the Humphrey and Nidek autorefractors provided more negative/less positive measurements, in comparison with subjective refraction.

Conclusions

The data from the present study indicate that the reproducibility of the Retinomax is similar to that reported for cycloplegic and noncycloplegic retinoscopy, subjective refraction, and autorefraction. Although our results indicate that the Retinomax provides consistent and accurate measured values of refractive errors under cycloplegic conditions, the variability in measurements is large enough to suggest that repeated Retinomax measurements or other methods should be used to determine the precise correction that should be prescribed for very young children.

The Retinomax may be a useful tool for obtaining definitive measurements of refractive error under cycloplegic conditions. However, the present study suggests that the Retinomax provides approximately 0.25 D more positive/ less negative measurements of refractive error than subjective refinement in children. We did not have the power to determine if this mean differs significantly from zero.

The results of the present study suggest that the Retinomax might be used successfully as a screening tool, as we were able to obtain measurements from the majority (96%) of the children in our study. The Retinomax requires very little training and practice to be used effectively, and it provides immediate printouts of measurements. These features would allow examiners in screening situations to identify children with significant refractive errors, explain the findings to the parents, and refer or schedule the child for a follow up examination. However, before widespread use of the Retinomax for refractive error screening, additional research would be required to evaluate the reproducibility and accuracy of the Retinomax under non-cycloplegic conditions, as cycloplegia is often impractical in screening settings.

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· Clinical Research·

Comparison of the Retinomax hand-held autorefractor versus table-top autorefractor and retinoscopy

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Abstract

· AIM: To compare noncycloplegic and cycloplegic results of Retinomax measurements with findings achieved after cycloplegia using table -top autorefractor and retinoscopy.

·METHODS: The study included ¹²⁷ patients (mean age 96.7mo, range 21 to 221). Retinomax (Rmax) (Nikon Inc., Japan) was used to obtain noncycloplegic refraction. Under cycloplegia, refraction was measured with Rmax, table -top autorefractor (TTR) (Nikon NRK 8000, Inc., Japan) and retinoscopy. The values of sphere, spherical equivalent, cylinder and axis of cylinder were recorded for Rmax, TTR and retinoscopy in each eye. All results were analyzed statistically.

·RESULTS: The mean spheric values (SV), spherical equivalent values (SEV) and cylindrical values (CV) of the noncycloplegic Rmax (SV: 0.64 D, SEV: 0.65 D and CV: 0.03 D, respectively) were found to be significantly lower than cycloplegic TTR (1.43 D, 1.38 D and 0.3 D; $P=0.012$, $P=0.011$ and $P=0.04$, respectively) and retinoscopy (1.34 D, 1.45 D and 0.23 D; $P = 0.04$, $P = 0.002$ and $P = 0.045$, respectively). Mean cycloplegic SV, SEV, CV were not significantly different between Rmax and TTR, Rmax and retinoscopy, TTR and retinoscopy. Cycloplegic or noncycloplegic axis values were not different between any method.

·CONCLUSION: Rmax may be used successfully as a screening tool but may not be accurate enough for actual spectacle prescription. Cycloplegic Rmax measurements may be able to identify refractive error in children because of approximate results to retinoscopy.

· KEYWORDS: autorefractor; hand-held refractors; retinoscopy; Retinomax

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INTRODUCTION

A bnormal refractive errors in childhood may lead to amblyopia $[1,2]$. Early detection and prompt treatment of refractive errors can prevent amblyopia and strabismus^[1,3]. For this reasons, to identify and correct the refractive errors as early as possible is crucial. The traditional method for identify refractive errors in children includes noncycloplegic and cycloplegic retinoscopy which performed by skilled experienced ophthalmologist. Conventional retinoscopy requires long training for examiners and cooperative patients. Therefore, there has been an effort to develop techniques and instruments that permit detection of refractive errors with minimal requirement of cooperation in children. Autorefractors have been used for some years but may not be suitable for use in small children becuse of their immobility^[48]. Currently, hand held autorefractors (HHR) allow refractive errors to be estimated rapidly. Several authors have already studied its accuracy and reproducibility as a screening device[7-11] .

The aim of this study was to investigate the accuracy of the Retinomax, to compare results of Retinomax measurement in children under noncycloplegic condition with findings achieved after cycloplegia using table-top autorefractor and retinoscopic results of an experienced pediatric ophthalmologist and to asses the agreement between these results.

SUBJECTS AND METHODS

One hundred and twenty-seven consecutive patients were evaluated for ophthalmological assesment. Written informed consent was obtained from parents of all children. The conduct of the study followed the tenets of the Declaration of Helsinki. This study was conducted in accordance with ethical guidelines. Visual acuities were obtained with Snellen letters, Allen pictures or Teller acuity card according to children ages. After initial ocular and systemic history visual acuities recorded, the full ophthalmic examination includes cover test, TNO stereotest and anterior segment examination.

Retinomax can be used as an alternative to retinoscopy

We excluded subjects with squint, media opacity, amblyopia or any cause of decreased vision before the study. Retinomax (Rmax) (Nikon Inc., Japan) was used to obtain noncycloplegic refraction. Cycloplegia was achieved by instillation of one drop of 1% cyclopentolate and one drop 1% tropicamid 5min apart. Refraction was measured with Rmax and table-top autorefractor (TTR) (Nikon NRK 8000, Inc., Japan) 45min after the last instillation. Subsequently, the child was manually refracted and refined by an experienced pediatric ophthalmologist who was masked to previous autorefractor's results. The refined refraction was accepted as the 'gold standard'. All measurements were made during same consultation. The values of sphere, spherical equivalent, cylinder and axis of cylinder were recorded for Rmax, TTR and retinoscopy in each eye. The spherical equivalent values (SEV) was calculated as the sum of the sphere plus half the cylindrical power. The pateints who could not be refracted by autorefractor because of poor compliance or whose measurements' reliability was under <8 were excluded. Moreover, in cycloplegic retinoscopic examination, the refraction results of -1.00 D or greater, +2.50 D or greater, and +1.00 D or greater were defined as myopia, hyperopia and astigmatism, respectively. The diagnostic accuracy of refractive errors was assessed by sensitivity and specificity.

SPSS statistical software, version 16.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Refraction techniques were compared by analysis of variance test (ANOVA). A variance ratio (F) was calculated to determine overall statistical differences. Paired t -test was then used to investigate individual statistical differences between the methods. A β -value of <0.05 was considered statistically significant.

RESULTS

One hundred and twenty-seven patients (254 eyes) were evaluated as a study group. The mean age of patients was ranged from 21-221mo (mean 96.7mo). Sixty-two of patients (48.8%) were female, 65 of patients (51.2%) male.

In noncycloplegic children, using the Rmax, the mean spherical value (SV) was 0.64 D (range -10.50-14.00), mean cylindrical value (CV) was 0.03 D (range -3.50-5.00) and mean axis measurement was 71.9° (range 0-180). The mean SEV was 0.65 D (range -11.75 to 15.88). According to SEV, 82 (32.3%) of eyes were myopic, 111 (43.7%) were hyperopic and 61 (24%) were plano. Astigmatism was found in 91 (35.8%) of eyes, 67 (73.6%) of these eyes had a CV more than 1.00 D.

In cycloplegic measurements, using the Rmax, the mean SV was 1.27 D (range -10.00-15.00), mean CV was 0.18 D (range $-3.75-5.00$) and mean axis measurement was 74.9°

Table 1 The mean sphere, spherical equivalent, cylinder and axis values

Mean values	Rmax (NC)	Rmax(C)	TTR	R
Sphere	$+0.64$	$+1.27$	$+1.28$	$+1.34$
Spherical equivalent	$+0.65$	$+1.36$	$+1.43$	$+1.45$
Cylinder	$+0.03$	$+0.18$	$+0.3$	$+0.23$
Axis	719°	74.9°	81.4°	759°
Retinomax; Rmax:	Noncycloplegic:		NC; Cycloplegic: C:	TTR:

Table-Top Autorefractor; R: Retinopathy.

(range 0-180).The mean SEV was 1.36 D (range -11.75- 15.88). According to SEV, 49 (19.3%) of eyes were myopic, 153 (60.3%) were hyperopic and 52 (20.4%) were plano. Astigmatism was found in 81 (33.1%) of eyes, 70 (83.3%) of these eyes had a CV more than 1.00 D.

The mean SV recorded with TTR was 1.28 D (range -10.75 -14.00), mean CV was 0.3 D (range -3.00-4.75) and mean axis measurement was 81.4° (range 0-180). The mean SEV was 1.43 D (range -12.63-14.75). A myopic SEV was found in 45 (17.7%) of the eyes, 153 (60.2%) were hyperopic and 56 (22.1%) plano. Astigmatism was diagnosed in 78 (30.7%) of eyes, 54 (69.2%) of these eyes had a CV more than 1.00 D.

The mean SV recorded using retinoscopy was 1.34 D (range -9.00-13.00), mean CV was 0.23 D (range -3.50-5.00) and mean axis measurement was 75.9° (range 0-180). The mean SEV was 1.45 D (range -10.00-14.00). According to SEV, 38 (15.0%) of eyes were myopic, 168 (66.1%) were hyperopic and 48 (18.9%) were plano. Astigmatism was found in 83 (32.7%) of eyes, 33 (39.8%) of these eyes had a CV more than 1.00 D. These findings were summarized in Table 1.

ANOVA testing of SV revealed an F ratio of 3.905 ($P=$ 0.009) which indicates an overall difference. Comparison of noncycloplegic Rmax with retinoscopy based on SV showed statisttically significant difference ($P=0.040$). Also, there was statistical difference between noncycloplegic Rmax and TTR results ($P=0.012$). The difference among cycloplegic Rmax, TTR and retinoscopy measurements was not statistically significant ($P > 0.05$, for all) (Table 2).

ANOVA testing for CV did not show any statistical differences ($F=1.866$, $P=0.136$). Statistically significance between the noncycloplegic Rmax versus TTR and noncycloplegic Rmax versus retinoscopy were demonstrated ($P=0.040$ and $P=0.045$, respectively). The difference among cycloplegic Rmax, TTR and retinoscopy measurements was not statistically significant ($P > 0.05$, for all) (Table 3).

ANOVA testing for SEV indicated an overall statistical difference($F=7.489, P=0.01$). Comparison of noncycloplegic Rmax versus TTR and noncycloplegic Rmax versus retinoscopy was statistically different ($P=0.011$ and $P=0.002$, respectively). The difference between cycloplegic Rmax,

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d: Mean difference between measurement technique; ANOVA: Analysis of variance test; CI: Confidence Interval; F: Variance ratio, Rmax: Retinomax; NC: Noncycloplegic; C: Cycloplegic; TTR: Table top autorefractor; R: Retinoscopy.

d: Mean difference between measurement technique; ANOVA: Analysis of variance test; CI: Confidence Interval; F: Variance ratio; Rmax: Retinomax; NC: Noncycloplegic; C: Cycloplegic; TTR: Table-top autorefractor; R: Retinoscopy.

Table 4 Statistical analysis of data for spherical equivalent values. Agreement between different techniques

d: Mean difference between measurement technique; ANOVA: Analysis of variance test; CI: Confidence Interval; F: Variance ratio; Rmax: Retinomax; NC: Noncycloplegic; C: Cycloplegic; TTR: Table-top autorefractor; R: Retinoscopy.

Table 5 Statistical analysis of data for axis values. Agreement between different techniques

d: Mean difference between measurement tecnique; ANOVA: Analysis of variance test; CI: Confidence Interval; F: Variance ratio; Rmax: Retinomax; NC: Noncycloplegic; C: Cycloplegic; TTR: Table-top autorefractor; R: Retinoscopy.

TTR and retinoscopy measurements was not statistically significant ($P > 0.05$, for all) (Table 4).

ANOVA testing for axis values did not show any statistical differences ($F=1.721$, $P=0.161$). Also, there was no statistical difference between any method in t -test in term of axis values (Table 5).

The sensitivity and specificity are shown for cycloplegic Rmax and TTR (Table 6).

DISCUSSION

Screening of amblyopia is difficult because visual acuity cannot be easily measured in children. Acuity cards are not accurate for the diagnosis of amblyopia and are difficult to use in the community screening situation where testing conditions are often less than ideal. Screening of children might best be carried out by detecting the risk factors for amblyopia such as strabismus and abnormal refractive errors

rather than directly measuring visual acuity. HHR would be useful for screening for abnormal refractive errors, in addition to its possible use in clinical management $[12-14]$.

The Rmax is a hand held instrument designed to provide a rapid estimate of refractive error. The portability and ease of use of the Rmax suggest that it might be a useful tool for providing definitive measurements of refractive error under cycloplegic conditions for use in research studies, and may be useful for screening young children for high refractive errors under noncycloplegic conditions [4]. But some studies showed that screening with the Rmax under noncycloplegic conditions resulted in overcorrection and too many false-positive referrals^[15].

El-Defrawy *et al*^[5] reported that the results of Rmax and retinoscopy under cycloplegia were similar for SV but the difference between the mean CV obtained by two methods was statistically significant, on the other hand this difference was clinically insignificant (0.23 D). And results using the Rmax without cycloplegic were grossly inaccurate. Kallay et al^[16] reported high agreement of three refractive measurements (sphere, cylinder and axis) between the on table autorefractor and Rmax under cycloplegia. Liang $et \, al^{[8]}$ reported the difference of SV under the cycloplegic condition was significantly different from that under noncycloplegic condition by Rmax and TTR (0.59 D). Although this difference is within a clinical acceptable range, SV in the cycloplegic eyes measured by the 2 types of autorefractors were almost identical. Difference of cylinder and axis was not significantly in either cycloplegic or noncycloplegic condition.

Prabakaran coworkers^[11] stated that mean SEV obtained from Rmax with cycloplegia (0.8 D) was significantly less than retinoscopy (1.09 D) while no significant difference was noted between TTR and retinoscopy. Astigmatism measured with Rmax (-0.89 D) and TTR (-0.83 D) were significantly greater than that retinoscopy (-0.58 D).

In present study, the mean SEV with cycloplegic Rmax 0.09 D more myopic than retinoscopy, but this diffrence was not statistically significant. Also, the difference of mean SV, SEV, CV and axis values under cycloplegia were not statistically significant between any methods (Rmax, TTR and retinoscopy).

Previous studies demonstrated Rmax measurements without cycloplegy were grossly inaccurate ^[5,15]. Similarly, the current study showed that noncycloplegic Rmax measurements (SV, SEV and CV) were significantly lower than all cycloplegic measurement methods.

A few studies involving cyclopleged children where little difference was noted in spherical, cylinder or axis

measurements for Rmax, TTR and retinoscopy [15-17]. In addition, Rmax, TTR and retinoscopy measurement with cycloplegic were revealed likely results most of studies in literature^[5,8,11,16,18,19].

Refractive errors definition differs between studies, there are wide ranges for sensitivity and specificity ratios were shown in these studies. Choong $et \, al$ ^[15] reported the sensitivity and specificity in detecting myopia greater than 0.50 D was 100% and 51%, whereas that for hyperopia greater than 0.50 D was 84% and 82%, respectively. The Vision In Preschool study group reported a sensitivity of 66% for significant refractive errors with Rmax ^[20]. In our study, sensitivity and specificity for the Rmax were 68% and 100% for myopia, 93% and 79% for hyperopia and 72% and 86% for astigmatism, respectively. Similar to other studies we found that, the Rmax had slightly lower sensitivity for detecting myopia^[9,21-23].

In conclusion, noncycloplegic Rmax values were significantly 'minus'. This difference was 0.80 D. This support the argument that, Rmax might be used successfully as a screening tool but may not be accurate enough for actual spectacle prescription. The accuracy of the Rmax and TTR when compared with retinoscopy were similar under cycloplegic condition. Because of the reliable results of measurements and easier to use in detection of refractive errors, cycloplegic Rmax can be used as an alternative method to cycloplegic retinoscopy in children.

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