

ORIGINAL ARTICLE

# 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 <8, 8, >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

The Retinomax Autorefractor has been identified as a useful tool for screening refractive error in preschool children.<sup>1-7</sup> This handheld autorefractor can be used by individuals with minimal ophthalmic experience<sup>2</sup> 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.<sup>8</sup> 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-

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.<sup>2</sup> 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,<sup>2</sup> 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 vans<sup>9</sup> 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,<sup>1</sup> cover testing at distance and near, and cycloplegic retinoscopy was conducted to determine whether a child had any of the four VIP targeted 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 amblyopia 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).<sup>1</sup> 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  $\geq 5.0$  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)  $\geq 0.5$  D, 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  $>3.25$  and  $<5.0$  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 meridians. 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

each child as Retinomax screening pass/failure.<sup>2</sup> 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 testing was (4, 5) and whose confidence number pairs from two repeated testings 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 testing or that of other repeated testing, the first reading associated 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 retesting 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 statistical 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).<sup>10</sup>

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).<sup>11</sup> 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 testing on each eye of a child, the lower confidence number ranged from E to 10, and initial testing 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 testing, the Retinomax Autorefractor provided a reliable measure (confidence number  $\geq 8$ ) of refraction in 95.4% of readings either from the initial testing 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,<sup>2</sup> 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 targeted conditions was also highest in children with confidence number <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-targeted conditions, whether considered by each severity level or each disorder type, was highest when the confidence

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)

Confidence Number	Lower confidence number between eyes of a child on initial testing:		Lower confidence number between eyes, based on highest confidence number obtained for each eye for all readings from a child	
	N	%	N	%
E	113	3.91	16	0.6
1	16	0.55	1	<0.1
2	17	0.59	4	0.1
3	31	1.07	3	0.1
4	44	1.52	3	0.1
5	103	3.57	13	0.5
6	164	5.68	19	0.7
7	489	16.9	75	2.6
8	1053	36.5	1594	55.2
9	850	29.4	1152	39.9
10	8	0.28	8	0.3
Total	2888		2888	

TABLE 2.

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

	Children (N)	Confidence number of reading <sup>b</sup>			p <sup>c</sup>	Adjusted p <sup>d</sup>
		<8 (n = 134)	8 (n = 1594)	>8 (n = 1160)		
Sensitivity						
Any condition	461	0.78	0.65	0.61	0.005	0.04
Group 1	209	0.90	0.89	0.81	0.19	0.49
Group 2	144	0.79	0.52	0.51	0.01	0.07
Group 3	108	0.50	0.38	0.35	0.29	0.49
Amblyopia	100	0.88	0.85	0.81	0.49	0.49
Strabismus	47	0.83	0.59	0.58	0.19	0.49
Refractive error	379	0.83	0.74	0.72	0.047	0.28
Reduced VA	117	0.65	0.49	0.40	0.09	0.45
Specificity	990	0.64	0.89	0.93	<0.0001	<0.0001

<sup>a</sup>Using the failure criteria at 90% specificity determined from Phase II of VIP.

<sup>b</sup>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.

<sup>c</sup>From linear trend test, with correlation of measures from same child adjusted by GEE.

<sup>d</sup>Adjusted 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  $p < 0.0001$ ).

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-

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

### 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

**TABLE 3.** Comparison of prevalence of ocular conditions between two confidence number groups of children based on the lower confidence number for a child

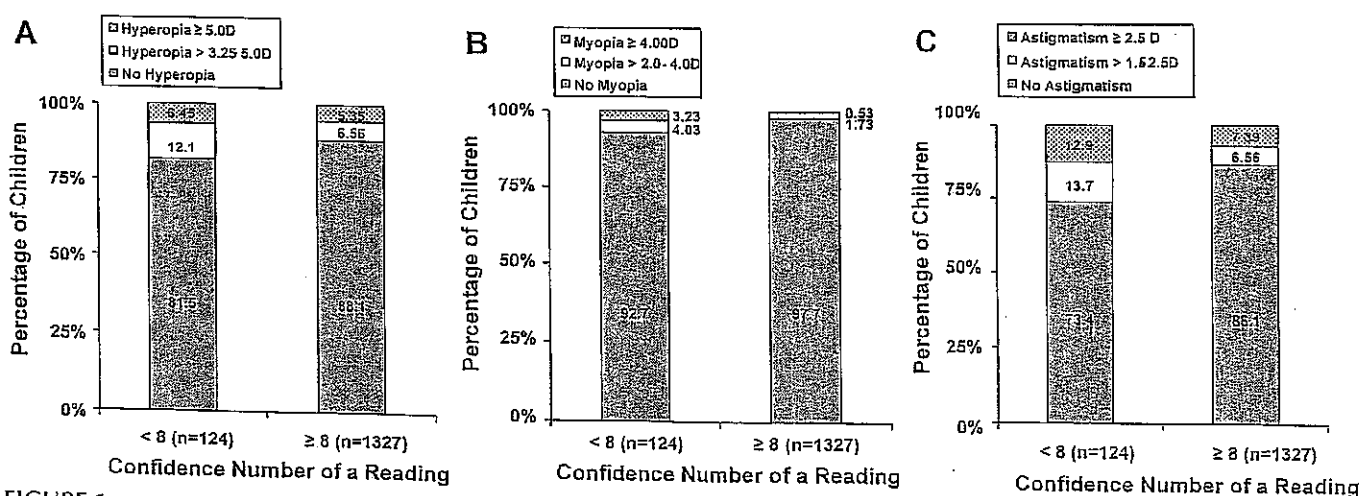
Ocular conditions	Children (N)	Confidence number of reading <sup>a</sup>		p <sup>b</sup>	Adjusted p <sup>c</sup>
		<8 measured by either lay or nurse screeners (n = 124)	≥8 measured by both lay and nurse screeners (n = 1327)		
Any condition	461	63 (50.8)	398 (30.0)	<0.0001	<0.0001
Group 1	209	29 (23.4)	180 (13.6)	0.0047	0.03
Group 2	144	21 (16.9)	123 (9.27)	0.006	0.03
Group 3	108	13 (10.5)	95 (7.16)	0.21	0.28
Amblyopia	100	15 (12.1)	85 (6.41)	0.025	0.10
Strabismus	47	6 (4.92)	41 (3.09)	0.28	0.28
Refractive error	379	55 (44.4)	324 (24.4)	<0.0001	<0.0001
Reduced VA	117	16 (12.9)	101 (7.61)	0.055	0.17

Values inside parentheses indicate percentages.

<sup>a</sup>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.

<sup>b</sup>From Fisher's exact test.

<sup>c</sup>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 p = 0.007) and significant refractive error (46.2% vs. 28.4%, 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).

TABLE 4.

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

	Children (N)	Confidence number of reading <sup>a</sup>		p <sup>b</sup>	Adjusted p <sup>c</sup>
		<8 in retesting by either lay or nurse screener (n = 117)	≥8 in retesting by both lay and nurse screeners (n = 654)		
Any condition	287	59 (50.4)	228 (34.9)	0.001	0.007
Group 1	124	28 (23.9)	96 (14.7)	0.01	0.06
Group 2	95	21 (18.0)	74 (11.3)	0.04	0.16
Group 3	68	10 (8.55)	58 (8.87)	0.91	0.91
Amblyopia	62	15 (12.8)	47 (7.19)	0.04	0.16
Strabismus	23	6 (5.22)	17 (2.60)	0.13	0.39
Refractive error	240	54 (46.2)	186 (28.4)	0.0001	0.001
Reduced VA	79	13 (11.1)	66 (10.1)	0.74	0.91

Values inside parentheses indicate percentages.

<sup>a</sup>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.

<sup>b</sup>Fisher's Exact test.

<sup>c</sup>Adjusted by the Hochberg procedure.

TABLE 5.

Comparison of sensitivity and specificity<sup>a</sup> 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

	Children (N)	Reading with confidence number <8 in initial testing (N = 965 readings)	Reading with highest confidence from repeated testing <sup>b</sup> (N = 965 readings)	p <sup>c</sup>
Sensitivity				
Any condition	287	0.71	0.70	0.32
Group 1	124	0.89	0.88	0.37
Group 2	95	0.64	0.64	1.00
Group 3	68	0.45	0.41	0.41
Amblyopia	62	0.86	0.86	1.00
Strabismus	23	0.75	0.78	0.56
Refractive error	240	0.79	0.77	0.43
Reduced VA	79	0.57	0.54	0.37
Specificity	484	0.81	0.86	0.002

<sup>a</sup>Using the failure criteria at 90% specificity determined from Phase II of VIP.

<sup>b</sup>Reading 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.

<sup>c</sup>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 confi-

dence numbers <8 (0.64) and confidence numbers >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

cases. In addition, the higher confidence number achieved by repeated 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 opaque condition of the cornea, crystalline lens or vitreous body, or if pupil has a diameter of 2.5 mm or less.<sup>8</sup> Our results indicate that several other ocular conditions including astigmatism, myopia, high hyperopia, and significant refractive error in general, are associated 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.

## ACKNOWLEDGMENTS

*This study was supported by grants from the National Eye Institute, National Institutes of Health, Department of Health and Human Services, Bethesda, MD U10EY12534; U10EY12545; U10EY12547; U10EY12550; U10EY12644; U10EY12647; and U10EY12648.*

*Presented, in part, at the Association for Research in Vision and Ophthalmology Annual Meeting, Fort Lauderdale, Florida, May 2006.*

*Received June 28, 2006; accepted October 17, 2006.*

## THE VISION IN PRESCHOOLERS STUDY GROUP

*Executive Committee:* Paulette Schmidt, OD, MS (Chair); Agnieszka Baumritter, MA; Elise Ciner, OD; Lynn Cyert, PhD, OD; Velma Dobson, PhD; Beth Haas; Marjean Taylor Kulp, OD, MS; Maureen Maguire, PhD; Bruce Moore, OD; Deborah Orel-Bixler, PhD, OD; Ellen Peskin, MA; Graham Quinn, MD, MSCE; Maryann Redford, DDS, MPH; Janet Schultz, RN, MA, CPNP; Gui-shuang Ying, PhD.

*Writing Committee:* Gui-shuang Ying, PhD (Chair), Velma Dobson, PhD; Maureen Maguire, PhD; Marjean Taylor Kulp, OD, MS; Graham Quinn, MD, MSCE; Paulette Schmidt, OD, MS.

## Participating Centers

(AA) = Administrative Assistant (BPC) = Back-up Project Coordinator; (GSE) = Gold Standard Examiner; (LS) = Lay Screener; (NS) = Nurse Screener; (PI) = Principal Investigator; (PC) = Project Coordinator; (PL) = Parent Liaison; (PR) = Programmer; (VD) = Van Driver; (NHC) = Nurse/Health Coordinator.

*University of California Berkeley School of Optometry, Berkeley, CA*  
Deborah Orel-Bixler, PhD, OD (PI/GSE); Pamela Qualley, MA (PC); Dru Howard (BPC/PL); Lempi Miller Suzuki (BPC); Sarah Fisher, PhD, OD (GSE); Darlene Fong, OD (GSE); Sara Frane, OD (GSE); Cindy Hsiao-Threlkeld, OD (GSE); Selim Koseoglu, MD (GSE); A. Mika Moy, OD (GSE); Sharyn Shapiro, OD (GSE); Lisa Verdon, OD (GSE); Tonya Watson, OD (GSE); Sean McDonnell (LS/VD); Erika Paez (LS); Darlene Sloan (LS); Evelyn Smith (LS); Leticia Soto (LS); Robert Prinz (LS); Joan Edelman, RN (NS); Beatrice Moe, RN (NS).

*New England College of Optometry, Boston, MA*  
Bruce Moore, OD (PI/GSE); Joanne Bolden (PC); Sandra Umaña (PC/LS/PL); Amy Silbert (BPC); Nicole Quinn, OD (GSE); Heather Bordeaux, OD (GSE); Nancy Carlson, OD (GSE); Amy Croteau, OD (GSE); Micki Flynn, OD (GSE); Barry Kran, OD (GSE); Jean Ramsey, MD (GSE); Melissa Suckow, OD (GSE); Erik Weissberg, OD (GSE); Martheda Chery (LS/PL); Maria Diaz (LS); Leticia Gonzalez (LS/PL); Edward Braverman (LS/VD); Rosalyn Johnson (LS/PL); Charlene Henderson (LS/PL); Maria Bonila (PL); Cathy Doherty, RN (NS); Cynthia Peace-Pierre, RN (NS); Ann Saxbe, RN (NS); Vadra Tabb, RN (NS).

*The Ohio State University College of Optometry, Columbus, OH*  
Paulette Schmidt OD, MS (PI); Marjean Taylor Kulp, OD, MS (Co-Investigator/GSE); Molly Biddle, MA (PC); Jason Hudson (BPC); Melanie Ackerman, OD (GSE); Sandra Anderson, OD (GSE); Michael Earley, OD, PhD (GSE); Kristyne Edwards, OD, MS (GSE); Nancy Evans, OD (GSE); Heather Gebhart, OD (GSE); Jay Henry, OD, MS (GSE); Richard Hertle, MD (GSE); Jeffrey Hutchinson, DO (GSE); LeVelle Jenkins, OD (GSE); Andrew Toole, OD, MS (GSE); Keith Johnson (LS/VD); Richard Shoemaker (VD); Rita Atkinson (LS); Fran Hochstedler (LS); Tonya James (LS); Tasha Jones (LS); June Kellum (LS); Denise Martin (LS); Christina Dunagan, RN (NS); Joy Cline, RN (NS); Sue Rund, RN (NS).

*Pennsylvania College of Optometry, Philadelphia, PA*  
Elise Ciner, OD (PI/GSE); Angela Duson (PC/LS); Lydia Parke (BPC); Mark Boas, OD (GSE); Shannon Burgess, OD (GSE); Penelope Copenhaven, OD (GSE); Ellie Francis, PhD, OD (GSE); Michael Gallaway, OD (GSE); Sheryl Menacker, MD (GSE); Graham Quinn, MD, MSCE (GSE); Janet Schwartz, OD (GSE); Brandy Scombordi-Raghu, OD (GSE); Janet Swiatocha, OD (GSE); Edward Zikoski, OD (GSE); Leslie Kennedy (LS/PL); Rosemary Little (LS/PL); Geneva Moss (LS/PL); Patricia Rorie (LS); Shirley Stokes (LS/PL); Jose Figueroa (LS/VD); Eric Nesmith (LS); Gwen Gold (BPC/NHC/PL); Ashanti Carter (PL); David Harvey (LS/VD); Sandra Hall, RN (NS); Lisa Hildebrand, RN (NS); Margaret Lapsley, RN (NS); Cecilia Quenzer, RN (NS); Lynn Rosenbach, RN (NHC/NS).

*Northeastern State University College of Optometry, Tahlequah, OK*  
Lynn Cyert, PhD, OD (PI/GSE); Linda Cheatham (PC/VD); Anna Chambless (BPC/PL); Colby Beats, OD (GSE); Jerry Carter, OD (GSE); Debbie Coy, OD (GSE); Jeffrey Long, OD (GSE); Shelly Rice, OD (GSE); Shelly Dreadfulwater, (LS/PL); Cindy McCully (LS/PL); Rod Wyers (LS/VD); Ramona Blake (LS/PL); Jamey Boswell (LS/PL); Anna Brown (LS/PL); Jeff Fisher, RN (NS); Jody Larrison, RN (NS).

*Study Center: The Ohio State University College of Optometry, Columbus, OH*  
Paulette Schmidt, OD, MS (PI); Beth Haas (Study Coordinator).

*Coordinating Center: University of Pennsylvania, Department of Ophthalmology, Philadelphia, PA*  
Maureen Maguire, PhD (PI); Agnieszka Baumritter, MA (Project Director); Mary Brightwell-Arnold (Systems Analyst); Christine Holmes (AA); Andrew James (PR); Aleksandr Kharatov (PR); Lori O'Brien (AA); Ellen

Peskin, MA (Project Director); Claressa Whearry (AA); Gui-shuang Ying, PhD (Biostatistician).

National Eye Institute, Bethesda, MD  
Maryann Redford, DDS, MPH.

## REFERENCES

1. Schmidt P, Maguire M, Dobson V, Quinn G, Ciner E, Cyert L, Kulp MT, Moore B, Orei-Bixler D, Redford M, Ying GS; The Vision in Preschoolers Study Group. Comparison of preschool vision screening tests as administered by licensed eye care professionals in the Vision In Preschoolers Study. *Ophthalmology* 2004;111:637-50.
2. The Vision in Preschoolers Study Group. Preschool vision screening tests administered by nurse screeners compared with lay screeners in the vision in preschoolers study. *Invest Ophthalmol Vis Sci* 2005;46:2639-48.
3. el-Defrawy S, Clarke WN, Belec F, Pham B. Evaluation of a hand-held autorefractor in children younger than 6. *J Pediatr Ophthalmol Strabismus* 1998;35:107-9.
4. Cordonnier M, Dramaix M. Screening for abnormal levels of hyperopia in children: a non-cycloplegic method with a hand held refractor. *Br J Ophthalmol* 1998;82:1260-4.
5. Cordonnier M, De Maertelaer V. Comparison between two hand-held autorefractors: the Sure-Sight and the Retinomax. *Strabismus* 2004;12:261-74.
6. Liang CL, Hung KS, Park N, Chan P, Juo SH. Comparison of measurements of refractive errors between the hand-held Retinomax and on-table autorefractors in cyclopleged and noncyclopleged children. *Am J Ophthalmol* 2003;136:1120-8.
7. Miller JM, Dobson V, Harvey EM, Sherrill DL. Comparison of preschool vision screening methods in a population with a high prevalence of astigmatism. *Invest Ophthalmol Vis Sci* 2001;42:917-24.
8. Nikon Retinomax 2 Autorefractor Operation Manual. Tokyo: Nikon Corporation; 1999.
9. The Vision in Preschoolers Study Group. Development and implementation of a preschool vision screening program in a mobile setting. *NHSA Dialog* 2005;1:16-24. Available at: [http://www.leaonline.com/doi/pdf/10.1207/s19309325nhsa0801\\_4?cookieSet=1](http://www.leaonline.com/doi/pdf/10.1207/s19309325nhsa0801_4?cookieSet=1). Accessed December 12, 2006.
10. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika* 1986;73:13-22.
11. Hochberg Y. A sharper Bonferroni procedure for multiple significance testing. *Biometrika* 1988;75:800-3.

The Vision in Preschoolers Study Group  
The Ohio State University, College of Optometry  
320 West Tenth Avenue  
P.O. Box 182342  
Columbus, OH 43218-2342