Screening for Refractive Errors with the Topcon PR2000 Pediatric Refractometer

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Purpose. The PR2000 (Topcon, Tokyo, Japan) is a photorefractor that has been used in a population study comparing different methods of screening preschool children. The present study was conducted to determine the accuracy of the device in a largely clinical population.

Methods. Two hundred twenty-two children less than 8 years of age were included. All children were examined by an orthoptist using the PR2000 without inducing cycloplegia. All children then underwent retinoscopy with cycloplegia by an examiner who was unaware of the results from the PR2000 examination.

Results. The PR2000 gave a numerical reading for 90% of the children's right eyes and the message "Out of range" for a further 5%. The readings underestimated the amount of hypermetropic or astigmatic refractive error found on retinoscopy by an amount proportional to the magnitude of the refractive error. Agreement with retinoscopy for the axis of astigmatism more than 0.75 D was moderately good (intraclass correlation coefficient [ICC] = 0.63). The PR2000 was more useful as a screener, especially for anisometropia for which it was 91% sensitive and 92% specific. The repeatability was good for sphere (ICC = 0.74), less so for astigmatism (ICC = 0.59), and better than the optometrist for anisometropia (ICC = 0.38). The presence of nonrefractive diagnoses and the age of the children examined made little difference in the screening results.

Conclusions. The PR2000 underestimated hypermetropic refractive errors when used without cycloplegia. However, it was at least as good a screening device as other similar instruments, especially when judged by its ability to detect anisometropia and the repeatability of the results. (*Invest Ophthalmol Vis Sci.* 2000;41:1031–1037)

Automated refractors have become commonplace tools for the examination of adult patients. Their effectiveness is well characterized, and an optometrist performing a subjective refraction frequently uses one to estimate errors before refinement.[1] In recent years, several devices have been developed for use in young children. Some have been proposed as suitable instruments for use in screening programs, to detect children with or at risk for amblyopia or strabismus associated with high refractive errors.[2–8] Other studies have found less favorable results.[9–12]

The PR2000 Pediatric Refractometer (Topcon, Tokyo, Japan) was designed for use in young children and was included in a longitudinal study of infant visual development, as a potential tool for preschool vision screening.[13] The purpose of this study was therefore to assess the accuracy and repeatability of readings obtained with the PR2000.

Materials and Methods

Two hundred twenty-two children were recruited into the study. Some (n = 68) were recruited from an ongoing population study of infant development. The remainder were children attending a hospital pediatric clinic (n = 154). All children were first examined by an orthoptist who conducted a cover test and then used the PR2000. Cyclopentolate drops (1.0%) were then instilled in each eye. After at least 20 minutes, eyes were refracted by an experienced pediatric optometrist who was unaware of the results obtained with the PR2000. If the retinoscopy reflex was not stable, the optometrist waited another 10 minutes, or until it was stable. Twenty-eight children who lived locally were re-examined using the same protocol, 1 week later. The examiners did not have access to their previous findings. Nineteen children were examined by an experienced user and by an inexperienced user, on the same day, each unaware of the other's results. The study was performed in accordance with the Declaration of Helsinki. All the parents accompanying the children had the purpose of the study explained and gave their consent.

The PR2000 is a video-enhanced, infrared photorefractor and was used in accordance with the manufacturer's instructions. The child was seated either alone or on a parent's lap, at a distance of 0.9 m from the machine in a darkened room. Built-in flashing red and green lights and a beeping sound were used to attract the child's attention. The operator observed the image of the child's face in the video screen and slid the

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machine forward or backward so that the pupil margins were clearly in focus. Both eyes were assessed simultaneously, unless there was an obvious strabismus, when monocular readings were taken. The PR2000 produced printouts with the refraction for each eye expressed as sphere, negative cylinder, and axis. There were confidence scores indicating which readings were estimated by the software to be very reliable (the average of at least three recordings; denoted by a star), unreliable (denoted by brackets) or moderately reliable (single readings only; no star, no brackets). The machine stored the images used for calculation for each subject. The measurable range was −5.0 D to +5.0 D for sphere and cylinder, in 0.25 steps. Estimations outside this range were denoted by error codes ≪+≫ or ≪−≫. Images that could not be analyzed by the software were denoted by the message ERROR. Axis determination was in gradations of 5°. The PR2000 showed warning messages of "Room Light up" or "Room Light down" if the ambient light levels needed adjustment. These instructions were followed on the rare occasions when they occurred. In accordance with the manufacturer's instructions, readings for sphere of −1.00 D or more have had 1.0 added, to take account of the child's accommodation to a target at 1 m. This results in a dead zone of between 0.0 D and −1.25 D, in which range there are no readings. For uniocular measures, only the right eyes from each individual have been analyzed. The statistical methods used were regression analysis, calculation of the intraclass correlation coefficient (ICC), the unweighted κ statistic, the sensitivity and specificity, and the positive (PPV) and negative (NPV) predictive values.

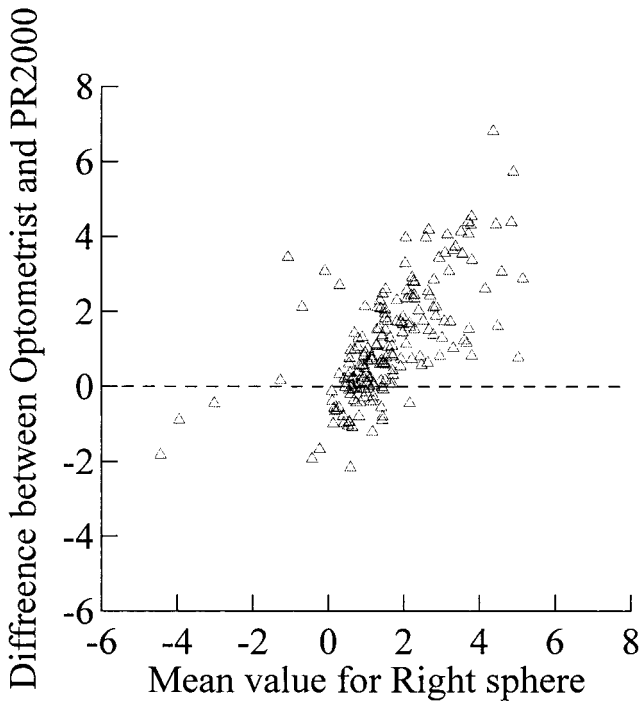

FIGURE 1. Differences between values for spherical refractive error by the PR2000 and by cycloplegic retinoscopy versus the mean of the two values (n = 199 right eyes). Values are diopters. Regression equation for difference in spherical refractive error versus mean spherical refractive error: difference y = (0.74 × mean) − 0.01 (r = 0.668, r^2 = 0.446; $P < 0.001$).

RESULTS

Results are means ± SD. The median age and interquartile range for the 222 children were 48.2 months and 12.5 to 68.7 months, respectively. The ethnicity of the children was not recorded. but almost all were white (over 90%) The nonrefractive conditions present were manifest strabismus (n = 35), lens opacities (n = 5), pseudophakia (n = 2), poor fixation (n = 13), nystagmus (n = 1), corneal scarring (n = 1), or iris coloboma (n = 1). For 48 children, accurate times were recorded for the instillation of drops and retinoscopy; the time between the two was 33 ± 5.9 minutes, and the range was 29 to 63 minutes.

Thirteen children (6%) registered ERROR and 10 children (5%) registered "Out of range," for the right eye. Of the remaining 199 right eye readings, 136 (68%) were "confidence 1, reliable," 39 (20%) were "confidence 2, moderately reliable," and 24 (12%) were "confidence 3, poor reliability." Readings (confidence 1–3) for both eyes were obtained for 189 children. Four children (2%) had error readings in both eyes. There was no difference in the magnitude of the differences between PR2000 and retinoscopy for any of the three confidence scores, for either spherical refractive errors (analysis of variance [ANOVA], df = 2, F ratio = 1.77, P = 0.17) or for astigmatism (ANOVA, df = 2, F ratio = 2.04, P = 0.13). Therefore, the data are presented for confidence readings 1 through 3 combined for the right eye (n = 199) for uniocular measures of accuracy, and for the children with confidence results 1 through 3 in both eyes (n = 189) for the results concerning anisometropia and screening.

Spherical Refractive Error

The PR2000 and cycloplegic retinoscopy readings for the spherical refractive error of the right eye were compared, and Figure 1 shows the differences between the two measurements plotted against the mean of the two measures. The mean difference between retinoscopy and the PR2000 was 1.16 ± 1.52 D. As Figure 1 shows, the differences between the two measures were related to the mean magnitude of the hypermetropic refractive error (r = 0.67, r^2 = 0.45, $P < 0.001$).

Anisometropia

The estimates of the PR2000 and the optometrist for the amount of anisometropia present were compared; Figure 2 shows a plot of the differences in anisometropia against the mean of the two values. The mean difference between the PR2000 and retinoscopy was 0.01 ± 0.83 D. However, in Figure 2 there is still a relation between the difference and the mean value (r = 0.53, r^2 = 0.28, $P < 0.001$), even when the outlying point is excluded (r = 0.38, r^2 = 0.15, $P < 0.001$).

Astigmatism

When inspected on a scatter plot (not shown), the data were approximately symmetrically distributed around the line of perfect agreement, and the mean difference between the two methods was −0.1 ± 0.61 D. There is again a relation between the differences and the mean value; r = 0.57, r^2 = 0.33; $P <$ 0.001. The axis of astigmatism was first assessed categorically, according to the direction of the positive component: with-the-rule if between 61° and 120°, against-the-rule if between 0°

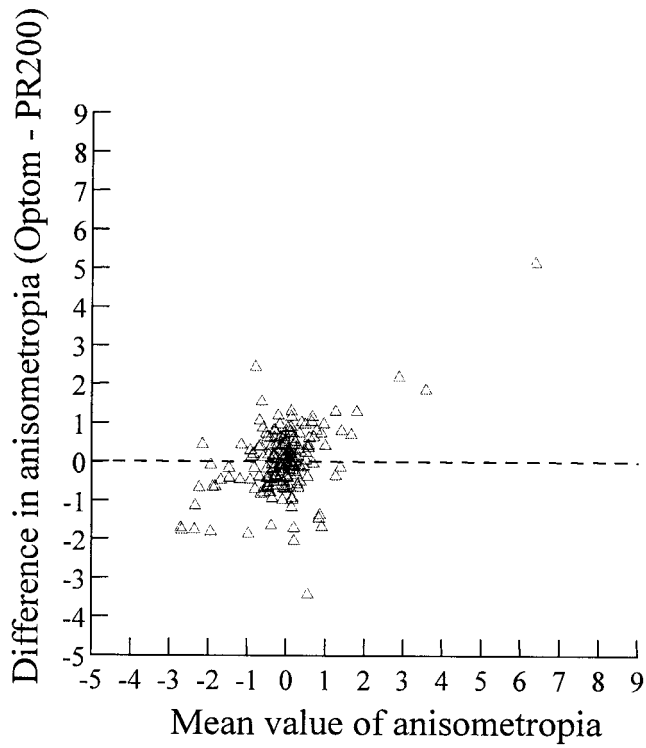

FIGURE 2. Differences between values for anisometropia by the PR 2000 and by cycloplegic retinoscopy versus the mean of the two values (n = 189). Values are diopters. Regression equation for difference in anisometropia versus mean anisometropia: difference y = (0.48 × mean) + 0.04 (r = 0.53, r^2 = 0.28; $P < 0.001$).

to 30° or 151° to 180°, and oblique for all other directions. Cases in which there was no astigmatic error were classified as none. For all 199 cases, the unweighted κ statistic (95% confidence interval [CI]) for agreement between the PR2000 and cycloplegic retinoscopy was κ = 0.33 (0.23–0.42). For 32 cases in which the PR2000 estimated the astigmatism as more than 0.75 D, the agreement with the optometrist was better (κ = 0.68, 0.45–0.90). The ICC for actual measurements of the axis was 0.20 for all 199 cases but increased to 0.63 for the 32 cases with more than 0.75 D astigmatism.

Children with and without Nonrefractive Diagnoses

The proportion of error readings in the right eye was 3 (5%) of 58 for the children with nonrefractive diagnoses, compared with 10 (7%) of 164 for the children with refractive errors only (P = 0.54, Fisher's exact test). The proportion of out-of-range values was 6 (10%) of 58 for the children with nonrefractive diagnoses, compared with 4 (2%) of 164 for the children with refractive errors only (P = 0.02, Fisher's exact test). Of the 189 children with results (confidence 1–3) for each eye, there were 35 children with nonrefractive problems (31 with strabismus, 2 with lens opacity, 1 with corneal scarring, and 1 with pseudophakia). The mean differences between the PR2000 and the retinoscopy results were larger for the children with nonrefractive problems than for the children with refractive errors alone. The differences were 1.8 ± 1.9 D versus 1.0 ±1.4 D for sphere, 0.29 ± 0.57 D versus 0.13 ± 0.62 D for astigmatism and 0.09 ± 0.83 D versus 0.008 ± 0.83 D for anisometropia. The only statistically significant difference between the two groups was in the results for sphere (ANOVA, df = 1, F ratio 7.8, P = 0.006). The differences were still related to the mean quantity measured, for all parameters in the children with refractive errors only and for the measurement of spherical error in the children with nonrefractive problems (ANOVA, df = 1, $P < 0.001$ in all cases).

Accuracy of the PR2000 for Different Age Groups

The 189 children with full results were classified into age groups: up to 36 months (n = 83), 36 to 59 months (n = 45), and more than 59 months (n = 61). The mean differences between the spherical refractive errors, measured by retinoscopy, compared with those measured with the PR2000 for the three age groups were; 0.84 ± 1.3 D, 1.3 ± 1.7 D, and 1.5 ± 1.6 D for children aged less than 36 months, 36 to 59 months, and more than 59 months, respectively (ANOVA, df = 2, F ratio = 3.8, P = 0.02). The only statistically significant individual difference was between the results for children aged less than 36 months compared with those for children aged more than 59 months (P = 0.02). The corresponding ICCs for agreement between the PR2000 and retinoscopy for sphere were 0.35, 0.61, and 0.59, respectively. The range of the retinoscopic errors for children aged up to 36 months was −1.25 to +7.5 D; for children 36 to 59 months, −4.5 to +7.75 D; and for children above 59 months, −5.5 to +6.7 D.

Repeatability of the PR2000 and of Cycloplegic Retinoscopy

The results estimating the repeatability of the PR2000 and of cycloplegic retinoscopy by the optometrist are shown in Table 1. The ICC values suggest that the PR2000 was less repeatable for sphere, spherical equivalent, and astigmatism but was more

TABLE 1. Repeatability of Results of the PR2000 and Cycloplegic Retinoscopy Examinations

Measure	PR2000	PR2000	Retinoscopy	Retinoscopy
	Mean Difference Between Visits (Diopters)	Intraclass Correlation Coefficient	Mean Difference Between Visits (Diopters)	Intraclass Correlation Coefficient
Spherical error	0.05 ± 0.38	0.74	0.17 ± 0.58	0.92
Spherical equivalent	0.02 ± 0.40	0.74	0.16 ± 0.56	0.92
Astigmatism	0.06 ± 0.62	0.59	0.02 ± 0.27	0.87
Anisometropia	0.04 ± 0.22	0.38	0.12 ± 0.38	0.01

n = 28 for all measurements. Differences are means ± SD.

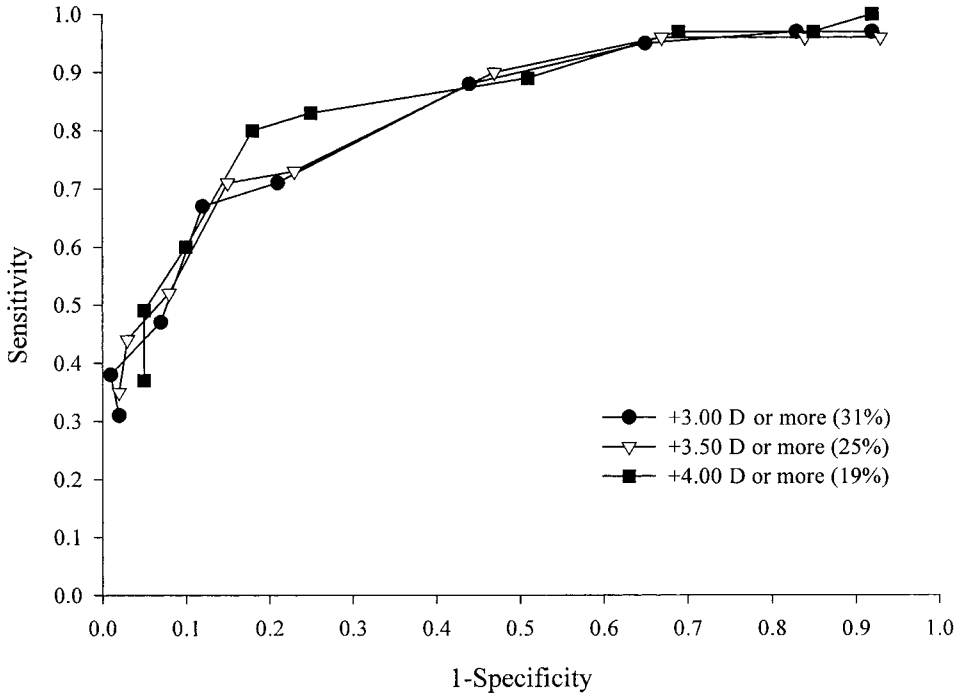

FIGURE 3. ROC chart showing sensitivity and specificity of the PR2000 when screening for hypermetropia of 3.0 D, 3.5 D, or 4.0 D. Symbol legend shows target refractive error screened for and its prevalence. The data points on each curve represent (from the *right*) PR2000 referral criteria of 0.25, 0.50, 0.75, 1.00, 1.25, 1.50, 1.75, 2.00, and 2.25 D, respectively.

repeatable for anisometropia than was retinoscopy. However, the differences in measures between visits are smaller for the PR2000 than for retinoscopy, except those relating to astigmatism. This discrepancy between the ICC and the magnitude of the differences is likely to be because the ICC is affected by the range of values, which was greater for the retinoscopy data than for the PR2000 data. The ICC for axis determination was 0.92 for the PR2000 and for retinoscopy was only 0.04. However, of the nine cases in which there was retinoscopic astigmatism on both occasions, six axes agreed exactly: one differed by 20°, one by 85°, and one by 175°. Of the eight cases in which the PR2000 detected astigmatism on both visits, seven axes agreed within 10° and 1 by 40°. The unweighted κ statistics for the repeatability of classification of the axis of astigmatism (with the rule, against the rule, or oblique), were $\kappa = 0.75$ for the PR2000 and $\kappa = 0.64$ for the optometrist.

Nineteen children were examined with the PR2000 by a trained user and by a completely inexperienced user on the same day. The mean agreement between the two users for the right eye results was 0.03 ± 0.14 D for spherical refractive error and 0.05 ± 0.17 D for astigmatism.

Accuracy of the PR2000 as a Screening Tool

Receiver operating characteristic (ROC) curves demonstrating the sensitivity and specificity of the PR2000, using different cutoff points for referral, are shown in Figures 3, 4, and 5 (for 189 children with full data). When screening is conducted for a relatively rare condition, cost considerations may necessitate using a very specific referral cutoff for the screening test, to avoid large numbers of overreferrals. Table 2 shows the results that were obtained, either when the sum of sensitivity + specificity was the greatest of those tested, or when the specificity was required to be 95% or greater. The sensitivities decline, but the PPV values increase, when the specificity is required to be at least 95%. Screening for anisometropia was more accurate than screening for hypermetropia or astigmatism in both situations.

Nonrefractive Diagnoses and the Age of the Subjects

The calculations in Table 2 were repeated with the exclusion of the 35 children with nonrefractive diagnoses. When the more specific (at least 95%) referral cutoffs are used, as shown in Table 2, the sensitivities, specificities, PPV, and NPV for hypermetropia were 54%, 95%, 76%, and 92%, respectively. The corresponding percentages for anisometropia and astigmatism were 69%, 96%, 65%, and 96% and 50%, 97%, 75%, and 91%, respectively, which are similar to those in Table 2. Repeat calculations were performed with the children divided into three subgroups according to age (Table 3). For all three target refractive errors, the PPV values were lower in the younger children; otherwise, there were few differences between groups.

DISCUSSION

The PR2000 provided useful data for 98% of the children and a full set of numerical data for each eye in 85%. The differences between the PR2000 and retinoscopy were related to the quantity measured and tended to underestimate any hypermetropia present. This was not unexpected. The PR2000 was used without cycloplegia, as would be practicable in a preschool screening program, whereas the retinoscopy was performed after cycloplegia. Previous studies have found a similar result.[9]

Many of the children had other diagnoses besides suspected refractive error. The differences between the PR2000 and retinoscopy were larger for the children with nonrefractive diagnoses, although this was only statistically significant for the measurement of spherical refractive error. This might

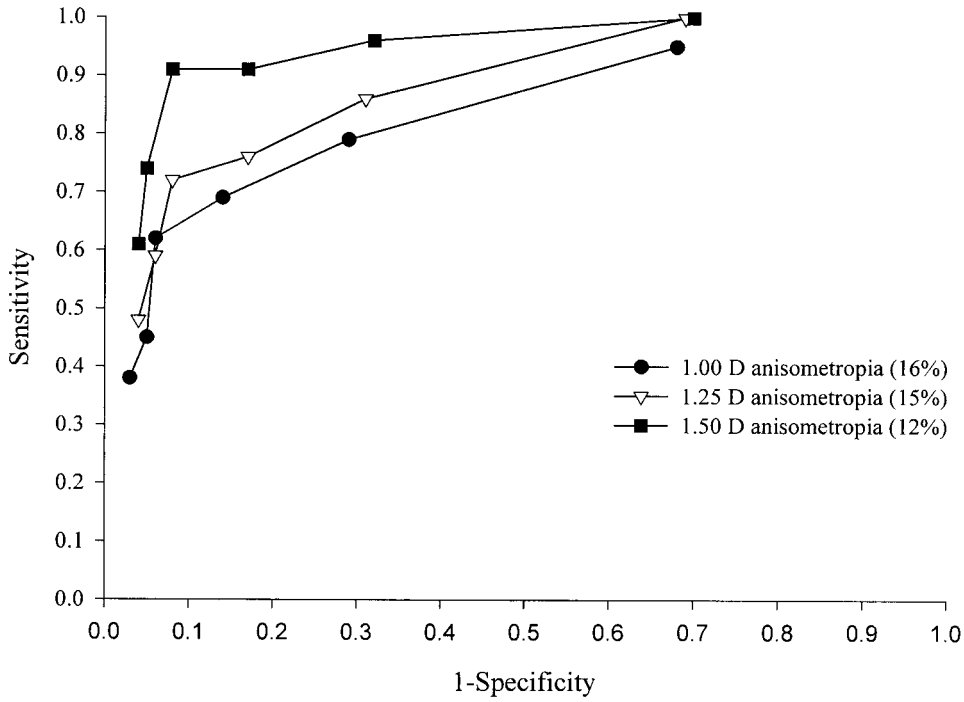

FIGURE 4. ROC chart showing sensitivity and specificity of the PR2000 when screening for anisometropia of 1.0 D, 1.25 D, or 1.5 D. Symbol legend shows target refractive error screened for and its prevalence. The data points on each curve represent (from the *right*) PR2000 referral criteria of 0.25 D, 0.50 D, 0.75 D, 1.00 D, 1.25 D, 1.50 D, respectively.

be expected, because many of these children had strabismus and may have a strong tendency to overaccommodate, which would mask any hypermetropic error in noncycloplegic conditions. However, the screening results for the PR2000 were similar whether the children with other problems were included or excluded.

There was no consistent effect of the age of the child on the accuracy of the PR2000. Although the differences between the PR2000 and the retinoscopy results for sphere were smaller for the youngest children (aged <36 months) than for the oldest children (aged >59 months), the ICC for agreement with retinoscopy was only 0.35 for the youngest children, whereas that for the other two categories was approximately 0.60. This apparent disagreement may be because the range of refractive errors was smaller in the youngest children. Because examination by the PR2000 requires very little cooperation from the child except brief fixation on the target, it is not surprising that age made little difference in these results. The

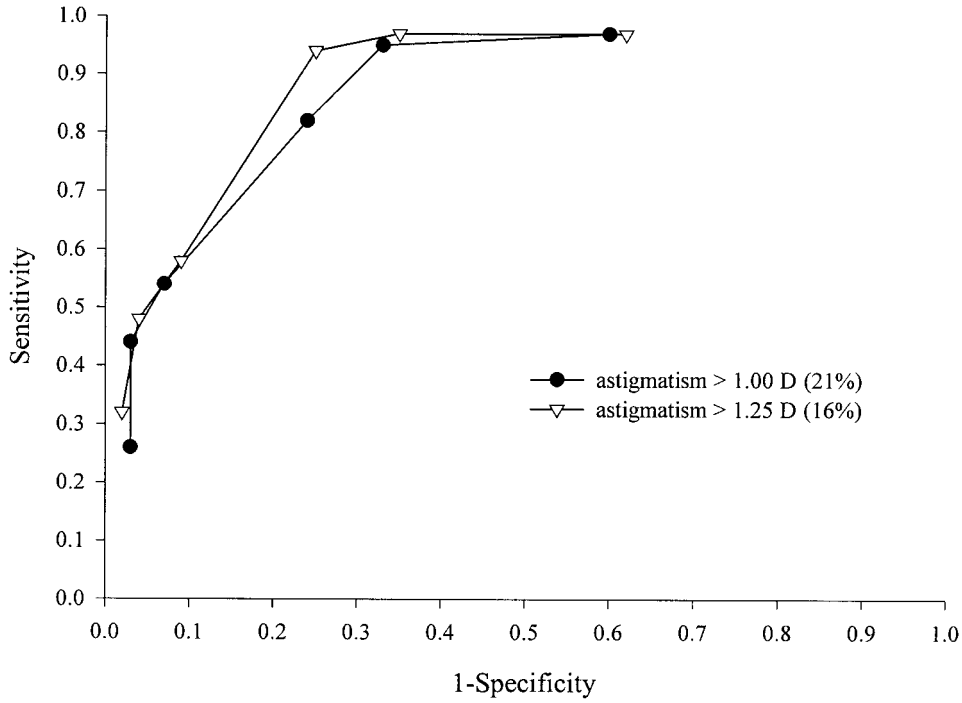

FIGURE 5. ROC chart showing sensitivity and specificity of the PR2000 when screening for astigmatism of 1.25 D or 1.5 D. Symbol legend shows target refractive error screened for and its prevalence. The data points on each curve represent (from the *right*) PR2000 referral criteria of 0.25 D, 0.50 D, 0.75 D, 1.00 D, 1.25 D, and 1.50 D, respectively.

TABLE 2. Percentages for Sensitivity, Specificity, PPV, and NPV for the PR2000, Using Different Criteria to Set the Referral Level

Criterion	Target	Prevalence of Target Error (%)	PR2000 Referral Level (Diopters)	Sensitivity	Specificity	PPV	NPV
Maximum sum of sensitivity + specificity	Spherical error > 3.75 D	19	1.5	80	82	51	95
	Anisometropia > 1.25 D	12	1.0	91	92	62	99
	Astigmatism > 1.25 D	16	0.75	94	75	43	98
Specificity at least 95%	Spherical error > 3.75 D	19	2.0	49	95	68	90
	Anisometropia > 1.25 D	12	1.25	74	95	65	96
	Astigmatism > 1.25 D	16	1.25	48	96	71	90

Sensitivity is the proportion of true cases correctly identified, and specificity is the proportion of true normal subjects correctly identified by the screening test. PPV is the proportion of referrals from the screening test that truly have the target condition and NPV is the proportion of individuals passed by the screening test who are free of the target condition. $n = 189$.

PPV values for screening the younger children were less than those for the older two groups (Table 3), but the prevalence of target conditions was also lower in this group, which would reduce the PPV.

The ROC curves and the data in Tables 2 and 3 indicate a more accurate profile for the PR2000 when screening for anisometropia than when screening for spherical or astigmatic errors. This might be expected, because both eyes were measured simultaneously. There are few data in the literature with which to compare these data, but a custom-built device detected both of two cases of more than 2.0 D anisometropia, whereas four infants with anisometropia between 2.0 and 1.5 D were missed, in a sample of 97 infants. These data suggest a lower sensitivity than found for the PR2000.[3]

The data in Tables 2 and 3 for hypermetropia and astigmatism also compare well with the results of screening obtained using other devices in children without cycloplegia. For the group using a custom-built device, the sensitivity was 85% and specificity only 53%,when screening for hypermetropia in excess of 3.25 D,[14] compared with 80% and 82%, respectively, in the present study (Table 2). Another group, using the VPR-1 (Clement Clarke, Harlow, UK), found that the sensitivity was only 12%, but with 99% specificity, when screening for hypermetropia of 4 D or more, whereas for astigmatism of more than 1.75 D, sensitivity was 54% and specificity was 62%.[10] The equivalent percentages in this study were 94% sensitivity and 75% specificity (Table 2). In two recent studies on the MTI photoscreener (Medical Technologies, Riviera Beach, FL), there was marked variability between different operators in the accuracy of grading the pictures.[12,15] In one of these studies, no individual grader achieved sensitivity and specificity both above 70%.[15] In the present study the PR2000 achieved this for all target conditions (Table 2). The Retinomax autorefractor (Nikon, Tokyo, Japan) had a sensitivity of 70%, specificity of 95%, PPV of 79%, and NPV of 92%, respectively, for hyperopia of 3.5 D or more in children aged 9 to 36 months.[8] These values suggest slightly greater sensitivity than the present study (Tables 2, 3). The percentages for astigmatism of more than 2 D detected with the Retinomax were 59% sensitivity and 95% specificity, with PPV of 71% and an NPV of 92%,[7] which again are slightly more sensitive but otherwise very similar to the results in the present study (Tables 2, 3).

The retinoscopy results were very repeatable, except those for anisometropia, for which the ICC was surprisingly low. However, this repeatability study was small, and the results should be interpreted cautiously. Although generally less repeatable than retinoscopy, the results for the PR2000 (Table 1) compare favorably with those given for the VPR-1, with which the mean difference between visits for assessment of spherical refractive error was 0.12 ± 1.1 D and for astigmatism was 0.2 ± 1.6 D.[9] The repeatability reported for the Retinomax was also worse than that found in the present study for sphere, with a mean difference between refractions of 0.05 ± 1.33 D. The results were similar to those in the present study for astigmatism; however, with a mean difference between refractions of 0.04 ± 0.45 D.[7] Autorefractors used in adults with pseudophakic eyes can be more repeatable: 0.04 ± 0.30 D for sphere and 0.02 ± 0.36 for astigmatism.[16]

Cycloplegic retinoscopy was the gold standard against which we judged the results from the PR2000. The results may differ from those that would have been obtained when comparing the PR2000 results with those of subjective refractions

TABLE 3. Effect of Age on the Accuracy of the PR2000, When Specificity Is at Least 95%

Age Group	Target	Prevalence of Target Error	PR2000 Referral Level (Diopters)	Sensitivity	Specificity	PPV	NPV
Less than 36 months ($n = 83$)	Spherical error > 3.75 D	8	2.00	57	97	57	97
	Anisometropia > 1.00 D	4	1.25	25	99	50	96
	Astigmatism > 1.25 D	7	1.25	67	95	50	98
36 to 59 months ($n = 45$)	Spherical error > 3.75 D	24	2.00	54	95	75	85
	Anisometropia > 1.00 D	15	1.25	63	96	71	94
	Astigmatism > 1.00 D	22	1.00	50	100	100	88
More than 59 months ($n = 61$)	Spherical error > 3.75 D	20	2.00	47	95	70	88
	Anisometropia > 1.00 D	30	1.25	65	95	79	90
	Astigmatism > 1.25 D	18	1.00	62	95	73	92

For definition of terms, see footnote to Table 2. $n = 189$.

in subjects without cycloplegia. The use of cycloplegic drops introduces further variability. It is possible that the use of a variable gold standard reduced the apparent accuracy of the PR2000. Alternatively, if cycloplegia had not been fully induced, in many children it would have led to an increased estimate of the sensitivity of the PR2000 for hypermetropia. These caveats also apply to the other studies quoted in which cycloplegic retinoscopy was used,[3,4,7–9,12,14,15] and therefore comparisons may still be made between the different devices tested.

In our institution, the most experienced retinoscopist was the senior hospital optometrist, who performed the refractions in this study, but different institutions may have other professionals who perform most of the retinoscopy. Many of the children were selected from hospital clinics, and the results therefore cannot be generalized to normal populations. Similarly, the results apply to a predominantly white population and may not be applicable in areas in which there is a much higher prevalence of children with heavily pigmented eyes. The PR2000 also provides an estimate of ocular alignment based on the corneal reflections. This feature was not assessed, because the PR2000 was not used in this respect in our longitudinal study. An earlier prototype of the PR2000 (the PR1100) was validated in this regard and found to be reliable but to have poor agreement with the results of a prism cover test.[17]

The current results suggest that the PR2000 provides repeatable results, has a more accurate screening profile than some devices in the literature (the VPR-1 and the MTI) and a comparable (although slightly less sensitive) profile to that of the Retinomax for sphere and astigmatism. However, the most accurate results were obtained when screening for anisometropia, and few comparable data were found for the other devices. Anisometropia may be labile in childhood,[18] and the nature of the relation between anisometropia and strabismus or amblyopia is as yet unclear.[19] Nevertheless, anisometropia is strongly associated clinically with strabismus and/or amblyopia.[20] When used in our main population study in children less than 37 months of age (results presented separately), the PR2000 was more sensitive than was visual acuity testing, especially when detecting straight-eyed amblyopia, which is commonly associated with anisometropia. In conclusion, the PR2000 was a reliable device, most accurate when assessing anisometropia but with sufficient sensitivity and specificity for other refractive errors to be of potential use in research or screening programs.

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