ABSTRACT

Purpose: To determine the accuracy of measurement by the Nikon Retinomax handheld autorefractor and its ability to relax accommodation.

Setting: Pediatric Section, Department of Ophthalmology, University of Mainz, Germany.

Methods: To perform a series of comparative measurements, autorefractor readings were obtained on healthy young adults (students) and on children aged 2 to 12 years. The autorefractor readings were compared with subjective refractions of the young adults and with cycloplegic retinoscopy of the children.

Results: In adults, the accuracy of the handheld autorefractor measurements was comparable to that of conventional tabletop autorefractors. In children, the autorefractor measurements performed under cycloplegia were reliable; when cycloplegic agents were not administered, 24% were overcorrected by more than −2.0 diopters.

Conclusion: Cycloplegia is often necessary to obtain accurate autorefractor results.


Accuracy and accommodation capability of a handheld autorefractor

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Over the past 25 years, many aspects of automatic eye refractors have been improved. The optical construction has been simplified and the measurement speed increased; additional features such as measurement of the central and peripheral curvature of the cornea and visual acuity tests have been added.

A disadvantage of most modern autorefractors is their relatively large size, which requires that the instruments be mounted on a table. Measurement of ametropia can therefore be difficult or impossible in disabled persons, patients who have to lie in bed, and children, especially when they are very young or handicapped. The Nikon Retinomax handheld autorefractor can be applied in many of these problematic cases, so it is important to investigate the accuracy of this autorefractor.

Since we have evaluated autorefractors in earlier studies,1–5 we were able to apply the same measurement procedures and compare the new handheld instrument with older autorefractors. We also wanted to investigate the effectiveness of the fogging system and determine whether accommodation can be reliably relaxed. This capability is especially important when measurements are to be taken during vision screening of children, in whom cycloplegia is normally prohibited.

Patients and Methods

Measurements of adult ametropic subjects were carried out in 50 students (100 eyes) aged 24 to 29 years. All had a visual acuity of at least 20/20. The median spher-
ical equivalent with subjective refraction was $-0.38$ diopter ($D$) (range $-10.00$ to $+3.00$ D; 63 eyes with myopia, 25 with hyperopia, and 12 with emmetropia). The mean cylinder power was $-0.45$ D $\pm 0.52$ (SD) (range 0 to $-2.25$ D).

The clinical evaluation of children was performed on 2 groups. All children were randomly selected from the young patients visiting the pediatric section of the Department of Ophthalmology in Mainz. Exclusion criteria were known or suspected eccentric fixation and opacities of the optical media.

Group 1 consisted of 27 children (50 eyes). The ages ranged from 2 to 10 years and were almost evenly distributed (2 to 4 years, $n = 15$; 5 to 7 years, $n = 16$; 8 to 10 years, $n = 19$). The median spherical equivalent calculated from cycloplegic retinoscopy was $+1.38 \pm 3.00$ D (range $-10.00$ to $+7.00$ D), and the mean cylinder power was $+1.00 \pm 0.95$ D (range 0 to $-3.50$ D).

Group 2 consisted of 40 children (79 eyes). The ages ranged from 2 to 12 years. The median spherical equivalent was $+1.13 \pm 3.00$ D (range $-18.00$ to $+7.50$ D) and the cylinder power, $-0.67 \pm 0.77$ D (range 0 to $-3.25$ D).

Method of Comparative Measurements

Adults. The result of an accurate subjective refraction was used as a comparison in all adults. The subjective refraction was always done before the autorefractor measurement. Jackson’s cross-cylinder technique was used, with special attention to binocular balancing. The final spherical power was defined as the highest plus value or the lowest minus value that gave the best visual acuity.

All autorefractor readings were taken with a Retinomax K-Plus immediately after the subjective refraction. This short interval was used to minimize errors from the well-known diurnal changes of ametropia. The specification K-Plus indicates that the instrument can also be used as a keratometer; however, this feature was not used. The operator started the measurement after adjusting the instrument to the eye and continued to take readings until at least 8 automatic refractions had been taken in rapid succession. The result was automatically calculated by the instrument as an average of the last 8 readings.

A “consistency value” is printed by the instrument. It is a measure of the reliability of measurements and can assume values from 0 to 10. In all measurements, the consistency value was at least 9, indicating a high reliability.

The handheld autorefractor contains a “quick mode” switch that controls the setting of the additional internal fogging system. When the quick mode is “off,” a preliminary measurement of ametropia is done prior to the actual measurement, and the vergence of the fixation target is adjusted according to the result of the preliminary measurement. When the quick mode is “on,” the autorefractor starts to take readings immediately after the alignment of the apparatus. To obtain additional information on the reliability of the fogging system, autorefractor measurements of 52 eyes of young adults were made with both settings (quick mode on and off).

Children, Group 1. The ametropia of all children in Group 1 was measured with the Retinomax by 2 orthoptists and by retinoscopy performed by an experienced ophthalmologist. Measurements were done using cycloplegic agents administered according to the following protocol:

Age 2 years: Atropine 0.125%, 1 drop and a second drop 10 minutes later; measurements after an additional waiting period of at least 1 hour.

Age 2 to 3 years: Atropine 0.5% administered as above.

Age older than 3 years: Cyclopentolate, 1 drop and a second drop 10 minutes later; measurement after another waiting period of 20 minutes.

Children, Group 2. The purpose of the measurements in this group was to learn more about the influence of accommodation and the effectiveness of the fogging system; specifically, to determine whether cycloplegic agents are necessary in children. Four measurements with and without cycloplegia were taken to determine the effectiveness of the automatic fogging system. The series of measurements started with 2 autorefractor measurements—1 with the automatic fogging system turned on (quick mode off) and the other with it turned off (quick mode on). After these measurements, eyedrops were administered according to the above protocol. After the prescribed waiting period, cycloplegic retinoscopy and then a third autorefractor measurement were done. All measurements were taken in less than 2 hours.
Criteria for the Accuracy of Measurement

To obtain information about the accuracy of the handheld autorefractor, the following comparison criteria were used:

Difference of the spherical equivalents (DSE)

\[ DSE = (S_t + 0.5 \times C_t) - (S_c + 0.5 \times C_c) \]

where \( S \) and \( C \) denote the spherical and the cylindrical powers. The subscripts \( t \) (test) and \( c \) (comparison) denote the instrument under test (Retinomax or Retinomax K-Plus) and the comparison technique (subjective refraction or retinoscopy). A positive DSE indicates that the handheld autorefractor displayed more “plus” than the comparison technique.

Difference of the cylindrical powers (DC)

\[ DC = C_t - C_c \]

A negative \( DC \) indicates that a stronger (negative) cylinder power was found by the autorefractor.

Weighted axes difference (DA)

\[ DA = 2C_c \times \sin(\Delta \phi) \]

The mathematical expression for \( DA \) multiplies the difference between the 2 cylinder axes (\( \Delta \phi \)) (measured in degrees) by the cylinder power (\( C_c \)). This makes it possible to combine all axes differences in a “magnitude of differences statistics” even when the actual cylinder powers are different.\(^1\)\(^4\) A disadvantage of the formula is that the resulting value, \( DA \), has the dimension “diopter.” An example of this criterion is that a \( DA \) of 0.5 D is equal to an axes difference of 14.5 degrees given a cylinder power of 1.0 D.

Difference of the cylindrical corrections (DCC)

\[ DCC = |\sqrt{C_t^2 + C_c^2 - 2C_tC_c\cos(2\Delta \phi)}| \]

The \( DCC \) is a summarizing measure of the deviations between the 2 cylinder powers and axes. The \( DCC \) is calculated as the absolute value of the vector difference between both cylindrical components and can assume positive values only.

The 4 criteria were used in our earlier studies;\(^1\)\(^4\) however, the names of the criteria were changed as discussed below.

Results

Accuracy of Measurement in Ametropic Adults

Difference of the spherical equivalents. The results of the comparison of spherical equivalents are presented in Figure 1. The histogram in Figure 1, \( a \), is not symmetric; it exhibits a shift toward positive values. Only 50% of all automatically determined values differed by less than \( \pm 0.25 \) D from the spherical equivalent obtained by subjective refraction. The maximal differences were \(-1.38\) and \(1.13\) D. On average, the Retinomax K-Plus delivered a spherical equivalent that was \( 0.28 \) D more “plus” than that of the subjective refraction (\( \sigma = \pm 0.38 \) D). This shift toward positive values is highly significant according to the Wilcoxon signed rank test (\( P < .0001 \)). Figure 1, \( b \), shows how the histogram changed after the automatically determined sphere was corrected by \(-0.25 \) D. The histogram shifted to the left and became almost completely symmetric.

Difference of the cylindrical powers. The cylinder powers determined automatically and subjectively were very similar. The mean difference was \(+0.05 \pm 0.32\) D. The distribution in Figure 1, \( c \), is almost symmetric and shows few cylinder power differences larger than \( \pm 0.50 \) D (in a total of 5 eyes).

Axes difference. The accuracy of the axis could be evaluated only in eyes in which a cylinder power of \( 0.25 \) D or greater had been determined with the method under test as well as the comparison technique. This occurred in 55 of the 100 eyes. The mean axes difference was \(+0.02 \pm 0.51\) D. The histogram is fairly symmetric (Figure 1, \( d \)). In a few cases, however, large differences were found; the largest were \(-1.50\) and \(2.19\) D (equivalent to an axes difference of \(-22\) degrees and \(33\) degrees for a given cylinder power of \(2.00\) D).

These 2 differences could not be attributed to random measurement errors because they could be replicated by additional subjective and automatic control measurements on the same and the following day.

Table 1 summarizes the histograms in Figure 1 to indicate the differences that were smaller than a selected criterion value, which can be interpreted as the “percentage of correct or almost correct results.” The DSE percentages were calculated in 2 different ways: original data (Figure 1, \( a \)) and autorefractor values corrected by \(-0.25 \) D (Figure 1, \( b \)). The correction compensates for the systematic shift toward positive values. After the cor-
rection, the percentage of correct or almost correct results increased from 75% to 88%.

The percentages of correct or almost correct results using an identical measurement procedure on 7 autorefractors of an earlier generation are also presented in Table 1. The accuracy of the handheld autorefractor did not differ from the mean accuracy of the tabletop instruments tested about 10 years ago.

**Accuracy of Measurement in Children**

*Difference of the spherical equivalents.* The distribution of the DSE (Figure 2, a and b) was similar to the distribution in adults (Figure 1, a and b). The distribu-

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**Table 1.** Frequency of “correct or almost correct results” obtained on adults (N = 100 eyes) with Retinomax K-Plus and subjective refraction. The percentages indicate how often the result of the Retinomax K-Plus differed from the subjective refraction by not more than ±0.5 D or 0.62 D. Data from a study using the same method on 7 autorefractors are presented for comparison.

<table>
<thead>
<tr>
<th>Comparison</th>
<th>DSE</th>
<th>DC</th>
<th>DA</th>
<th>DCC</th>
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<tr>
<td>Retinomax K-Plus and subjective refraction</td>
<td>75.0</td>
<td>88.0</td>
<td>95.0</td>
<td>87.3</td>
</tr>
<tr>
<td>Range of 7 autorefractors (Wesemann and Rassow)</td>
<td>84–95</td>
<td>84–95</td>
<td>90–97</td>
<td>84–93</td>
</tr>
</tbody>
</table>

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*Original data
†Spherical autorefractor data corrected by −0.25 D
tion of the differences (Figure 2, a) was not symmetric about the origin but shifted toward positive values. The mean spherical equivalent obtained with the Retinomax was 0.59 D more “plus” than with retinoscopy ($\sigma \pm 0.44$ D). The maximum differences were $-0.38$ D and 1.63 D. After the sphere determined automatically was corrected by $-0.50$ D (similar to Figure 1, b), the histogram became almost symmetric (Figure 2, b).

Difference of the cylinder power. The mean cylinder power difference was almost zero ($+0.06 \pm 0.47$ D, Figure 2, c). The histogram shows larger differences than those found in the adult group (Figure 1, c). The largest deviations were $-1.00$ D and 1.75 D.

Axes difference. The mean axis determined with the handheld autorefractor was almost equal to that determined by retinoscopy ($+0.05 \pm 0.46$ D, Figure 2, d). The maximum axis differences were smaller than the maximum differences found in adults ($-1.69$ and 0.68 D).

A summary of all cycloplegic results is presented in Table 2. As in Table 1, the DSE is presented as original data and spherical power of the autorefractor corrected by $-0.25$ and $-0.50$ D. After a correction of $-0.50$ D, the percentage of correct or almost correct results increased from 44% to 78% in Group 1 and from 51% to 82% in Group 2. This large increase is a consequence of the systematic bias of the spherical power displayed by the autorefractor.

Effectiveness of the Fogging System in Adults

Comparison of the results obtained with the fogging system on and off showed no systematic differences. The spherical equivalents differed on average by only 0.07 D.

Accommodation and Effectiveness of the Fogging System in Children

Figure 3 compares the spherical equivalents found with the handheld autorefractor (applied with and without cycloplegia) with the results of retinoscopy under
cycloplegia. The data points obtained under cycloplegia (circles) lie very close to but slightly above the uppermost diagonal line and illustrate the tendency of the autorefractor to display spherical equivalents that are similar but “more plus” (median $1.00 \text{D}$) than the values obtained with cycloplegic retinoscopy. Most data points obtained with the handheld autorefractor without cycloplegia (squares) lie slightly lower than but also very close to the uppermost diagonal line and indicate a high accuracy. In addition, a fairly large number of children showed a tendency to accommodate during the automatic measurement without cycloplegia; 12 of 79 eyes showed a minus overcorrection of $2.00$ to $4.00 \text{D}$ and 7 showed an even larger minus overcorrection of $4.00$ to $10.00 \text{D}$. The median of the difference between the spherical equivalents with and without cycloplegia was $1.13 \text{D}$.

The amount of minus overcorrection without cycloplegia did not depend on the setting of the fogging system. The mean spherical equivalent obtained with the fogging system turned off ($\text{SE}_{\text{off}}$) was identical to that obtained with the fogging system turned on ($\text{SE}_{\text{on}}$). The median of the difference ($\text{SE}_{\text{on}} - \text{SE}_{\text{off}}$) was $0$. The $25\%$ and $75\%$ percentiles lay at $-0.25 \text{D}$ and $+0.25 \text{D}$, respectively.

The data indicate that the danger of a substantial minus overcorrection without cycloplegia may be age dependent (Figure 4). Minus overcorrected spherical values up to $-4.0 \text{D}$ occurred at all ages in the group. Extreme deviations from the true spherical value of ametropia, however, occurred predominantly at 2 to 4 years of age.

**Discussion**

**Comparison Criteria**

The purpose of the 4 comparison criteria was to estimate the accuracy of measurement of the instrument under test. In this context, Edwards and Llewellyn$^8$ point out that accuracy means validity, i.e., “the degree with which tests measure what they claim to measure” and they continue: “It has been pointed out . . . that not only the instrument under test but also the comparison techniques are prone to bias and error. However at present they (i.e., subjective refraction and retinoscopy) are the norm and it is only natural that they should be the main criteria against which these autorefractors should be validated.” In short, the comparison techniques serve as a gold standard. Since we do not want to overemphasize the validity of our comparison techniques (the gold standard), we decided to change the technical term “error of the spherical equivalents” used by Wesemann and Rassow$^4$ to the more neutral expression “difference of the spherical equivalents” already used in our work on subjective refraction.$^9$ This problem was also addressed by Bullimore and coauthors.$^{10}$

**Accuracy of Measurement**

The frequency of correct or almost correct results found with the handheld autorefractor in adults lies in the middle of the range found by Wesemann and Rass-
sow using the same methods on 7 different automatic eye refractors. The four characteristic differences were not larger than 0.50 or 0.62 D in 87% to 95% of all cases. This indicates that the handheld autorefractor has a sufficiently high accuracy, although it is not higher than it was 10 years ago.

The agreement between the handheld autorefractor and retinoscopy in children is not as good as in adults. The differences were not larger than the criterion values in 72% to 87% of cases. We speculate that this result may be caused partly by higher inaccuracy of the handheld autorefractor in children (e.g., unstable fixation may be a problem) and partly by higher inaccuracy of the retinoscopic findings in children.

Bias Toward Spherical Plus

In adults as well as in children, the handheld autorefractors displayed spherical values that averaged 0.25 to 0.50 D more “plus” than subjective refraction or retinoscopy. After an inquiry at Nikon Europe, we were told that the small systematic deviation is intended by the manufacturer. We had received a similar answer from the company (Nidek) during our earlier investigations. The argument then was that a slightly positive starting value guarantees that subjective refraction starts from a slightly fogged state and reduces the danger of minus overcorrection.
How Efficient Is the Fogging System?

The efficiency of the fogging system (quick mode off) was evaluated in 52 eyes of adults without cycloplegia as well as in all 79 eyes of the children in Group 2. In both groups, the spherical equivalents with the quick mode on and off were virtually identical. This means that the additional, time-consuming fogging procedure did not improve the reliability of the results.

In adults, the small difference between spherical equivalents with the quick mode on and off was surprising, since it seems natural to expect a minus overcorrection when fogging techniques are not applied. Closer inspection of the measurement procedure used in the handheld autorefractor suggests a possible explanation. The fixation target is fogged even when the quick mode is on. In most autorefractors, accommodation is relaxed only once prior to the start of the measurement. The handheld autorefractor, however, seems to change the vergence of the fixation target after each of the various individual measurements, which occur in rapid succession. Thus, a fairly reliable spherical value can be obtained in adults even when the quick mode is on.

How Reliable Is the Autorefractor Without Cycloplegia in Children?

An ideal objective refraction technique should be able to determine the “actual” ametropia without cycloplegic agents. To achieve this, modern autorefractors use well-designed fixation targets to attract the attention of the patient and sophisticated fogging techniques to relax accommodation. In this respect, autorefractors are technically more developed than “photorefractors” for which no suitable fogging technique has been proposed. But even today, the fogging techniques in modern automatic eye refractors do not work well on all children. This problem was demonstrated by Rassow and Weseemann in a small number of children (aged 7 to 13 years) with autorefractors made by Canon, Humphrey, and Topcon. In their study, minus overcorrections from −1.0 to −2.0 D occur frequently. The maximal minus overcorrection is −6.0 D. In the present study, we increased the number of children and included very young children.

Our results indicate that a fairly accurate objective refraction is possible without cycloplegia in most young patients (\(|DSE| < 1.25 \text{ D in 70\%}\)). About a quarter of the children, however, accommodated and developed an instrument myopia from −2.0 to −10.0 D. Further analysis (Figure 4) indicated that the frequency and magnitude of minus overcorrection increased as the patient age decreased. Unfortunately, we were unable to predict which children were going to accommodate during the automatic measurement and which were not. Therefore, we cannot determine which children can be accurately autorefracted without cycloplegia.

Power Matrix Approach

It has been suggested that autorefractor results should be analyzed in terms of the dioptric power matrix.\(^{11,12}\) The power matrix can be reduced to 3 numbers that are commonly referred to as vertical, torsional, and horizontal components of the refraction measured. We acknowledge that this method is a modern approach with a number of advantages. However, we decided to use our old criteria because we think they are much easier for the practitioner to understand. They allow one to answer such questions as, Is there a tendency toward a minus overcorrection? Are the cylinder powers too large or too small? This information is difficult to obtain from the power matrix approach.

Conclusion

The present study has shown that the measurement accuracy of the handheld autorefractor in adults is comparable to that of conventional tabletop instruments. When the small spherical bias is taken into account, the results are accurate in most adults and children. The accuracy of measurement in children is high under cycloplegia. Without cycloplegia, a minus overcorrection of more than −2.0 D was observed in 24% of cases. This fairly high incidence is obviously a handicap when the autorefractor is used in small children and will reduce the sensitivity and the specificity of the method.

We recommend that additional independent diagnostic techniques such as near retinoscopy or visual acuity tests be used in children to reduce the number of false positive and negative results.

Since the results in adults differed (in sphere, cylinder, and axis) from the comparison values by more than ±0.5 D in 5% to 12% of cases, optometrists and ophthalmologists should definitely not prescribe spectacles from the autorefractor printouts. It is still necessary to check and improve the displayed values by subjective
refraction or retinoscopy. In addition, optometrists and ophthalmologists should check the binocular refractive balance during the final steps of the subjective refraction procedure, because the spherical errors made by an autorefractor in both eyes individually may add up binocularly in an undesirable manner.

References
1. Rassow B, Wesemann W. Moderne Augenrefraktometer; Funktionsweise und vergleichende Untersuchungen. Buch Augenarzt 102, 1984