Repeatability and Validity of the PowerRefractor and the Nidek AR600-A in an Adult Population with Healthy Eyes

Running title: PowerRefractor and Nidek AR600-A

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Abstract

We assessed the repeatability and validity of the PowerRefractor and the Nidek AR-600A autorefractor. This is the first independent study conducted on adults to evaluate the performance of these instruments in a laboratory setting. Fifty subjects (23 M and 27 F) aged 16 to 61 years (mean 37±12 years) participated in the study. The validity of the PowerRefractor and the Nidek autorefractor readings were determined by comparing them to subjective refraction. Measurements of refractive error were obtained from the two instruments on two separate occasions to assess their repeatability. The measured refractive error was converted into a dioptric power matrix for data analysis. No significant difference was found between the measurements obtained with the two instruments and the subjective refraction. The estimate of refractive error given by the two instruments was also found to be repeatable. In addition to measuring the refractive error the PowerRefractor also offers the facility to measure eye position, pupil size and dynamics of accommodation. We suggest some improvements to the PowerRefractor measurement technique in order to standardize its clinical use and to improve accuracy.

Key words: Autorefractor, Photorefraction, PowerRefractor, Validity, Repeatability

The PowerRefractor is a new infrared autorefractor based on the principle of photorefraction. It was primarily intended to be a screening device especially suitable for detecting refractive errors in children and subjects with poor co-operation. Our interest in this instrument is in its use as a clinical and research tool for objective refraction. The advantage of the PowerRefractor over most autorefractors is that it can measure eye position, pupil size and dynamics of accommodation in addition to refractive error.

Early photorefraction devices had a limited range and were less accurate at detecting astigmatism than generally available autorefractors [1,2]. The use of the PowerRefractor to determine the refractive error in humans was first described by Schaeffel *et al.*[3]. The technique was further improved by Gekeler *et al.*[4] using the three-meridian infrared photoretinoscope, allowing measurement of astigmatism.

The present study is the first independent study to assess the performance of the PowerRefractor and the Nidek AR600-A autorefractor. The study aimed to validate and standardize the use of these two instruments, on an adult population, in clinical and laboratory settings. The refractive error determined by each instrument was compared with the results from subjective refraction. We found that both the PowerRefractor and the Nidek AR600-A performed well in all functions examined.

Methods

Fifty normal subjects (23M, 27F) took part in the study. The mean age was 37 with a standard deviation of 12 years (ranging from 16 years to 61 years). Inclusion criteria were: best corrected visual acuity of at least 20/20 and absence of any history of ocular pathology. Subjects wearing contact lenses or those with a history of strabismus or amblyopia were excluded from the study.

The data collection was partially masked with one investigator (PA) determining the refractive error by subjective refraction, and the other (HR), determining the refractive error using the Nidek autorefractor and PowerRefractor. The order in which the above techniques were conducted was randomized with at least five minutes between each measurement with the automated devices.

Subjective refraction was completed without any knowledge of the objective estimates of the refraction and the spherical end point was determined with Humphriss Immediate Contrast technique[5].

The Nidek autorefractor, using the ‘autoshot’ and ‘autotracking’ facilities, estimates the refractive error by averaging three successive readings in each session. The autotracking mechanism enables the machine to follow small losses of fixation by the subject. The autoshot function permits automated serial measurements when the instrument is in focus. The results obtained from two such successive sessions, separated by at least five minutes, were used to determine the repeatability.

The PowerRefractor offers five different measuring modes to determine refractive error. Two of these modes (‘monocular’ and ‘complete refraction’) were evaluated in this study. The ‘monocular’ mode gives a dynamic measurement of refractive error in the vertical meridian of one eye. The refractive error and pupil size are continuously measured at a frequency of 25Hz over a period of time. Series of readings were obtained by the ‘monocular’ mode, for 10 seconds (250 readings).

The ‘complete refraction’ mode is a binocular measurement of the refractive error. Each measurement using the ‘complete refraction’ mode was obtained over a 10 second period. The results from the ‘complete refraction’ mode include the sphere, cylinder and axis for each eye. To assess the repeatability of both the ‘monocular’ and the ‘complete refraction’ modes, two successive sessions, at least five minutes apart were completed.

A chin-rest and a brow bar were used to minimise errors caused by head movements. Although the PowerRefractor can measure refractive error with a pupil diameter above 3mm the best signal to noise ratio is achieved when the pupil diameter is greater than 4mm. To ensure that the pupil size remained above 4mm, the room illumination was subdued.

The effect of fixation distance on the results of the PowerRefractor was investigated on subgroup of five subjects. With a mean age of 29 $\pm$ 10SD (range from 22 years to 45 years). Refractive error measurements (‘monocular’ mode) were obtained at fixation distances of 6m, 3m, 1m and 40cms. All the measurements used for comparison were performed with subjects fixating at 6 metres.

Dioptric power was expressed as a dioptric power matrix[6-10] for data analysis. The vector form of the matrix facilitates the statistical treatments, as the components can be treated in a simple algebraic manner.

This research followed the tenets of the Declaration of Helsinki. Informed consent was obtained from all subjects.

Results

The mean spherical error of 50 right eyes as measured by subjective refraction was -0.65 ± 1.7 D, ranging from +3.62 D to –6.00 D. The mean cylindrical error was –0.53 ± 0.68 D, with a maximum cylindrical power of –3.50 D. The mean vector components are shown in Table 1.

The refractive error estimated by the PowerRefractor was found to be dependent on the fixation distance as shown in Figure 1.

Validity

A two-tailed paired t-test indicated no significant difference (p>0.05) between readings obtained with the PowerRefractor (‘complete refraction’ and ‘monocular’) modes and subjective refraction for all the three vector components. The estimated refraction with the Nidek AR600-A also showed no significant difference (p>0.05) in comparison to subjective refraction with the paired t-test.

Figure 2 (a), (b) and (c) show the plot of the mean difference between PowerRefractor readings, (horizontal, torsional and vertical components respectively), and subjective refraction results as a function of their mean (Bland and Altman plot[11]) for the ‘complete refraction’ mode. The 95% limits of agreement for the vector components were: horizontal +1.28D to –0.67D, torsional +0.50D to -0.40D and vertical +0.97D to –0.58D. It can be noted that the mean difference for the horizontal component is found to be slightly hyperopic indicating that the refractive error estimated was more hyperopic when compared to the subjective refraction horizontal component. Figure 2 (d) shows the Bland and Altman plot for the PowerRefractor ‘monocular mode’ with the 95% limits of agreement ranging from +1.25D to –0.95D. Figure 2 (e), (f) and (g) show the Nidek autorefractor Bland and Altman plots for the horizontal, torsional and vertical components respectively. For all the three components with the autorefractor the mean was found to be nearly equal to zero indicating no overall bias between the autorefractor readings and the subjective refraction. The 95% limits of agreement with the Nidek autorefractor for the vector components were: horizontal +0.68D to –0.73D, torsional +0.47D to –0.37D and vertical +0.63D to –0.69D.

A direct comparison of the subjective refraction results with the PowerRefractor and Nidek autorefractor readings are shown in Figure 3 and Figure 4 respectively. The vertical and horizontal components measured with both the instruments show a regression line very close to equality. Figures 3(b) and 4(b) represent the readings for torsional component and show no convincing correlation to subjective refraction.

Repeatability

Figure 5 (a), (b) and (c) show the plot of the mean difference between test and retest readings for the PowerRefractor, ‘complete refraction’ mode as a function of the mean (Bland and Altman plot). The 95% limits of agreement for the vector components were: horizontal +0.47D to –0.45D, torsional +0.22D to -0.21D and vertical +0.46D to –0.43D respectively. Figure 5 (d) shows the Bland and Altman plot for the PowerRefractor ‘monocular mode’ with the 95% limits of agreement ranging from +0.26D to –0.32D. Figure 5 (e), (f) and (g) show the Nidek autorefractor Bland

and Altman plots. The 95% limits of agreement with the Nidek autorefractor for the vector components were: horizontal +0.45D to –0.45D, torsional +0.14D to –0.16D and vertical +0.48D to –0.45D.

The root mean square differences between the test retest readings were found to be horizontal 0.226D, torsional 0.077D and vertical 0.237D for the Nidek autorefractor. For the PowerRefractor the root mean square difference was horizontal 0.382D, torsional 0.138D and vertical 0.358D, and 0.148D for the ‘monocular’ mode.

The test-retest readings with PowerRefractor and Nidek autorefractor were found to be very repeatable as shown in Figures 6 and 7 respectively. Repeated measures of all vector components, measured with both the instruments, show a regression line very close to equality.

Discussion

The results of the present study show that the PowerRefractor and Nidek autorefractor results agree well with subjective refraction results. Elliot *et al.*[12] defined the ‘co-efficient of accuracy’ as 1.96 times the standard deviation of the difference between the readings from the two instruments. In a previous study Choi *et al*.[13] found the coefficients of accuracy for the PowerRefractor to be 1.529, 0.189 and 1.187 for the horizontal, torsional and vertical components. While studying the application of the PowerRefractor as a clinical and research tool in adults we found the coefficient of accuracy lower than the previous study for the horizontal and vertical components. The coefficients of accuracy for the current study were found to be 0.793, 0.363 and 0.905 for the horizontal, torsional and vertical components respectively. The Nidek

AR600-A autorefractor was also found to be more accurate when compared to the Nidek AR-1000 and the Nikon NRK-8000 as described by Elliot *et al*[12]. In addition the readings obtained from the PowerRefractor and the Nidek AR600-A autorefractor were also found to be very repeatable.

The improvement in accuracy of the PowerRefractor was possibly due to a slight alteration in the measurement technique. The subjects fixated a spotlight at 6 meters throughout the study. Choi *et al*.[13] did not find any difference in the refractive error obtained using viewing distances of either 3 meters or 1 meter, viewing distance whilst using the instrument on children. Our results show that to use the instrument to measure refractive error in adults, or for clinical and research purposes, it would be better to use a fixation target close to clinical infinity. To assess the accuracy of the PowerRefractor Choi et al[13] instructed the subjects to fixate the photoretinoscope. In the present study the spotlight was positioned in such a way that the visual axis was within 5º of the photoretinoscope axis.

With the PowerRefractor the most favourable signal/ noise ratio for measuring refraction is achieved when the pupil size is above 4mm. The PowerRefractor gave a 'green' reading whenever the pupil size was above 4mm and the fixation was within 10° horizontally and 5° vertically. A 'red' reading was obtained when these criteria were not met. Only 'green' readings were included for analysis in this study. This was easily achieved in all but one of our subjects by subduing the room illumination. The PowerRefractor gave no readings from the eyes of one Asian subject whose pupil size was smaller than 4mm even with the lights subdued. This is particularly of concern if the instrument is to be used for measuring accommodation levels, as the pupils will get smaller when the subject accommodates.

The PowerRefractor ‘monocular’ mode produced a reading every 0.04 seconds. The readings obtained over a 10-second period were exported to Microsoft Excel for further analysis. On closer inspection it was found the ‘monocular’ mode gave more myopic measurement of the refractive error every time the subject blinked. An average blink lasts between 0.3 and 0.4 seconds[14]. The myopic shift is likely to be the result of reduction in the palpebral aperture affecting the intensity gradient of the reflex. The PowerRefractor results were occasionally contaminated by stray light reflections from around the pupil, particularly when the pupil size was small. While looking at the PowerRefractor monitor the examiner could see a ‘green’ reading being obtained from structures other than the eye.

The erroneous measurements, due to blinks and reflections, were identified by the occasional large deviation in measured pupil size during data analysis. These errors were manually removed from the data files. This was a time consuming process. When the palpebral aperture was too small to obtain a measurement the PowerRefractor did not give any reading for refractive error or pupil size. To account for the blinking artefacts the readings 0.04 before the blanks and 0.08 seconds after the blanks were removed during data analysis. The readings contaminated by stray light were removed by deleting the readings with large deviations in pupil size.

The PowerRefractor results demonstrate a consistent hyperopic error of approximately 0.20D for the horizontal and vertical components as shown in Figures 2(a,c) and 3(a,c).

One limitation for using the PowerRefractor in clinical practice is that it can only measure refractive error ranging from –6.00D to +4.00D. Although this instrument can be successfully used in the majority of patients, the limited range makes it unsuitable for use with patients who have high refractive errors. The Nidek AR600-A, on the other hand, can measure refractive errors ranging between –18 D and +23 D.

The repeatability of the PowerRefractor ‘complete refraction’ mode was found to be better for the left eye in comparison to the right eye. This difference was found to be consistent for all subjects included in the study. The reason for this difference in repeatability is unclear but presumably this reflects some variation in alignment of the two eyes with the PowerRefractor.

The results obtained with PowerRefractor ‘monocular’ mode correlate well with the ‘complete refraction’ mode for the vertical meridian after removing the erroneous readings caused by blinking and reflections. The PowerRefractor ‘monocular’ mode has the advantage of providing refractive error data at a frequency of 25 Hz, whereas the ‘complete refraction’ mode gives only one value for refraction. The ‘complete refraction’ mode does not provide any information regarding variations in refractive error due to fluctuations in accommodation. However, the ‘complete refraction’ mode can be used as a good alternative to objective refraction in clinical situations as the examiner can get an immediate single estimate of the refraction. Refraction with the ‘monocular’ mode would be more suitable for studying accommodation.

In summary the Nidek AR 600-A autorefractor and the PowerRefractor perform well in a clinical setting. With suitable data monitoring the PowerRefractor can also be used to measure refractive error over time.

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Figure Legends

Figure 1: Average PowerRefractor readings (in diopters) as a function of fixation distance (in diopters) for the right eye of five subjects. The error bars represent the standard error for the 5 subjects.

Figure 2: Mean difference between PowerRefractor and Nidek autorefractor readings and subjective refraction results plotted as a function of their mean. The upper and lower limiting lines indicate the 95% limits of agreement and the dashed line indicates the mean. Data is only shown for the right eye of the fifty subjects. (a) PowerRefractor, Horizontal component, (b) PowerRefractor, Torsional component, (c) PowerRefractor, Vertical component, (d) PowerRefractor, Monocular mode (Vertical component), (e) Nidek autorefractor, Horizontal component, (f) Nidek autorefractor, Torsional component, (g) Nidek autorefractor, Vertical component.

Figure 3: PowerRefractor readings versus subjective refraction reading for the right eyes of 50 subjects. (a) Horizontal component, (b) Torsional component, (c) Vertical component, (d) Monocular mode.

Figure 4: Nidek autorefractor readings versus subjective refraction reading for the right eyes of 50 subjects. (a) Horizontal component, (b) Torsional component, (c) Vertical component.

Figure 5: Mean difference between test and retest readings for the PowerRefractor and the Nidek autorefractor plotted as a function of their mean. The upper and lower

limiting lines indicate the 95% limits of agreement and the dashed line indicates the mean. Data is only shown for the right eye of the fifty subjects. (a) PowerRefractor, Horizontal component, (b) PowerRefractor, Torsional component, (c) PowerRefractor, Vertical component, (d) PowerRefractor, Monocular mode (Vertical component), (e) Nidek autorefractor, Horizontal component, (f) Nidek autorefractor, Torsional component, (g) Nidek autorefractor, Vertical component.

Figure 6: PowerRefractor test versus retest readings for the right eyes of 50 subjects. (a) Horizontal component, (b) Torsional component, (c) Vertical component, (d) Monocular mode.

Figure 7: Nidek autorefractor test versus retest readings for the right eyes of 50 subjects. (a) Horizontal component, (b) Torsional component, (c) Vertical component.

Table Legends

Table 1: The average subjective refractive error of 50 subjects in horizontal, torsional and vertical vector components. The table present the mean reading in diopters followed by the standard deviation.

Table 1

Horizontal		Torsional		Vertical	
Right Eye (D)	Left Eye (D)	Right Eye (D)	Left Eye (D)	Right Eye (D)	Left Eye (D)
-1.03±1.96	-0.89±1.72	-0.04±0.24	-0.03±0.26	-1.17±2.00	-1.02±1.85