Article • Comparison Between the Instant Vision Assessment Device (IVAD) and the Focometer in Determining Refractive Error

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ABSTRACT

Background: Uncorrected refractive error is a common cause of preventable blindness. In developing countries, eye care professionals and refraction tools are in scarce supply to meet the great demand for correcting refractive error. This study aims to compare the Focometer and the Instant Vision Assessment Device (IVAD) in obtaining subjective refractions.

Methods: Self-refractions were performed with the Focometer and the IVAD, respectively, on the right eye of 27 subjects. The range of age was from 23 to 51 years, and the mean age was 37.4±7.8 years. Subjects were in a rehabilitation center in Osaka, Japan. The spherical equivalent refraction findings obtained with both instruments were compared. Paired t-test, regression analysis, and Bland-Altman plot were used for statistical analysis.

Results: The mean spherical equivalent refraction and the standard error measured by the IVAD in the right eye was -2.00±0.46 D. With the Focometer, these were -1.89±0.47 D. The difference in the measurement and the standard error between the IVAD and the Focometer was -0.12±0.16 D, which was not statistically significant ($p = 0.46$, $t = 0.75$). The results obtained by the 2 instruments were highly correlated ($R2 = 0.89$; $p = 0.00$), and there was no systemic measurement difference between the two instruments.

Conclusions: Refractive error findings obtained with the Focometer and the IVAD are comparable to each other. Both instruments are valid and useful tools for determining spherical equivalent refractive error.

Keywords: blindness, Focometer, Instant Vision Assessment Device, refractive error

Introduction

Uncorrected refractive error is the most common cause of blindness in the world. According to the World Health Organization (WHO), uncorrected refractive error has caused 123.7 million people to have vision impairment affecting distance visual performance.[1] Vision impairment may lead to significant loss in economic productivity and decreases in quality of life and visual functions.[2-4] Consequently, eye care services and corrective devices are in great demand, especially in the under-served populations.[5] Simple, affordable, and easy-to-use refraction tools are required to meet the need. Self-refraction is one of the viable options.

Many studies have been carried out to explore the feasibility of self-refraction.[6-18] The Focometer is an accurate and low-cost device to provide refractive measurement.[7,10,14,15] The Instant Vision Assessment Device (IVAD) has also been found to be a practical, reliable, and valid means to determine refractive error.[9,18,19]

The Focometer makes use of the Badal Optometer Optics.[20] It enables correction of a person's refractive error by rotating the monocular focusing system, the rotating collar, until a clear distant target is achieved.[15] The correction needed is then shown on the linear diopter scale. The Focometer was used to help aphakic people improve vision after cataract extraction and

was adopted in eye care service in Tanzania, Thailand, Mexico, and Brazil.[21,22] Accuracy of the Focometer was confirmed in various studies. The difference in spherical equivalent refraction was within ±0.50 D when the Focometer results were compared with spherical equivalent auto-refraction and subjective refraction in both children and adults.[15] Reliability was also shown when the Focometer was compared with Adspecs and subjective refraction in Boston and in Nicaragua[7] and with auto-refractor findings in sub-Saharan Africa and in Australia.[10,14]

The IVAD was originally developed for conducting refractive measurement in low vision patients.[16] It makes use of the Galilean focusable binocular telescope. Its back vertex power is varied by adjusting the length of the telescope, which changes the power in a continuous manner.[9,17,23] It has been found that the mean spherical equivalent of this instrument and subjective refraction differed by ±0.03 D.[19] The IVAD has also been proven to be accurate and practical for determining refractive error in both normal children and adults, as well as low vision patients.[9,18] Its simple and electricity-free design, like the Focometer, allows the application of the IVAD to help the underserved populations in developing countries where eye care services are limited.

Both the IVAD and the Focometer have been reported to be reliable.[7,9,10,14-17] Therefore, we hypothesized that the spherical equivalent refraction results obtained by these two instruments are comparable to each other. In this study, we aimed to compare spherical equivalent refraction findings elicited from both devices and investigate whether they could produce similar spherical equivalent refraction findings.

Methods

IVAD

The IVAD is a 90-gram Galilean focusable binocular telescope of 2.4x magnification, as shown in Figure 1. The objective is 23 mm in diameter and consists of two lenses made of polymethyl methacrylate and polycarbonate, respectively. The eyepiece is 10 mm in diameter and made of polymethyl methacrylate. The magnification changes from 1.7x at the shortest length to 2.7x at the longest length. The diameter of the exit pupil changes from 13.5 mm to 8.5 mm as the telescope focuses from the shortest to the longest length. There are thirty marked positions, ranging from +0.62 D to -9.0 D. An extra lens cap of +0.50 D at the objective can be placed to increase the range of refractive measurement.[9]

Figure 1. Instant Vision Assessment Device (IVAD)

Figure 2. The Focometer

Focometer

The Focometer is a 500-gram monocular, hand-held refractive measurement device, as shown in Figure 2. The refractive error result is shown on the dioptric scale, with a range from -8.00 D to +10.00 D, corrected to the nearest 0.5 D.[15]

Measurements

Measurements with the IVAD and the Focometer were performed in the same room. The PolyU tumbling chart and the Japanese Landolt chart were placed on different sides of the room. The lighting condition for the IVAD was 288 lux, while that for the Focometer was 346 lux. Refraction was performed first with the IVAD, followed by the Focometer.

This study aimed to have enough statistical power to detect a 0.5 D difference between the two methods of measurement. This difference was based on the 95% agreement of about 0.5 D for the repeatability of subjective refraction.[24,25] Assuming a standard deviation of 0.75 D, the number of subjects that would give an 80% chance of finding a statistically significant difference between two sample means, at a two-sided 0.05 alpha level, was 20.[26] To account for possible out-of-range refractive measures, 27 subjects were recruited in the Nippon Lighthouse rehabilitation center in Osaka, Japan. Informed consent was obtained from each of them. The age of the subjects ranged from 23 to 51 years old.

In this study, the right-eye spherical equivalent refraction findings were obtained by the IVAD at three

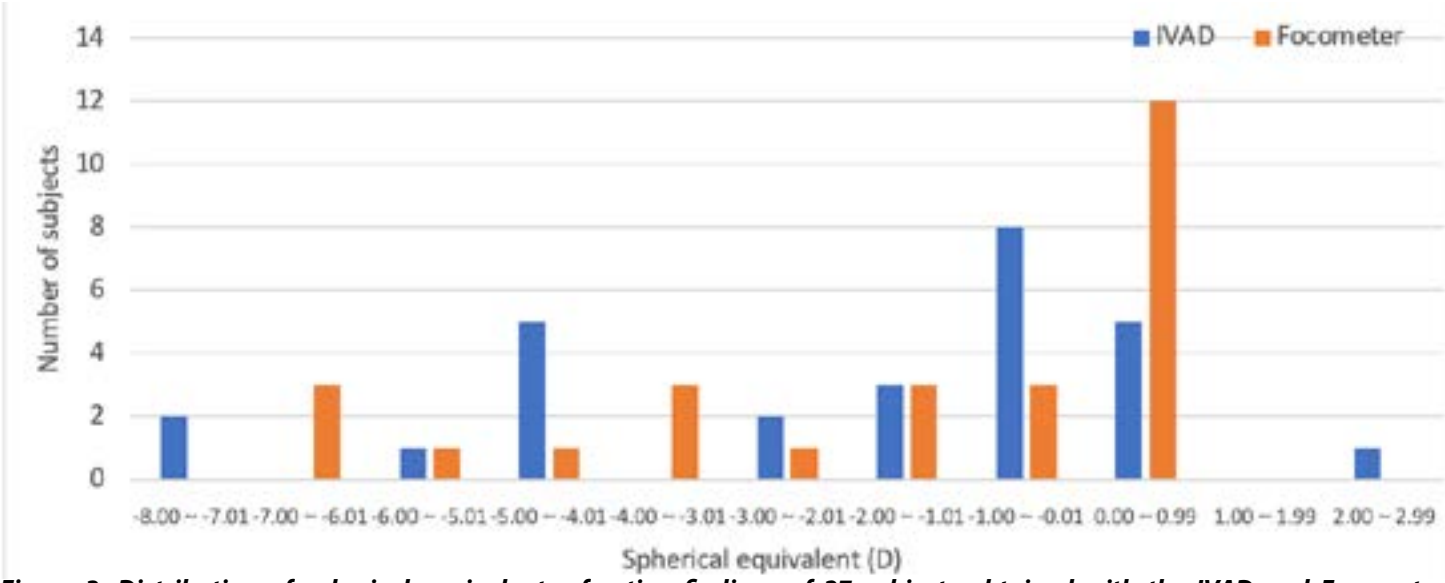

Figure 3. Distribution of spherical equivalent refraction findings of 27 subjects obtained with the IVAD and Focometer, respectively

meters with the PolyU tumbling E chart. The pupillary distance was set before the measurement. The vertex distance of the telescope was 10 mm. The left eye, which was not being tested, was covered. The subjects were asked to reduce the length of the telescope from the maximum plus until the smallest target on the visual acuity chart was carefully and slowly focused and clear. Three readings were repeated, and the last reading was taken as sample data.

The spherical equivalent refraction findings of the right eye were obtained at five meters by the Focometer with a Japanese Landolt ring chart. The subject was first asked to focus the distance target by rotating the knob on the Focometer from the positive end until a sharp and clear image was obtained in the right eye. Meanwhile, the left eye was covered. Three measurements were taken; the last reading was taken as sample data.

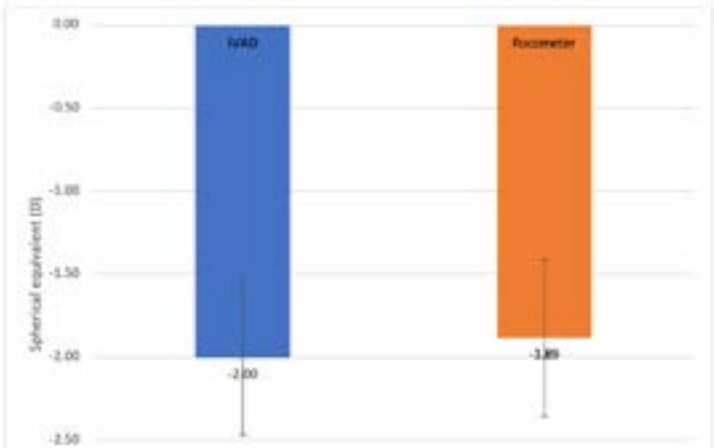

Figure 4. Mean spherical equivalent refraction of the right eye with standard error obtained with the IVAD and Focometer

The reason why the third reading was taken as the sample data is that these instruments may be used in developing countries where people may have limited training on performing refraction. Averaging the refractive errors obtained involves complicated calculations, which may be impractical in clinical settings. A learning effect may give more reliable refractive results, with examples of the third reading being comparable to the readings obtained by autorefractor.[10]

Statistical analysis

Spherical equivalent results taken by the IVAD and the Focometer in the right eye were analyzed by paired t-test, regression analysis, and Bland-Altman plot. Paired t-test was used for the comparison between the measurement results obtained by the IVAD and the Focometer. The correlation between them was evaluated by regression analysis. A Bland-Altman plot was used to determine the level of agreement between the two instruments. P-value less than 0.05 was considered statistically significant.

Results

The subjects ranged in age from 23 to 51 years old, with a mean age of 37.4±7.8 years. Only the right eye data were collected and analysed. The spherical equivalent refraction results obtained by the IVAD and the Focometer are shown in Figure 3. The mean spherical equivalent refraction and the standard error with the IVAD was -2.00±0.46 D, while the mean spherical equivalent refraction and the standard error with the Focometer was -1.89±0.47 D, shown in Figure 4. The difference in the measurement and the standard error between the IVAD and the Focometer was -0.12

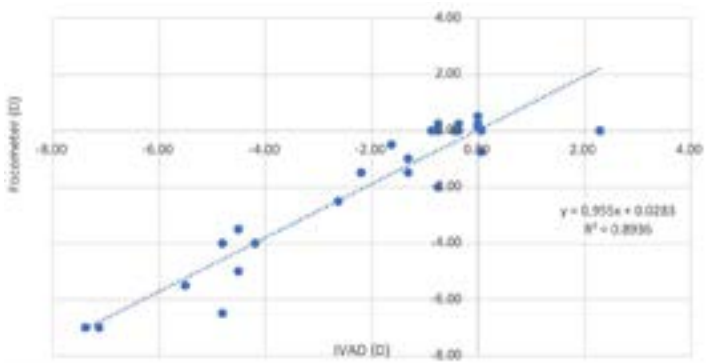

Figure 5. Regression analysis of the Focometer on the IVAD in the right eye

±0.16 D, which was not statistically significant (p = 0.46, t = 0.75).

Regression analysis was performed to evaluate the correlation between the Focometer and the IVAD. As shown in Figure 5, the results obtained by the Focometer and the IVAD in the right eye (R2 = 0.89; p = 0.00) were highly correlated.

The Bland-Altman plot in Figure 6 demonstrated the differences between the IVAD and the Focometer measurements in the right eye. The 95% limits of agreement for the difference were ±1.60 D. There were 17 of 27 (63%) of the refractive measurements obtained by the two devices where the difference of the measurements was within ±0.75 D.

Discussion

Refraction results by the IVAD and the Focometer showed that 63% of the refractive measurements obtained by the two instruments had a difference within ±0.75 D. This matches the repeatability of non-cycloplegic subjective refraction as suggested by Zadnik, Mutti & Adams.[27] Since only spherical equivalent refraction was done, the component of astigmatism corrected only by best spherical power might have caused the target not to be clear enough to achieve a definite measurement endpoint. Considering this factor and the high correlations demonstrated by statistical analysis, the proportion of measurement difference (within 0.75 D) between the two devices would still be acceptable.

Usefulness of the IVAD and the Focometer

In this study, it was found that the IVAD and the Focometer showed no significant difference in terms of refractive measurements, and both devices showed reliability consistent with previous studies on the use of the IVAD, the Focometer, and the Adspecs.[7,9,10,14-17] The IVAD and the Focometer are feasible to use in rural and under-developed places for self-refraction and overcome limitations of access to trained eye care practitioners or electricity. The instruments are easy to use by rotating knobs to obtain a clear distance target. However, limits in needed hand dexterity may cause difficulty for older patients whose hands may be too unsteady to manipulate the devices.[10] This is especially a problem for the Focometer, as it is substantially heavier than the IVAD. The heavier Focometer requires the patient to hold the instrument, whereas the lighter IVAD can be placed in front of the eyes like glasses when performing self-refraction.

Limitations of the study

There are a few limitations in this study. The use of different testing distances and visual acuity charts between the IVAD and the Focometer may limit their level of comparability. The test order of IVAD and

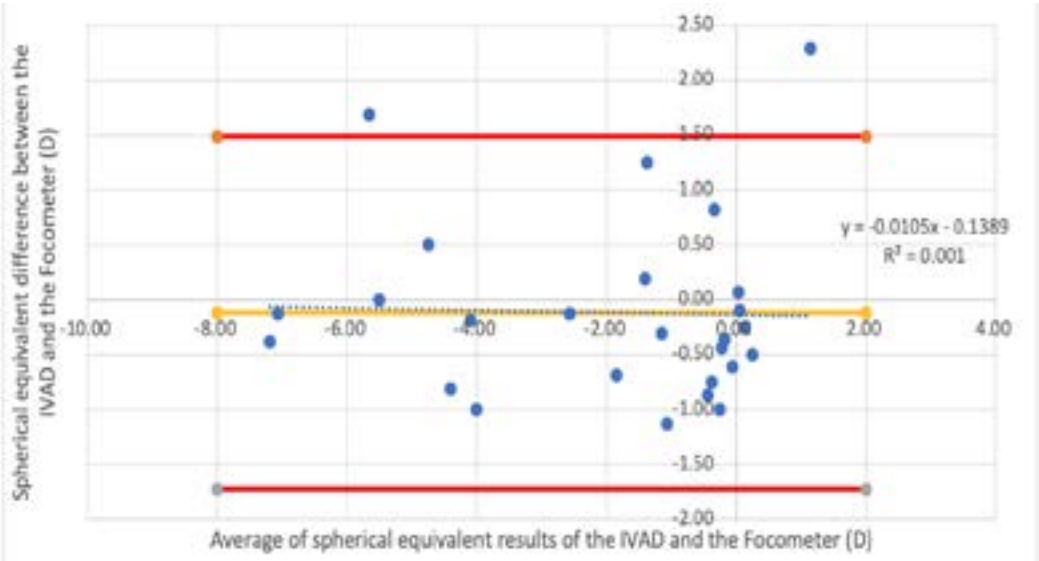

Figure 6. Spherical equivalent refraction difference between the IVAD and the Focometer (IVAD-Focometer) (D) against the average of spherical equivalent refraction results ((IVAD+Focometer)/2) (D). The red lines indicate the 95% limits of agreement. The yellow line indicates the mean difference. The dotted line is the regression line.

Focometer was not randomized, and only the right eye data were analysed. Visual acuity can be assessed to see whether the refractive prescription is practical enough for improving vision. It would also be better to have more subjects to eliminate the effect of extreme data and to reduce the 95% limits-of-agreement range.

Conclusion

The IVAD and the Focometer are both practical and comparable devices to determine refractive errors. They are useful tools for health workers in countries where there are few optometrists in under-served communities.

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