Title of Manuscript: Clinical evaluation and reproducibility of the 2Win VideoRefractor – A Pilot study.

Running Title: Validity of 2Win videorefractor measurements

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Abstract

Purpose: An independent study to assess the performance of the 2Win eccentric videorefractor in relation to subjective refraction and table-mounted autorefraction.

Methods: Eighty-six eyes of 86 adults (46 males and 40 females) aged between 20 and 25 years were examined. Subjective refraction, autorefraction using the table-mounted Topcon KR8800 and the handheld 2Win videorefractor were carried out in a randomized fashion by three different masked examiners. Measurements were repeated about one week after to assess instrument reproducibility and the inter-test variability was compared between techniques. Agreement of the 2Win videorefractor with subjective refraction and autorefraction was assessed for sphere and for cylindrical vectors at 0° (J_0) & 45° (J_{45}).

Results: Reproducibility coefficients for sphere values measured by subjective refraction, Topcon KR8800, 2Win (±0.42, ±0.70 and ±1.18, respectively) were better than their corresponding J_0 (±1.0, ±0.85 & ±1.66) and J_{45} (±1.01, ±0.87, ±1.31) vector components. The Topcon KR8800 showed the most reproducible values for mean spherical equivalent refraction (MSER) and the J_0 and J_{45} vector components, while reproducibility of spherical component was best for subjective refraction. The 2Win videorefractor measurements were the least reproducible for all measures. All refractive components measured by the 2Win videorefractor did not differ significantly from those of subjective refraction, in both sessions ($P > 0.05$). Considering the Topcon KR8800 autorefractometer, the 2Win videorefractor measured significantly more positive spheres and MSER ($P < 0.0001$) but the J_0 and J_{45} vector components were similar ($P > 0.05$), in both sessions.

Conclusion: The 2Win videorefractor compares well with subjective refraction and performed better than the Topcon autorefractor. The reproducibility values for the 2Win videorefractor were considerably worse than either subjective refraction or autorefraction.

However, the limits of reproducibility of the 2Win videorefractor are probably within acceptable ranges for a screening device.

Keywords: Autorefraction; Subjective Refraction; Videorefractor; Vision screening; Refractive Error; Astigmatism

In many developed countries, amblyopia and strabismus are the most common visual disorders of childhood. The most common amblyogenic factors in these countries are strabismus, refractive errors and media opacities.[1-3] Although only a few screening programs (to identify amblyogenic factors) have been conducted on infants,[3-9] there is evidence to show that very early screening (of infants) leads to earlier detection of amblyogenic factors which, if effectively managed, can reduce the prevalence of amblyopia in childhood.[10, 11] Photo/Video screeners have been tested extensively for their ability to detect amblyogenic disorders of childhood, and their principal advantage is that they require very little cooperation from the infant or child. Also, captured images from the eye show the overall reflection of light from the fundus. These images give an idea about the presence or absence of media opacities, refractive errors, and of strabismus.[12]

The 2Win videorefractor (Adaptica, Padova, Italy) is the newest handheld video screener on the market. It has no internal fixation target, thus it reduces the risk of proximal accommodation and enables the observation of real-world targets in a range of environments. It is small, easy to use, and has incorporated several important technologies to assist with a faster and more accurate screening process and with more efficient record keeping. Similar to two popular photo screeners - the MTI photo screener (Medical Technology, Iowa City, IA, USA)[13] and the VRB-100 photo screener (Fortune Optical, Padova, Italy)[14] – the 2Win videorefractor (as stated in the user's manual) operates on the principle of eccentric photorefraction using infrared light. This operating principle is different from isotropic refraction, which essentially measures accommodative lag and relates this lag to the refraction of the subject (as with some previous videorefractors). Results from an earlier study[15] showed that the 2Win videorefractor returned lower sensitivity and specificity than the Plusoptix S12 photoscreener values but it showed similar sensitivity and higher specificity value than another photoscreener (the Spot). In that study,[15] the 2Win was able to obtain measurements from some subjects for whom the other two photoscreeners could not obtain any readings.

The accuracies of earlier photo/video screeners have been evaluated against reference values, usually obtained using cycloplegic refraction. Compared with autorefractometry and retinoscopy, subjective refraction most closely approximates the results of cycloplegic refraction, [21, 22, 23-28] with autorefractomemters tending toward the overestimation of myopia and the underestimation of hyperopia.[21, 22, 29] The difference in mean spherical equivalent with and without cycloplegia was reported to be between 0.21D to 0.71D[21, 22, 29] in children and small (about 0.14D) in adults.[29] As a result, even though previous studies[15, 20, 25, 26] validated photo/ video screeners against cycloplegic refraction, some studies[22, 27, 29] have also used non-cycloplegic refraction. This study was designed to compare the 2Win videorefractor with non-cycloplegic objective (using an autorefractometer) and subjective refraction. In addition to subjective refraction, the Topcon KR8800 autorefractometer was included in this study as an independent objective method with which to compare the 2Win videorefractor (similar to some previous studies). Also, the authors are not aware of previous studies which have compared the Topcon KR8800 with subjective refraction in the absence of cycloplegia.

The rationale for assessing the performance of the 2Win on adult eyes was to determine if the refraction values returned would be a close approximation of the true refraction in this subject group in which the 2Win would be expected to show good agreement with subjective refraction (and perhaps better agreement with the autorefractometer). We reasoned that such a good agreement would be necessary if the 2Win would be of any value in the screening of young children in whom accommodation, inattention and lack of corporation would necessarily complicate the estimation of refractive error as has been reported.[15] Another reason for assessing the 2Win on adult eyes is because, the user's manual states that it was also designed for use in adult subjects for whom autorefraction is not convenient or possible, such as elderly or disabled subjects.

Therefore, the main purpose of this study was to assess the accuracy and test-retest reproducibility of refractive measurements made by the 2Win videorefractor compared to subjective refraction under non-cycloplegic conditions. Similar comparisons were made between the Topcon KR8800 and both the 2Win videorefractor and subjective refraction.

Methods

Subject Population

The study was approved by the Research Ethics Committee of College of Applied Medical Sciences, King Saud University, and consent was obtained from participants after fully understanding the nature of the study. The study adhered to the tenets of the 1967 Declaration of Helsinki as revised in Edinburgh in 2000. Eighty-six eyes of 86 healthy participants, all of whom were students from the College of Applied Medical Sciences, were included in this study. Inclusion criteria were age ≥18 years and a corrected visual acuity (VA) of 0.1 logarithm of the minimum angle of resolution (LogMAR) (6/7.5) or better. Exclusion criteria were objective evidence (obtained by the slit-lamp and/or ophthalmoscopy) of ocular pathology (including any condition known to interfere with autorefractor performance, e.g., asteroid hyalosis[31] or abnormality including amblyopia and strabismus and any previous ocular surgery). Measurements were obtained from both eyes of participants but only measurements from the right eye of each subject were included in the study. The left eye was used only when the right eye did not meet the inclusion criteria.

The study was conducted between January and April 2014. Subjective refraction was performed by an experienced optometrist (KO), autorefraction using the 2Win videorefractor was carried out by another optometrist (UO) and Topcon KR8800 autorefractor was used to measure refraction performed by (WA). In order to assess reproducibility, participants were required to return for another measurement session, at approximately the same time of day, about one week after obtaining the first measurement. Both times, measurements were made between about 10am and about 3pm depending on the availability of the subjects. In both measurement sessions, the order of measurement with all three techniques was randomized, and the last two examiners were masked to the results of the previous refractive measurements. To ensure masking, subjects were examined in three separate rooms and the flow of subjects from one room to the next was managed by one examiner (MA). Randomization was conducted with the aid of a series of random numbers generated from Microsoft excel spread sheet.

Subjective Refraction

Monocular subjective refraction was performed on each subject at six meters using static retinoscopy as the starting point for refraction. This was followed by cross-cylinder axis refining (in 2.5° increments) and power refining (in 0.25D increments) of the cylinders. Using binocular balancing and duochrome testing to a red-equals-green endpoint, the maximum plus sphere with best corrected visual acuity was measured. Subjective refraction was performed twice for each subject.

2Win Videorefractor

The 2WIN (Adaptica, Padova, Italy) is a handheld infrared video-refractor that measures binocular refraction simultaneously via eccentric infrared photo-refraction. It evaluates the gaze direction, ocular alignment, pupil diameter, pupil distance and the accommodative balance/imbalance between the 2 eyes. An infrared target is projected through the pupils of the subject onto the retina and depending on the refractive error, the reflected light forms a specific crescent-shaped brightness pattern within the pupil. The spherical refraction is calculated based on this crescent pattern and the cylinder/axis measurements are based on the same kind of calculation, repeated on four meridians. This device performs the measurement one meter away from the patient and with the instrument automatic sound sensor, this distance can be checked. A continuous corneal reflex tracking ensures that binocular alignment is maintained. It accepts pupil diameters between 4 and 7 millimetres and therefore, measurements must be taken in a dim light environment to ensure sufficient pupil size and to reduce accommodation.

During data capturing, the examiner held the instrument horizontally with both hands, approximately at the same height of the patient's eyes. Subjects were instructed to keep their eyes wide open and to fixate on the small central target located at the centre of the camera. By pressing and holding the 'START' button of the videorefractor, the examiner adjusts the measurement distance until the image comes into focus while looking at the corneal reflexes. At this point, two green circles linked by a horizontal line appear around the patient pupils and the focus bar appears in a green area. By releasing the 'START' button the 2WIN automatically displays the measurement on the screen. As advised by the manufacturer, measurements were only recorded if they had a reliability index higher than 5 (maximum is 9) and when the reliability index was 5 or less, measurements were repeated. In line with manufacturer's instructions, the measurement sensitivity was set to ± 0.25 D for power, and 1° for axis and since the 2Win videorefractor has no mechanism for internal averaging, two accurate measurements were recorded for each visit while the averages were used for statistical analysis.

Topcon KR8800 Autokerato-refractometer

The KR8800 (Topcon Inc., Tokyo, Japan) autorefractor is a multifunctional device which determines corneal refractive status using a rotary prism measurement system to increase accuracy.[32] It measures objective spherical refractive power, cylindrical refractive power, the direction of the astigmatic axis, corneal curvature, the direction of the principal meridian, and the corneal refractory power. It enables refraction measurements with a minimum pupil size of 2mm and, using a 3D auto alignment function, measurement can be made easily even by an unskilled operator.

The Topcon KR8800 uses the Scheiner double pinhole principle for data capturing. In this case, two light sources are imaged in the plane of the pupil to simulate the Scheiner pinhole apertures. A photodetector observes the degree of coincidence between the two images on the fundus. The focus is adjusted by the axial displacement of the illumination and detection systems. First, the Badal system is focused in one meridian, and then continuous measurements are taken through 180° using a rotating prism system. A “fogging” target is also used to relax accommodation.[33] Utilizing the automatic capture mode of the device, measurements were twice taken in rapid succession for each visit and the average of each four reading was recorded and used for further statistical analysis. Measurement accuracy was set to 0.12D for power and 1° for axis as advised by the manufacturer.

Statistical Analysis

The recorded averages (in negative cylinder form) were used to calculate the mean spherical equivalent refraction (MSER: sphere + cylinder/2) and due to the inherent problems of analysing conventional cylinder components, the cylinder, and axis were converted into vectors using the formulae described by Thibos et al.[34] The resulting vector components were Jackson cross-cylinders at 0°[J_{0} = - (cylinder/2) x cos(2 x axis)] and at 45°[J_{45} = - (cylinder/2) x sin(2 x axis)]. The calculated values are tabulated descriptively as mean ± standard deviations (SD) and range of values for all tests, in each session. To examine the level of association between techniques, correlation was assessed for all refractive components tested (both session measurements were pooled) using the Pearson correlation coefficient. All statistical analyses were conducted using the GraphPad Prism software (version 6.00 – Graph pad Software Inc., La Jolla, CA, USA). Differences were considered statistically significant when, the *P* value was < 0.05, and with 84eyes the study had a power of 80% as calculated using the G* Power software 3.1.10 version.

Analysis of the limits of agreement between refractive techniques

Agreement between methods in each session was assessed for sphere, MSER, J_0 and J_{45} vector components using Bland and Altman plots. The plots were made to show the agreement between the 2Win Videorefractor and subjective refraction, subjective refraction and KR8800, and between the 2Win videorefractor and KR8800 autorefractor. The mean of the differences between methods and the 95% limits of agreement (LoA) between measurements expressed as mean difference ± 1.96SD of differences[35] were calculated. Differences between the three methods in each session were compared using repeated measures analysis of variance (*RMANOVA*).

Assessment of reproducibility and instrument variability

The mean and standard deviation of the differences between test and retest (i.e. session one and session two) was calculated for sphere, MSER, J_0 and J_{45} vector components in each method. The coefficient of reproducibility (CoR) for each technique was also calculated as 1.96 x SD of differences between sessions. Differences between sessions for each technique were compared using paired *t*-tests. Bland-Altman plots showing the 95% confidence intervals (mean ± SD of between-session differences) for each technique were also conducted. We also assessed the differences in inter-test variability by comparing the between session mean differences for all 3 methods.

Results

Of the initial subject cohort of 89 subjects, three subjects were excluded. Two were lost to follow up after completing the first session of measurements and for the third subject, it was not possible to get a reading with the 2Win videorefractor. In all, forty-six men (53.5%) and forty women (46.5%), whose ages ranged from 22 to 25 years, completed the study and were included in the analysis this study. Based on MSER of subjective refraction, the percentage of myopes (≤ -0.75D), emmetropes (±0.50D) and hyperopes (≥ +0.75D) in this study was 32.5%, 53.5% and 14%, respectively. The mean ± SD spherical refractive error, MSER, the cylindrical component and the J_0 and J_{45} vector components determined by subjective refraction, 2Win videorefractor and Topcon KR8800 autorefractor with the results of comparative analysis between methods in each session are shown in Table 1. Regarding the cylindrical power measured in all participants, it ranged from -5.00 to 0.00D, -5.63 to 0.00D and -4.50 to 0.00D for Topcon KR8800 autorefractor, 2Win videorefractor and subjective refraction, respectively, in the first visit. In the second visit, the corresponding cylindrical values ranged from, -5.50 to 0.00D, -5.13 to 0.00D and -4.25 to 0.00D, respectively.

Values of refractive error measured by 2Win videorefractor were significantly correlated (P <0.0001, for all) with subjective refraction and autorefraction for sphere (r = 0.92 & 0.92), cylinder power (r = 0.89 & 0.90) and MSER (r = 0.93 & 0.93). The autorefraction values were also significantly correlated (P <0.0001, for all) with subjective refraction for sphere (r = 0.97), cylinder power (r = 0.96) and MSER (r = 0.97).

Agreement between methods of refraction

The spherical component, MSER and cylindrical power were significantly different between methods for session one (P< 0.0001, for all) and session two (P< 0.0001, for all) but J_0 and J_{45} vector components were not significantly different between-methods (RMANOVA: P > 0.05 for both). *Post-hoc* tests showed that in each session, the spherical refractive errors and the MSER measured by subjective refraction were statistically significantly different (P < 0.0001) from those obtained by Topcon KR8800 autorefractor, but were similar (P > 0.05) to those measured with the 2Win videorefractor, for both measurement sessions (Table 1). There were statistically significant differences in the cylindrical component between the 2Win videorefractor and subjective refraction (P < 0.0001 in both sessions) but not between the Topcon autorefractor and the subjective refraction (P > 0.05 for both sessions).

Combined-session Bland-Altman plots showing the LoAs for the spherical component of the refractive error, MSER, J_0 and J_{45} vector components between subjective refraction and Topcon KR8800 autorefractor are shown in Figures 1a, b, c and d respectively while the corresponding LoA plots between subjective refraction and 2Win videorefractor are also shown in Figures 2a, b, c & d, respectively. From the figures, it can be deduced that the 2Win videorefractor performed better than the Topcon KR8800 autorefractor when compared with subjective refraction for spherical refractive error (maximum bias: 0.10D vs -0.35D) and MSER (maximum bias: 0.16D vs -0.38D). The Topcon KR8800 autorefractor consistently returned more myopic measurements than the subjective refraction (Figures 1a & b).

In all sessions, about 60% of the MSER estimated using the Topcon KR8800 was within ±0.50D of subjective refraction and for the 2Win videorefractor, 59% of the MSER was within ±0.50D of subjective refraction (Table 2). There were no significant differences in the cylindrical vectors measured by the Topcon KR8800 autorefractor (Figure 1c) and the 2Win videorefractor (Figure 2c) when compared with subjective refraction. However, a significant difference was evident in the mean cylinder powers measured by the 2Win videorefractor with respect to subjective refraction (Table 1). In all sessions, the difference in mean refractive components between techniques is depicted in table 3.

When the Topcon KR8800 autorefractor was compared with the 2Win videorefractor, the former measured statistically significantly more myopic sphere and SER than the latter (2Win videorefractor) with a maximum bias of, 0.45D (P < 0.0001) for sphere (Figure 3a), and 0.29D (P < 0.0001) for MSER (Figure 3b). The mean cylinder powers measured by the Topcon autorefractor was also statistically significantly (P < 0.0001) more positive than 2Win videorefractor measured values, in both sessions. The LoA between the two techniques for the measured cylinder powers ranged from -0.62 to 1.24D and -0.53 to 1.14D in session one and session two, respectively. In contrast, the cylindrical vectors determined by the 2Win videorefractor and the Topcon KR8800 autorefractor were not statistically significantly different (P > 0.05) as shown in Table 1 and for this reason the corresponding Bland-Altman plots plots were not shown.

Reproducibility of Refraction techniques

The calculated coefficients of reproducibility for the three techniques are shown in Table 3. From the table it can be deduced that reproducibility was good for all techniques but the Topcon KR8800 autorefractor was the best for measurements of all refractive components except spherical refractive error, the component for which subjective refraction showed the best reproducibility. The plots shown in Figure 4 are combined reproducibility plots for all measured refractive components by the three techniques. They show that for the Topcon KR8800 autorefractor and subjective refraction, the bias was very small for all refractive components (< 0.04D) and smallest for J_{45} vector components. Considering the 2Win videorefractor, the maximum bias was observed for MSER (0.13D), and the inter-test variability was greatest for the measured J_0 vector component (±1.5D) in comparison with those of Topcon KR8800 autorefractor and subjective refraction. Between techniques, inter-test variability (comparing the between session mean differences) did not differ significant for sphere (P = 0.2029), MSER (P = 0.1642), J_0 (P = 0.6816) and J_{45} (P = 0.9254) measured values.

Discussion

The results from this study show that the 2Win videorefractor is comparable to subjective refraction in its ability to measure spherical refractive error and MSER in young adults. There was a consistent difference of means (which was not statistically significant) in spherical refractive error between the 2Win videorefractor and the subjective refraction, but the LoA were large (ranging from -1.67 to 1.73D, Figure 2A). Despite this good agreement with subjective refraction, the 2Win showed a slight tendency to underestimate refractive errors especially in high myopes (lower than 5.00D) and high hyperopes (greater than +4.00D) as shown in Figure 2B.

The mean sphere and MSER measured by the 2Win videorefractor were within ±0.50D of that found by subjective refraction in about 64% and 60% of all eyes, respectively. Conversely, the 2Win videorefractor measured significantly higher negative cylinder values than the subjective refraction. About 72% and 94% of the mean cylinder power measured by the 2Win videorefractor were within ±0.50D and ±1.00D of that found by subjective refraction (Table 2). With regard to the cylindrical vectors, no significant difference was observed in the J_0 and J_{45} vectors measured by the 2Win videorefractor and the subjective refraction and the J_0 and J_{45} were within ±0.50D of that found by subjective refraction in 84% and 77% of all eyes, respectively. These findings are comparable or better than those reported for other photo/video screeners used in previous studies.[26, 36, 37] The MTI photo-screener measurements were reported to be within ±0.50D of the MSER measured by subjective refraction in 67% of all adult eyes and 74% were within ±0.50D of the cylindrical component of the subjective refraction.[38] Unlike the 2Win videorefractor, the spherical values measured by the MTI photo-screener in that study,[38] were statistically significantly more positive than those measured with subjective refraction, and, the measured cylinder values were higher than those measured by subjective refraction in young adults. In a similar vein, Schimitzek and Lagrèze[34] observed that the PlusOptix PowerRefractor leads to a considerable myopic shift in young subjects.

The Topcon KR8800 autorefractor measured significantly more negative and less positive values of sphere and MSER than subjective refraction but the LoA were small (ranging from -1.35D to 0.74D, Figure 1). Even with the significant differences in measured values between the autorefractor and subjective refraction, about 61% of the spherical component and MSER measurements in all sessions were within ±0.50D of the subjective refraction. Between the autorefractor and subjective refraction, the measured cylindrical power and vector components were similar. In all, about 94% of J_0, and 95% of J_{45} vector components estimated using the Topcon KR8800 autorefractor were within ±0.50D. Almost all (99%) J_0 *and* J_{45} vector components were within ±1.00D of subjective refraction. These results show that the Topcon KR8800 autorefractor tends to measure more negative values than subjective refraction, and are consistent with previous reports on autorefractor measurements, [25, 39-42] including a study which reported results on measurements obtained using an earlier version of the Topcon KR8000 autorefractometer.[33]

Overall, measurements obtained by both instruments in this study compare well with the results reported for the validation of other autorefractors,[25, 39-42] even though the videorefractor-measured values were better 2Win than the Topcon KR8800 autorefractor-measured values. The cylindrical power component, returned by the 2Win videorefractor, was less reliable than the axis component, returning significantly higher negative cylinders than subjective refraction and the Topcon autorefractometer. The autorefractor measured significantly more minus spherical refractive error values than the videorefractor (Figure 3). This finding is consistent with previous reports comparing video/photo refractor measurements with measurements obtained by autorefraction in adults.[19, 26] More that the 2WIN videorefractor should neither is shown, it be confused with a table-top autorefractometer nor be considered a small portable auto-refractometer as was clearly stated in the manufacturers manual. Unlike the 2Win videorefractor, autorefractors are designed to measure refractive errors of one eye at a time, in an artificial condition of far fixation. Similar to the findings of the current study, Choi et al, [26] Schimitzek & Lagrèze[37] also observed that the cylindrical refractive components measured by the autorefractor and the videorefractor, were not significantly different.

The results that the 2Win videorefractor closely approximates (but returns more positive sphere readings compared to) subjective refraction indicate that it would be a useful addition in the eyecare practitioner’s clinic to examine certain categories of adult patients whom it would be very difficult or impossible to refract. These results also suggest that the 2Win could be useful for screening very young children for the refractive causes of amblyopia. Its size, portability and innovative features, in addition to good preliminary results from this study and from an earlier report,[15] could make it an invaluable addition to the clinics of not just eyecare practitioners, but paediatricians and general practitioners as well.

Though photoscreeners are designed for use on very young children[3, 8, 9, 27] they are unreliable in some children as old as 3 years.[14] This unreliability is based on the large, variable accommodation of subjects in this age group, and on poor cooperation of the subjects.[15] The 2win videorefractor was deliberately designed to return more positive spherical refractive error values than non-cycloplegic refraction to help mitigate the effects of accommodation in young children (personal communication with the manufacturers).

With regard to reproducibility, we observed that all refractive measurements obtained by subjective refraction, 2Win videorefractor and the Topcon KR8800 autorefractor were reproducible (Figure 4) but, the Topcon KR8800-measured values were considerably more reproducible than those of the 2Win videorefractor (Table 2). Subjective refraction has CoR lower than the other techniques when the sphere and cylinder power were analysed (Table 2), and as such, can be used as a gold standard in studies on refraction in adults. In contrast, the 2Win videorefractor displayed the highest CoR with variability indices that were consistently large in comparison with other techniques. This was especially true for the cylinder vectors (Figure 4), where the limits of reproducibility were double those of the Topcon KR8800 (Table 2). Nevertheless, the 2Win videorefractor reproducibility values were better than those reported for previous videorefractors [5, 42] although for a considerably smaller sample subjects. of adult

Cycloplegia, which increases the accuracy of autorefractometers,[39, 40] was not used in this study mostly because we considered that, in the group of adult subjects whom we enrolled, the role of accommodation would be very small, such that subjective refraction would be a close approximation of the true refraction in most of these subjects. In addition, non-cycloplegic subjective refraction is generally accepted by eye care practitioners for adult prescribing, and has been widely used for validation of refraction techniques.[5, 23-25, 29] On the other hand, retinoscopy was used as a starting point and not as a reference standard because, in adults, they play a similar role as autorefractors by assisting the optometrist to quickly and accurately reach the endpoint of subjective refraction.[5,28] Also, we did not analyse the pictures taken by the 2Win videorefractor because they were irrelevant to our purposes. Furthermore, we observed that the 2Win videorefractor slightly underestimated refraction values in high myopic subjects but this tendency did not reach statistical significance probably because the subjects in this study were mostly emmetropes. Assessing the validity of the 2Win videorefractor measurements, in highly myopic would further explore this observation. In spite of these limitations, there are a number positive aspects to our study design. The clinicians were masked to all refractive measurements in each session and the same clinician performed measurements using the same technique in both sessions. This ensured that intra-observer and inter-observer bias were negated. Again, our study population consisted only of adults, who would be expected to be significantly more cooperative than the young children the 2Win videorefractor was designed to screen. The use of adults made it possible to compare the refractive data returned by the 2Win with those of an autokeratorefractometer and subjective refraction.

In conclusion, the results suggest that the handheld 2Win videorefractor is a practical, reliable and effective device for refraction over the range of refractive errors assessed in this study. The device is more reliable in the estimation of cylindrical axis than it is for cylinder power. The Topcon KR8800 autorefractometer returned significantly more negative spherical values than subjective refraction but the cylinder power and axis estimated by the autorefractor were comparable with those of subjective refraction. Reproducibility coefficients of sphere and cylinder measures were best for subjective refraction, followed by autorefraction which also was best for estimation of the MSER, J_0 and J_{45} vector components. For all refractive measures, reproducibility was considerably poor for the 2Win videorefractor in relation to the other techniques, but they are probably acceptable ranges for a screening device. Large scale studies would need to be conducted to confirm these results.

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Figure Legends

1. Difference between subjective refraction and Topcon KR8800 autorefractometer objective a) mean sphere measures, b) mean spherical equivalent refraction (MSER) measures, C) Mean Jackson cross-cylinders at 0° (J_0) and D), Mean Jackson cross-cylinders at 45° (J_{45}). (solid lines are session one; dotted lines are session 2)
2. Difference between subjective refraction and 2Win videorefractor objective a) Mean sphere measures, b) Mean spherical equivalent refraction (MSER) measures, C) Mean Jackson cross-cylinders measures at 0° (J_0) and D), Mean Jackson cross-cylinders measures at 45° (J_{45}). (solid lines are session one; dotted lines are session 2)
3. Difference between Topcon KR8800 autorefractometer and 2Win videorefractor objective a) Mean sphere measures, and b) Mean spherical equivalent refraction (MSER) measures. (solid lines are session one; dotted lines are session 2)
4. Reproducibility plot of a) mean sphere values, b) mean spherical equivalent refraction, c) mean cylinder vector component values measured at 0° (J_0) and @ at

45° (J_{45}), measured by Subjective refraction (solid lines), Topcon KR8800 autokerato-refractometer (long dashed lines) and 2Win videorefractor (dotted lines)

Tables

1. Comparison of mean values of sphere, spherical equivalent refraction (MSER), cylindrical power and vector components by the 2Win videorefractor with both subjective refraction and Topcon KR8800 autokerato-refractometer objective refraction in both sessions.

Refraction	Subjective	Topcon 8800	2 Win Videoref	*P*-Value[#]	*P*-Value[†]	*P*-Value[‡]
Session One						
Mean Sphere ± SD (D)	-0.26 ± 1.97	-0.61 ± 2.12	-0.16 ± 1.95	<0.0001	>0.05	<0.0001
Range	-6.50 to 5.50	-6.62 to 6.62	-5.50 to 5.75			
Mean SER ± SD (D)	-0.58 ± 2.03	-0.96 ± 2.21	-0.66 ± 1.96	<0.0001	>0.05	<0.0001
Range	-7.25 to 5.13	-7.81 to 6.37	-6.00 to 4.91			
Mean Cyl ± SD (D)	-0.64 ± 0.83	-0.70 ± 0.93	-1.00 ± 1.07	>0.05	<0.0001	<0.0001
Range	-4.50 to 0.00	-5.00 to 0.50	-5.63 to 0.13			
Mean J_0 ± SD (D)	0.07 ± 0.41	0.10 ± 0.47	0.03 ± 0.53	>0.05	>0.05	>0.05
Range	-0.94 to 2.23	-0.90 to 2.48	-1.03 to – 2.66			
Mean J_{45} ± SD (D)	0.01 ± 0.32	0.01 ± 0.33	0.02 ± 0.51	>0.05	>0.05	>0.05
Range	-0.84 to 1.36	-0.77 to 1.19	-2.78 to 2.96			
Session Two						
Mean Sphere ± SD (D)	-0.30 ± 2.00	-0.59 ± 2.12	-0.27 ± 2.00	<0.001	>0.05	<0.001

Range	-6.00 to 6.00	-6.13 to 7.45	-6.00 to 4.38			
Mean SER ± SD (D)	-0.63 ± 2.06	-0.96 ± 2.19	-0.79 ± 2.05	<0.0001	<0.0001	<0.0001
Range	-6.75 to 5.63	-7.06 to 7.10	-6.50 to 3.75			
Mean Cyl ± SD (D)	-0.66 ± 0.80	-0.74 ± 0.95	-1.05 ± 0.97	>0.05	<0.0001	<0.0001
Range	-4.25 to 0.00	-5.50 to 0.00	-5.13 to 0.25			
Mean J_0 ± SD (D)	0.03 ± 0.38	0.08 ± 0.48	-0.06 ± 0.56	>0.05	>0.05	>0.05
Range	-1.61 to 1.74	-0.62 to 2.73	-2.33 to 1.90			
Mean J_{45} ± SD (D)	0.03 ± 0.35	0.05 ± 0.36	0.01 ± 0.43	>0.05	>0.05	>0.05
Range	-1.38 to 1.09	-1.37 to 1.26	-1.21 to 1.21			

P-Values are results of comparison: Topcon versus Subjective ([#]), 2Win versus Subjective ([†]) and Topcon versus 2Win (‡), autorefractometers. *SER = spherical equivalent refractive error (sphere + 0.5*cylinder); Cyl = cylinder*

2. Difference in mean refractive components of the final prescription between techniques (*2win videorefractor minus Subjective Refraction/*Topcon KR 8800 autorefractometer minus subjective refraction) in all sessions.

	Sphere	MSER	Cylinder	J_0	J_{45}
Mean Difference	*0.06*/-0.32	*-0.13*/-0.35	*-0.38*/-0.07	*-0.07*/0.04	*-0.02*/0.01
SD of differences	*0.81*/0.52	*0.77*/0.55	*0.47*/0.27	*0.67*/0.41	*0.65*/0.30
Within ±0.25 D (%)	41/39	*30*/27	*44*/83	*56*/82	*51*/83
Within ±0.50 D (%)	62/65	*59*/60	*72*/95	*84*/94	*77*/95
Within ±1.00 D (%)	87/94	*90*/94	*94*/99	*95/*99	*93*/99

MSER, mean spherical equivalent refraction; J_0, Jackson cross-cylinder at 0°; J_{45}, Jackson cross-cylinder at 45°. *2win/*Topcon

3. The coefficient of reproducibility values for sphere, mean spherical equivalent refraction (MSER) and cylinder power and cylinder vector components at 0° (J_0) and 45°(J_{45}) measured by the 2Win videorefractor, subjective refraction and Topcon KR8800 autokerato-refractometer.

Techniques	Sphere	MSER	Cyl	J_0	J_{45}
Topcon KR8800	0.70	0.69	0.44	0.85	0.87
2Win	1.18	1.09	0.86	1.66	1.31
Subjective Refraction	0.42	0.83	0.41	1.00	1.01

coefficient of reproducibility (CoR) = 1.96 x SD of differences

3. Results of correlation analysis between techniques for all measured refractive components in all sessions (expressed as Pearson correlation coefficient, *r*).

Between techniques	Sphere	SER	Cyl	J_0	J_{45}
2Win vs Subjective Refraction	0.92	0.93	0.89	0.01	-0.26
P values	<0.0001	<0.0001	<0.0001	0.93	0.0005
2Win vs Topcon KR8800	0.92	0.93	0.90	0.29	-0.08
P values	<0.0001	<0.0001	<0.0001	0.29	0.301
Topcon KR8800 vs Subjective Refraction	0.97	0.89	0.57	0.57	0.61
P values	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

J_0 and J_{45} are cylinder vector components at 0° & 45° respectively; $P < 0.05$ is considered significant

Figure 1

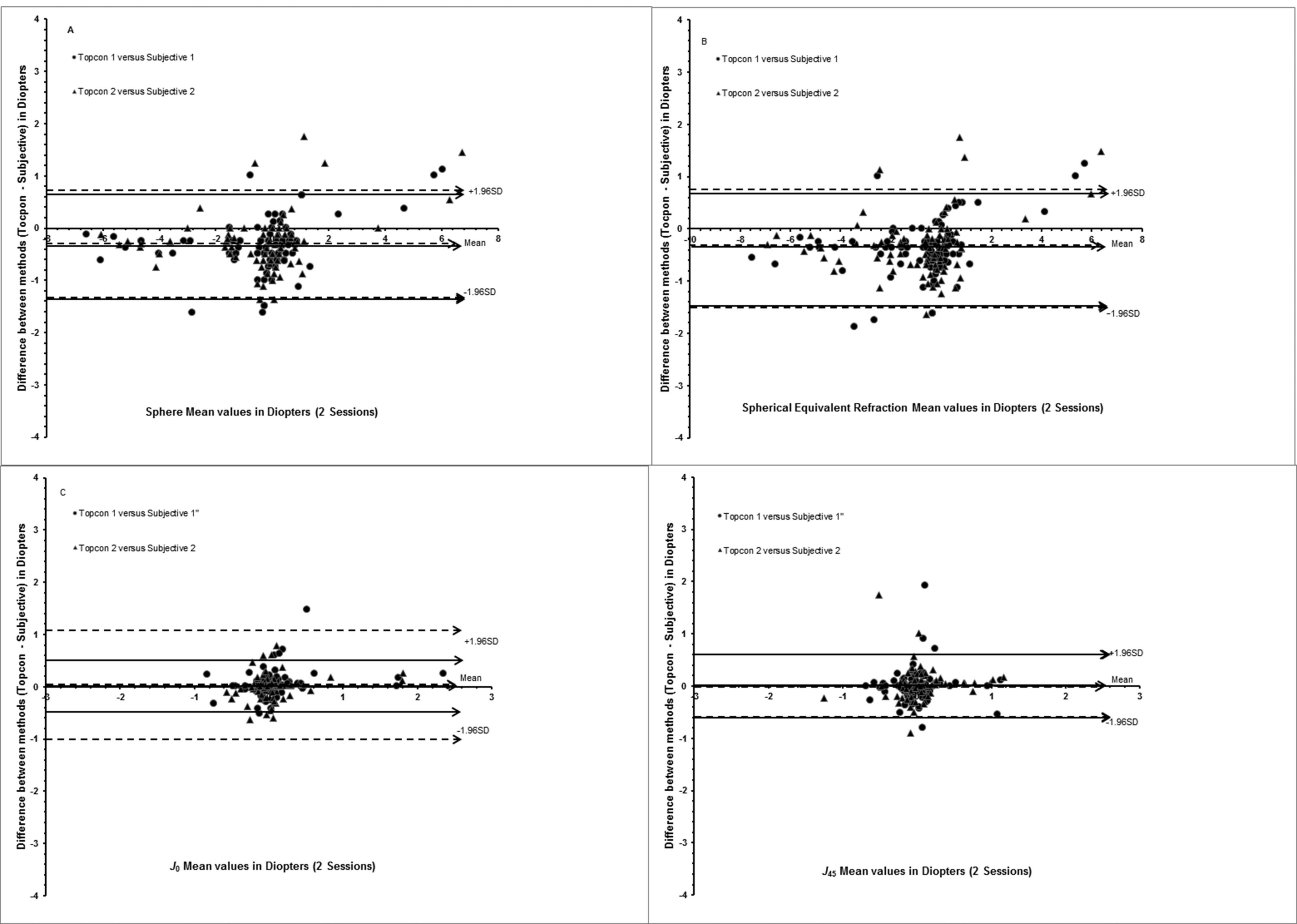
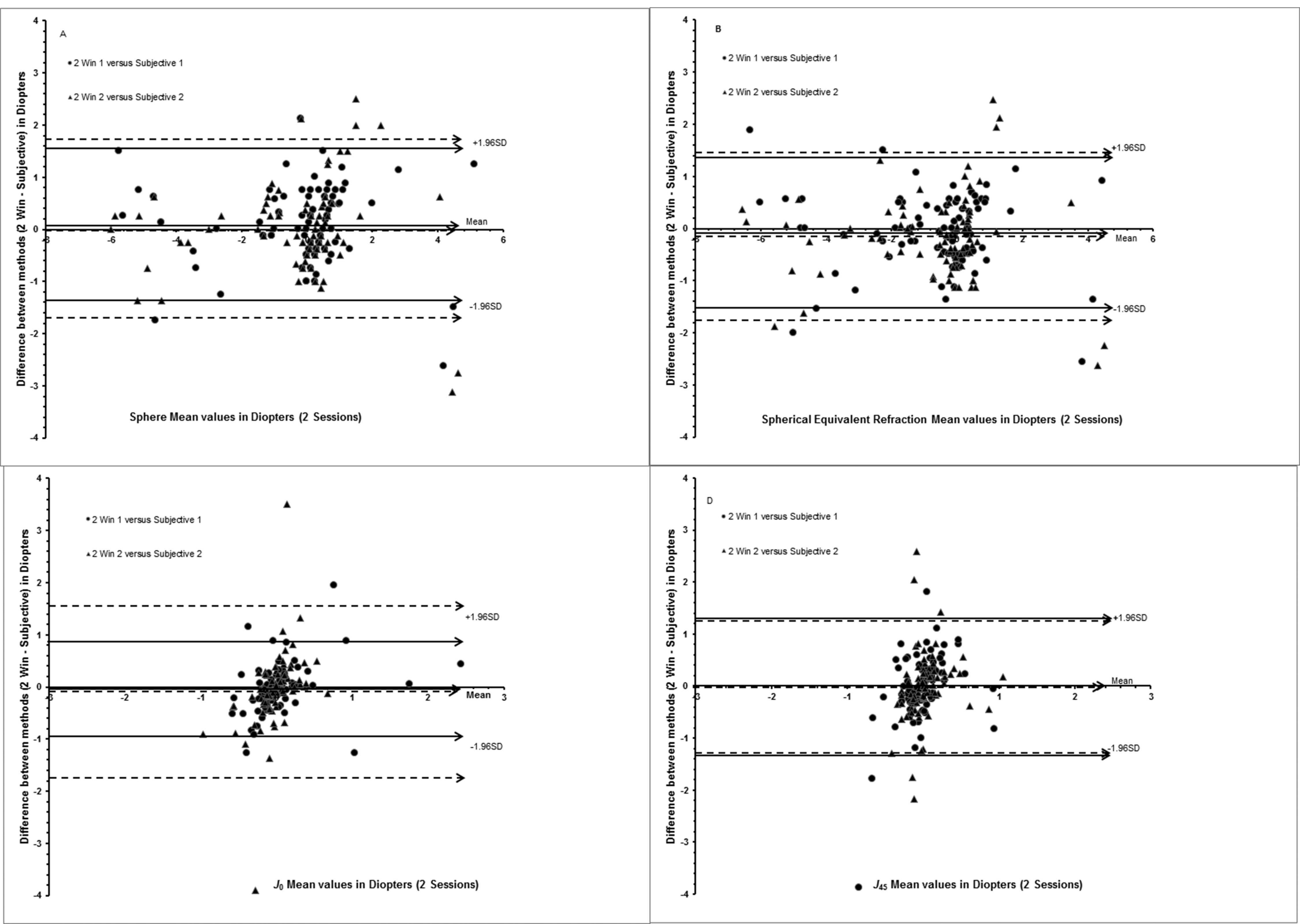

A
Topcon 1 versus Subjective 1
Topcon 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (Tocpon - Subjective) in Diopters
Sphere Mean values in Diopters (2 Sessions)
B
Topcon 1 versus Subjective 1
Topcon 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (Topcon - Subjective) in Diopters
Spherical Equivalent Refraction Mean values in Diopters (2 Sessions)
C
Topcon 1 versus Subjective 1"
Topcon 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (Topcon - Subjective) in Diopters
J0 Mean values in Diopters (2 Sessions)
Topcon 1 versus Subjective 1"
Topcon 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (Topcon - Subjective) in Diopters
J45 Mean values in Diopters (2 Sessions)

Figure 2



A
2 Win 1 versus Subjective 1
2 Win 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (2 Win - Subjective) in Diopters
Sphere Mean values in Diopters (2 Sessions)
B
2 Win 1 versus Subjective 1
2 Win 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (2 Win - Subjective) in Diopters
Spherical Equivalent Refraction Mean values in Diopters (2 Sessions)
2 Win 1 versus Subjective 1
2 Win 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (2 Win - Subjective) in Diopters
J_0 Mean values in Diopters (2 Sessions)
D
2 Win 1 versus Subjective 1
2 Win 2 versus Subjective 2
+1.96SD
Mean
-1.96SD
Difference between methods (2 Win - Subjective) in Diopters
J_{45} Mean values in Diopters (2 Sessions)

Figure 3

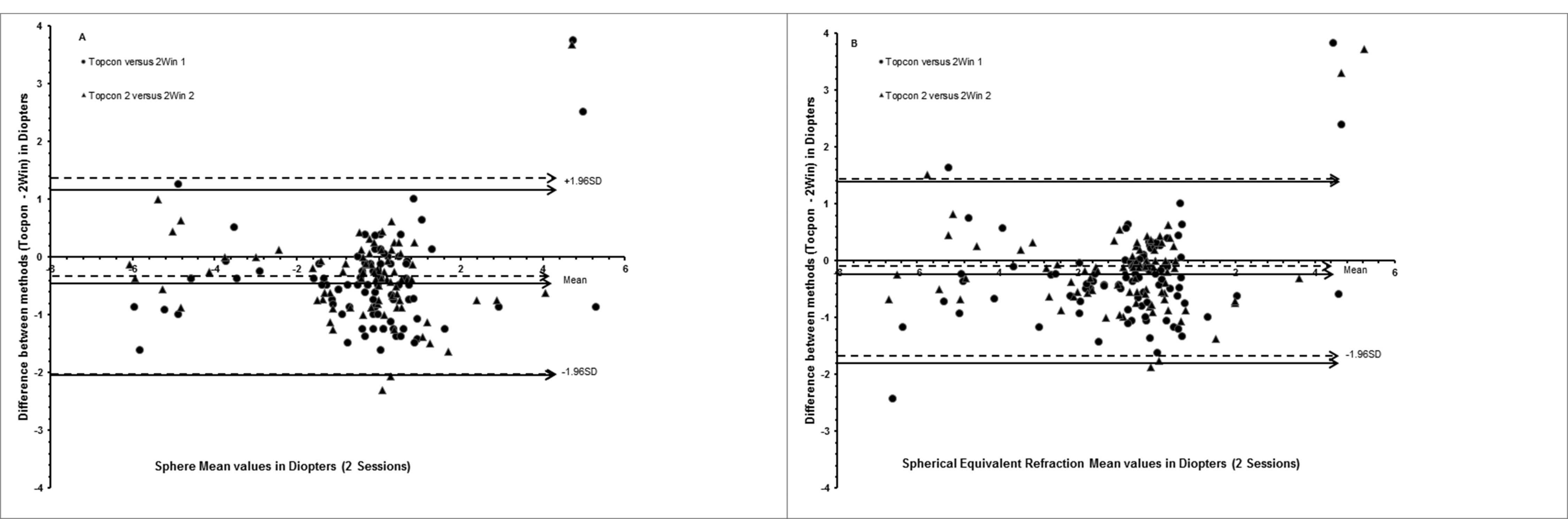
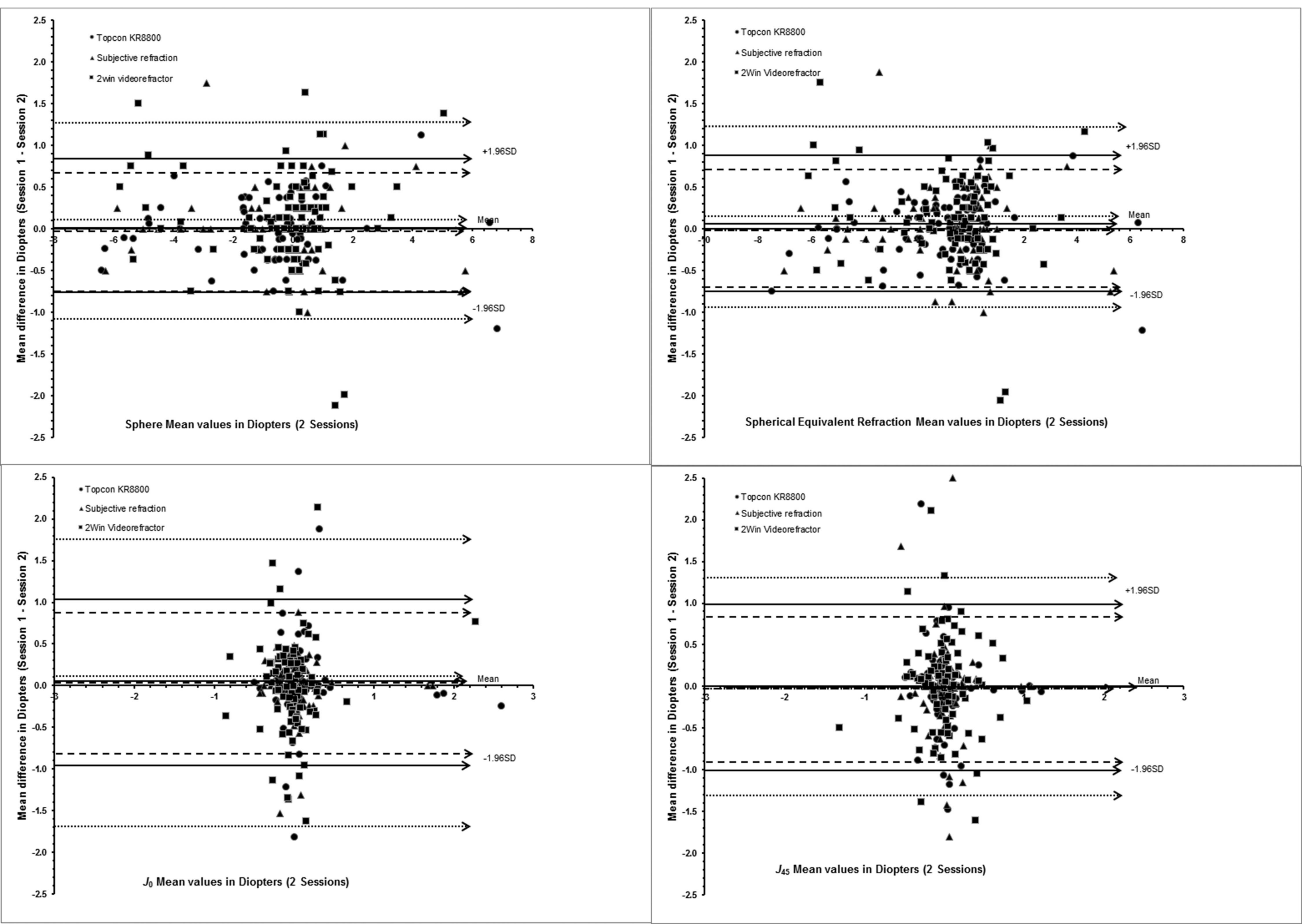

A
Topcon versus 2Win 1
Topcon 2 versus 2Win 2
+1.96SD
Mean
-1.96SD
Difference between methods (Tocpon - 2Win) in Diopters
Sphere Mean values in Diopters (2 Sessions)
B
Topcon versus 2Win 1
Topcon 2 versus 2Win 2
Mean
-1.96SD
Difference between methods (Tocpon - 2Win) in Diopters
Spherical Equivalent Refraction Mean values in Diopters (2 Sessions)

Figure 4


Topcon KR8800
Subjective refraction
2win videorefractor
Mean difference in Diopters (Session 1 - Session 2)
+1.96SD
Mean
-1.96SD
Sphere Mean values in Diopters (2 Sessions)
Topcon KR8800
Subjective refraction
2Win Videorefractor
Mean difference in Diopters (Session 1 - Session 2)
+1.96SD
Mean
-1.96SD
Spherical Equivalent Refraction Mean values in Diopters (2 Sessions)
Topcon KR8800
Subjective refraction
2Win Videorefractor
Mean difference in Diopters (Session 1 - Session 2)
Mean
-1.96SD
J_0 Mean values in Diopters (2 Sessions)
Topcon KR8800
Subjective refraction
2Win Videorefractor
Mean difference in Diopters (Session 1 - Session 2)
+1.96SD
Mean
-1.96SD
J_{45} Mean values in Diopters (2 Sessions)