· Investigation ·

Comparison between two autorefractor performances in large scale vision screening in Chinese school age children

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Abstract

● **AIM:** To evaluate the effectiveness of Grand Seiko Ref/Keratometer WAM-5500 compared to Topcon KR800 autorefractor in detecting refractive error in large scale vision screening for Chinese school age children with the WHO criteria.

● **METHODS:** A total of 886 participants were enrolled with mean age of 9.49±1.88y from Tianjin, China. Spherical equivalent (SE) was obtained from un-cycloplegic autorefraction and cycloplegic autorefraction. Topcon KR 800 (Topcon) and Grand Seiko WAM-5500 (WAM) autorefractors were used. Bland-Altman Plot and regression were generated to compare their performance. The overall effectiveness of detecting early stage refractive error was analyzed with receiver operating characteristic (ROC) curves.

● **RESULTS:** The mean SE was -0.98±1.81 diopter (D) and the prevalence of myopia was 48.9% defined by WHO criteria according to the result of cycloplegic autorefraction. The mean SE of un-cycloplegic autorefraction with Topcon and WAM were -1.21±1.65 and -1.20±1.68 D respectively. There was a strong linear agreement between result obtained from WAM and cycloplegic autorefraction with an R^2 of 0.8318. Bland-Altman plot indicated a moderate agreement of cylinder values between the two methods. The sensitivity and specificity for detecting hyperopia were 90.52% and 83.51%; for detecting myopia were 95.60% and 90.24%; for detecting astigmatism were 79.40% and 90.21%; for detecting high myopia were 98.16% and 98.91% respectively.

● **CONCLUSION:** These findings suggest that both Grand Seiko and Topcon autorefractor can be used in large-scale vision screening for detecting refractive error in Chinese population. Grand Seiko gives relatively better performance in detecting myopia, hyperopia, and high myopia for school age children.

● **KEYWORDS:** myopia; vision screening; autorefraction; spherical equivalent; Grand Seiko WAM-5500

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INTRODUCTION

Myopia is one of the most common cause of vision impairment in children and teenagers[1]. It has become a public health problem in many parts of the world, especially in Asian countries. The prevalence of myopia has increased all over the world in recent years to a prevalence of 20%-30% in western countries and 40%-70% in Asian populations[2-4]. Uncorrected refractive error often leads to a loss of visual acuity and a decrease in quality of life. It has also been defined as one of the risk factors of amblyopia[5] in children.

Thus, it is especially necessary to detect refractive error for young children to prevent myopia progression by introducing large scale vision screening. For decades, vision screenings focusing at refractive error were brought into school-age children in many countries all over the world[6-12]. However, it has been shown in recent studies that not only refractive error, but also other ocular parameters help providing better delineation of eye health statement, such as axial length, corneal topography, pupil size, and accommodation[13-16]. As result, it increases the work for screening team to acquire multiple parameters with difference instruments during large scale vision screening.

Instrument-based screening is a quick process that needs little cooperation of children and has been regarded as the preferred option for vision screening[17]. It has been shown in previously studies that the majority of modern autorefractors are reliable and highly accurate compared to subjective refraction[6-7,11-13,18-21]. Among them, Topcon KR series autorefractor (Topcon, Japan) was commonly used for refraction in large scale vision screening[20,22-23]. With a high stability, it has been widely used in comparison with other autorefractors[24-30]. However, it can give a better prediction of refractive error distribution and eye health description of population when more completed database is acquired. During vision screening, refraction, keratometry, accommodation as well as other ocular biological parameters needs to be accessed within one visit. Thus, the selection of equipment is one of the most important issues. Concerning about both variance of measurements and the most instruments that a vision screening team is able to obtain, the instruments designed for multiple clinical parameters measurements seem to give a better option.

The Grand Seiko Auto Ref/Keratometer WAM-5500 (Grand Seiko Co. Ltd., Hiroshima, Japan) is a binocular open-field autorefractor and keratometer. During the measurement, the examiner asks the subject to look through the open-field aperture. An image of an infra-red measurement ring, reflected off the retina, is initially brought into rough focus by rapid movement of a lens on a motorised track. With the cornea successfully brought into focus, the device automatically calculates the refractive status and keratometry immediately[31-33]. Accommodation of the subject can be evaluated with trial lenses and extra target at certain viewing distance under un-cycloplegic condition[33-37]. Recently, there have been some reports of using the Grand Seiko for keratometry and accommodative response in both lab and clinic[16,19,38-41]. The performance of the Grand Seiko in the detection of refractive error under un-cycloplegic condition has not been determined for the Chinese populations, which has a high prevalence of myopia. Therefore, the purpose of the present study was to evaluate the effectiveness of Grand Seiko Ref/Keratometer WAM-5500 compared to Topcon KR800 autorefractor in detecting refractive error in Chinese school age children with the WHO criteria.

SUBJECTS AND METHODS

Ethical Approval Subjects were recruited from elementary school and middle school in Taida District and Dagang District, Tianjin, China. This study has been approved by the Ethics Board of Tianjin Medical University Eye Hospital. Parental consent was obtained prior to the start of the study. With the consent form, all questions and concerns were addressed before it was assigned. The conduct of the study followed the tenets of the Declaration of Helsinki.

Subjects and Methods Subjects attending vision screening with age of year from 6 to 17 were enrolled. All subjects were examined in the following order: 1) autorefraction with Topcon KR800; 2) autorefraction with Grand Seiko Ref/ Keratometer WAM-5500; 3) cycloplegia; 4) autorefraction with Topcon KR800. In the autorefraction procedure, a printed red crossing was used as target, with a viewing distance of 6 m. The subject was instructed by examiner to set the forehead and chin properly on the instrument, then eye patch was placed in front of the other eye by the examiner during the measurement. Cycloplegia was induced with compound tropicamide eye drops, 5 mg/mL, one drop every five minutes for four times. Refraction with Topcon was performed 20 to 25min following the final instillation. Autorefraction was done by the same examiner. The examiner was masked from results of the Gran Seiko autorefractor to avoid potential bias.

Refractive errors [spherical (DS), cylinder (DC), axis (a)] were measured three times by Topcon in each eye, and mean value was calculated as final result. Spherical equivalent (SE) was calculated according to the following formula: SE=S+C/2. Myopia was defined SE<-0.50 D, hyperopia as SE>0.50 D, astigmatism as DC>1.50 D in any meridian, high myopia as SE<-5.0 D.

Statistical Analysis Descriptive statistics included measurements of means, standard deviations and frequencies. Since Kolmogorov-Smirnov test indicated that data were not normally distributed, Wilcoxon signed-rank test was applied to test if the difference between the results obtained from cycloplegic autorefraction, Grand Seiko and Topcon was significant. Bland-Altman plots were used to assess the agreement between Grand Seiko, Topcon autorefractor and cycloplegic autorefraction. Receiver operating characteristic (ROC) curve was employed to select the best cutoff points related to appropriate sensitivity and specificity of the Grand Seiko to detect refractive error in large scale vision screening. All statistical analyses were performed using R programming package (version 3.3.1). Statistical significance was defined as $P<0.05$.

RESULTS

A total of 1019 individuals (2038 eyes) were enrolled, and 881 individuals completed all examinations and cyclo-autorefraction. Measurement was successfully obtained with age ranging from 6-17y (mean age=9.49±1.88y). Four hundred and fifty-one (51.2%) were girls and 430 (48.8%) were boys. Four hundred and thirty-three (49.1%) students were myopia as defined by WHO criteria according to the result of cycloplegic autorefraction. Meanwhile, 147 (16.7%) students had hyperopia, 17 (1.92%) students had high myopia, 55 (6.24%) children had astigmatism. The distribution of SE is

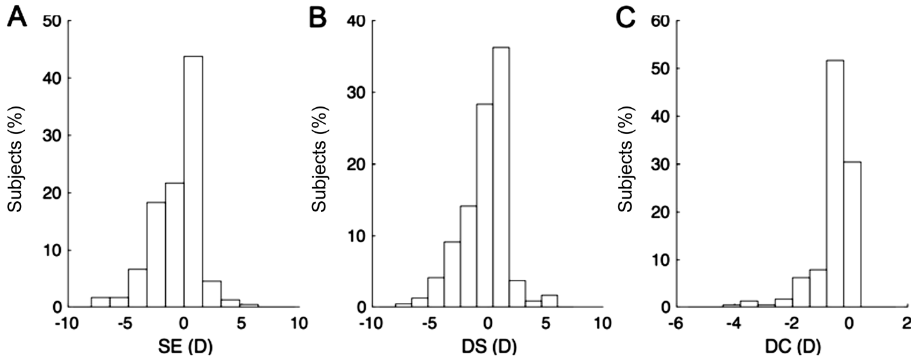

Figure 1 Histogram illustrating the distribution of refractive error in diopter A: SE; B: DS; C: DC.

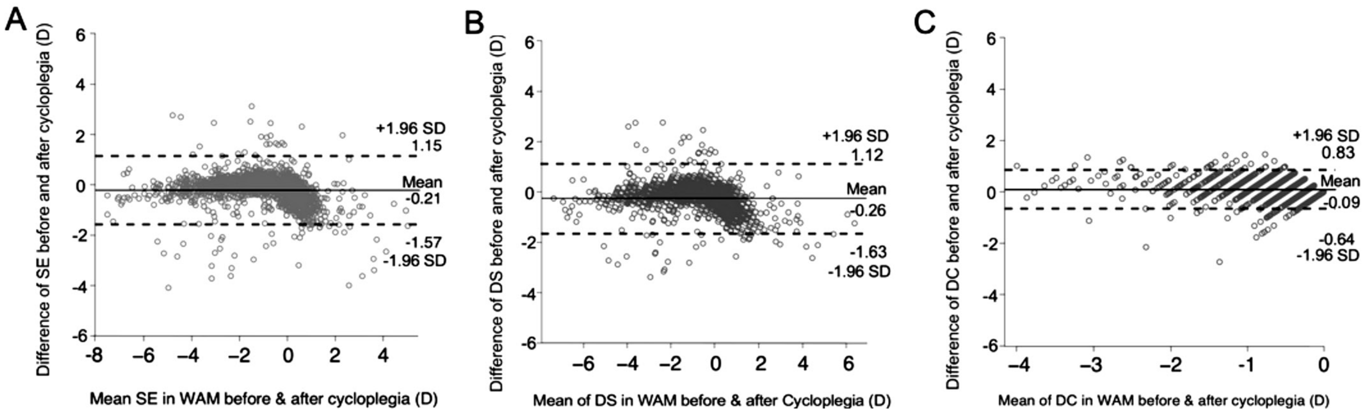

Figure 2 Bland-Altman plots showing agreement between the Grand Seiko and cycloplegic Topcon autorefraction A: SE; B: DS; C: DC.

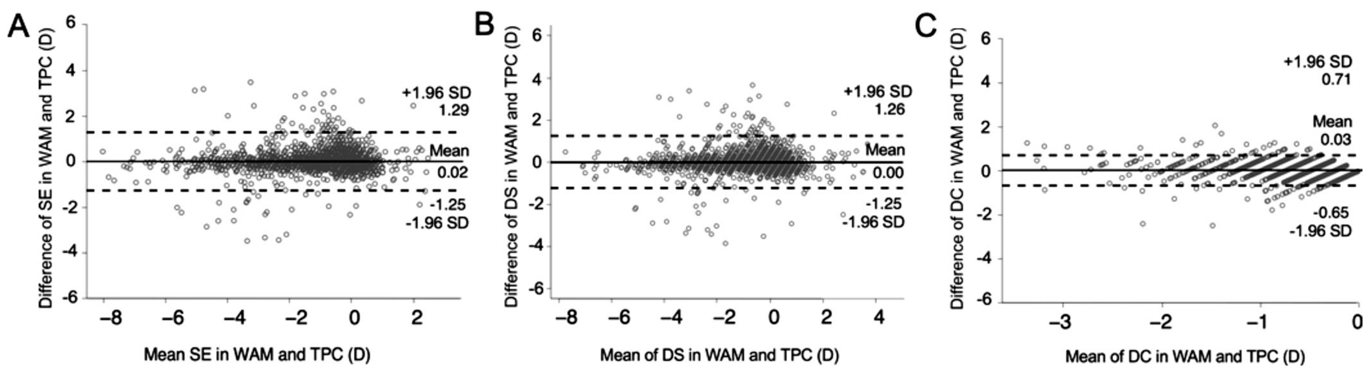

Figure 3 Bland-Altman plots showing agreement between the Grand Seiko and un-cycloplegic Topcon autorefraction A: SE; B: DS; C: DC.

shown in Figure 1. The mean refractive errors measured with cycloplegic Topcon autorefractor are summarized in Table 1.

The difference (WAM_SE *vs* Cyc_SE) is plotted against the average values [(Cyc_SE+WAM_SE)/2] in Figure 2. In 86.3% of the subjects, the differences (WAM_SE *vs* Cyc_SE) were within ±1.96 SD. Meanwhile, the differences of DS in 90.6% of the subjects and the differences of DC values in of 94.2% of the subjects were within ±1.96 SD.

The difference (WAM *vs* SE-TPC_SE) is plotted against the average values [(TPC_SE+WAM_SE)/2] in Figure 3. In 90.3% of the subjects, the differences (WAM_SE *vs* TPC_SE) were within ±1.96 SD. Meanwhile, the differences of DS in 91.5% of the subjects and the differences of DC values in of 97.3% of the subjects were within ±1.96 SD.

Table 1 The mean SE, spherical and cylinder power values obtained with cycloplegic Topcon autorefraction, un-cycloplegic Topcon, and un-cycloplegic Grand Seiko WAM-5500

Mean	SE (D)	DS (D)	DC (D)
TPC_cyc	-0.98±1.81	-0.63±1.82	-0.71±0.60
TPC	-1.21±1.65[a]	-0.89±1.63[a]	-0.65±0.58[a]
WAM	-1.20±1.68[a]	-0.89±1.66[a]	-0.61±0.53[a]

[a]Comparison with TPC_cyc: $P<0.001$.

Regression was used to evaluate the quantitative relationship between the results of the Grand Seiko and cycloplegic Topcon autorefraction. For SE of Grand Seiko, a linear regression model (SE_WAM =-0.368+0.847×SE_cyc, R^2=0.8318, $P<0.01$, black line Figure 4) captured a majority of the variance and

Table 2 AUC, sensitivity and specificity to detect refractive error with Grand Seiko and Topcon cutoff values derived from ROC curves

WHO criteria	Myopia (<-0.5 D)	Astigmatism (>1.5 D)	Hyperopia (>0.5 D)	High myopia (<-5.0 D)
WAM				
AUC	0.966	0.931	0.917	0.992
Cutoff	-0.805	-0.67	-0.105	-4.900
Sensitivity	95.60%	79.40%	90.52%	98.16%
Specificity	90.77%	92.03%	81.37%	94.29%
TPC				
AUC	0.968	0.964	0.925	0.999
Cutoff	-0.750	-0.75	0.00	-4.875
Sensitivity	90.24%	90.21%	83.51%	98.91%
Specificity	91.74%	93.02%	86.82%	100.00%
Significance in AUC	*P*=0.761	*P*<0.001	*P*=0.3678	*P*=0.091

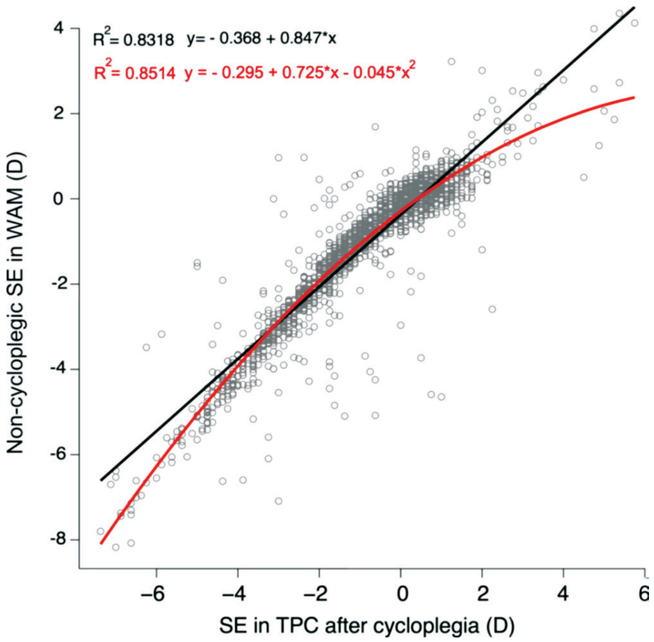

Figure 4 The correlation between un-cycloplegic SE measured with Grand Seiko and SE measured with Topcon after cycloplegia in D.

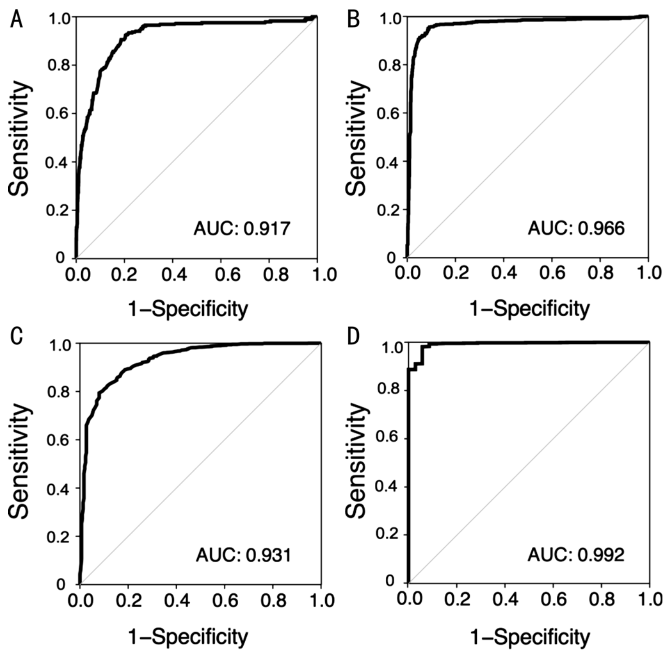

Figure 5 ROC curves for detecting refractive error A: Hyperopia; B: Myopia; C:Astigmatism; D: High myopia.

indicated strong linear correlation. Quadratic and cubic models did not improve the explained variations much, with R^2=0.8514 for both quadratic and cubic fitting (red line in Figure 4).

The sensitivity and specificity of the Grand Seiko and Topcon under un-cycloplegic condition in detecting refractive error are shown in Table 2. There's no significant difference between Grand Seiko and TPC in AUC except when detecting astigmatism of subjects. The ROC curve was used to determine the effectiveness of the Grand Seiko in detecting refractive error (Figure 5).

DISCUSSION

In this study we compared the refractive error estimates of un-cycloplegic Grand Seiko to un-cycloplegic Topcon measurements and cycloplegic Topcon autorefraction. Then their sensitivity and specificity were evaluated in the detection of refractive error. Totally 881 students ranging in age from 6 to 17y from Tianjin area were recruited in our study. The Bland-Altman analysis showed moderate agreement between the Grand Seiko and cycloplegic Topcon autorefraction, as well as Grand Seiko and un-cycloplegic Topcon autorefraction. Grand Seiko showed high sensitivity and specificity in detecting refractive error. The performance could be further improved by optimizing referral criteria based on ROC analysis.

Comparison Between Grand Seiko and Cycloplegic Autorefraction High consistency with a slightly myopic shift was found in the mean of refraction with Grand Seiko (-1.20±1.68 D) compared to cycloplegic Topcon (-0.98±1.81 D; Table 1, Figure 1). In this study, the SE obtained from Grand Seiko and cycloplegic Topcon autorefraction was well described by a linear regression model. Fitting the data with quadratic or cubic model improved R^2 from 0.83 to 0.85

(Figure 4). Although there was a good linear relationship between the measurements from Grand Seiko and cycloplegic autorefraction, the intercept was not zero. With an intercept of -0.368, Grand Seiko tended to underestimate hyperopia and overestimate myopia. This tendency was also found in other autorefractors such as PlusoptiX Photoscreener, Retinomax Autorefractor, Nidek ARK-510A and Huvitz HRK-7000A[25,28,30]. In comparison, Grand Seiko showed a relatively better performance in both agreement and correlation. This can be explained by decrease of the accommodative response which could not be fully controlled without cycloplegia. Instead of virtual target, it uses real target either at distance or at near through the open-field aperture. Under un-cycloplegic condition, a real distant target can introduce an open loop accommodation and decrease the amount of accommodative response that could be induced by simulated target from the instrument when Grand Seiko is used as autorefractor[42-44]. However, the tendency still exists. Since the subjects were measured monocularly, we can simply rule out the interaction of accommodation and vergence. We attribute this tendency to accommodation turbulence when the subject looking through a frame with filter about 20 cm away from their eyes, even though the target was 6 m away. A real target could lead to natural response of the subject, however, it also brought more possibility for the subject to be affected by the environment surrounding the open frame and target during the measurement. Previous studies also found that the repeatability could be decreased when the alignment was determined by both examiner and subject at different session[45]. In school age children, it has been reported that the variability of the accommodation during autorefraction is quite large with some accommodate up to 4.0 D[46]. Several factors, such as the attention of the subjects and accommodative lags in myopia children, may contribute to this large variability.

Comparison Between Grand Seiko and Un-cycloplegic Autorefraction It has been shown that both Grand Seiko and Topcon autorefraction were little affected by induced accommodation in this study (Table 1). We finished autorefraction for the same subjects under un-cycloplegic condition with Grand Seiko and Topcon KR800 autorefractor. Compared to cycloplegic SE, both instruments showed reliable measurement. In previous studies, measurement with Topcon autorefractor has been found to be about 0.24 to 2 D more myopic[27,47]. Besides, under un-cycloplegic condition, hand-held autorefractor was found to be more minus than table-mounted autorefractor[26].

A better fitting was found in Bland-Altman Plot when comparing Grand Seiko with Topcon autorefraction under un-cycloplegic condition (Figure 3). However, there was a relatively larger variance in SE measured by Grand Seiko in both descriptive and correlation analysis model (Figure 2). With an intercept of -0.368, R^2=0.8318, together with the Bland-Altman plot, showed that the measurement with Grand Seiko is affected more by individual. This could be explained by the need of cooperation between subject and examiner during measurement for Grand Seiko. Through the open aperture, the attention is easily affected by surroundings.

Considering about the convenience of acquiring multiple biological parameters in screening, the measurement from Grad Seiko is still acceptable for detecting refractive error. Besides, it gives multiple outcome. Grand Seiko autorefractor can acquire refraction, keratometry, pupil size, accommodative response at variance distance with only one instrument. By connected to an external PC *via* an RS-232 port, it also permits dynamic measurement of refraction and pupil size at the same time[48]. Davies *et al*[18] found that Grand Seiko provided reliable measurement in accommodation in dynamic mode. It is significantly important in China considering its large population and very few professional eye care specialists.

Sensitivity, Specificity, and the Choice of Criteria in Detecting Refractive Error For large-scale vision screening, we aim at detecting myopia as well as other possible refractive error that could lead to visual impairment at early stage[1]. The screening process requires the appropriate balance of sensitivity and specificity. High specificity produces adequate positive predictive value for screening. However, since the prevalence of refractive error in this population is high[2,4,6,11-12], it is more important to achieve high sensitivity. An awareness of myopia onset in time gives the family more option when the subject referred to optometrist for myopia control. On the opposite, an excess of false negative referrals would lead to carelessness of general eye health and in consequence of early myopia progression.

Both Grand Seiko and Topcon autorefractor were found to have high sensitivity and specificity in detecting myopia and high myopia (Table 2, Figure 5). For detecting astigmatism, Grand Seiko had a significant lower sensitivity than that of Topcon. Meanwhile, both of them showed lower specificity of hyperopia, more likely to give a false positive result. However, considered that Grand Seiko provided relatively higher sensitivity with 90.52% in hyperopia, 95.60% in myopia, and 98.16% in high myopia, it gives better performance in detecting general refractive error in vision screening.

Limitation of This Study It has been limited that accommodative lag was not evaluated by Grand Seiko in this study, since accommodative response was shown as one of the important parameters in vision screening. Further study is still needed.

In conclusion, in present study, the refraction measured from Grand Seiko autorefractor was shown to have a moderate agreement from cycloplegic Topcon autorefraction. The performance of Grand Seiko in detecting individual refractive error was satisfactory, although could be further improved by optimizing criteria based on ROC curves. These findings suggested that Grand Seiko could be a very useful tool for large-scale population screening in Chinese population.

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