

Comparability of Measurement of Astigmatism between URk-800F Auto Refractometer and MS-39 Anterior Segment Optical Coherence Tomography in Patients with Refractive Error

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ABSTRACT

Introduction: Accurate refractive error assessment is the first and the most important step of ocular examination. A reliable screening method of refractive status is important for early detection and prevention of blinding complications of uncorrected refractive error.

Objectives: To evaluate the comparability of astigmatism measured by an auto-refractometer (URk-800F) with the measurements of the gold standard anterior segment optical coherence tomography (AS-OCT)

Materials and methods: This cross-sectional observational study was conducted in a tertiary eye centre in Kathmandu from February 2023 to June 2023. A total of 100 patients with best corrected visual acuity of $\geq 20/20$, spherical refractive error with cylindrical error of more than and equal to -0.75 and no pathology detected on slit lamp examination were taken by consecutive sampling method. Ethical approval was taken for the study. The data were entered into Microsoft Excel and analysed using Bland-Altman analysis.

Results: The mean cylindrical power and axis was -2.33 D and 88 degrees for the right eye and -2.32 D and 122 degrees for the left eye respectively, as measured by MS-39 AS-OCT. For URK 800-F Auto-refractometer, the mean cylindrical power and axis was -2.31 D and 89 degrees for the right eye and -2.27 D and 124 degrees for the left eye.

Conclusion: The findings of this study conclude that an auto-refractometer can be used as an effective tool for identification of spherical refractive error as well as measurement of accurate cylindrical power and cylindrical axis in low resource primary care settings.

Key words: Amblyopia; astigmatism; corneal topography; refractive errors.

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INTRODUCTION

Accurate measurement of refractive error is a vital step for vision screening. A reliable screening method of refractive status is very important for early detection and prevention of blinding complications of uncorrected refractive error like amblyopia and subclinical keratoconus (Galindo-Ferreiro et al., 2017). The overall prevalence of uncorrected refractive errors according to a meta-analysis is high (7.3%) in Nepali population that point towards the need for better access and identification of refractive error services in our country (Bist Jeewanand et al., 2023). While spherical refractive error may be identified accurately with retinoscopy, accurate diagnosis of astigmatism based on retinoscopy or manual keratometry is a difficult task. Corneal topography has better accuracy in terms of description of corneal curvature and detection of corneal irregularity. In our country, with the rapid increase in the number of eye care centres, the prescription of glasses may not always be accurate, given the availability, cost, the technical expertise and learning period required to afford a corneal topography. The study aims at comparing the accuracy of measurement of cylindrical power and cylindrical axis measurement with a keratometer as compared to corneal topography. The standard instrument that has been used is the MS- 39 Anterior segment Optical coherence tomography. The Autorefractometer used for comparison in this study is the Unicos URK-800f which uses the principle of keratometry. We also aimed to describe the demographic characteristics of the study population, to find out the mean spherical error of the patients by Autorefractometer and to evaluate the comparability of keratometry reading by both instruments.

MATERIALS AND METHODS

This was a non-randomised, cross-sectional observational study of consecutive patients who presented to the general outpatient department of Matrika Eye Centre, Kathmandu, Nepal from 2023 February to 2023 June.

This study adheres to the tenets of the Declaration of Helsinki. The ethical approval was taken from Nepal Health Research council on 27th January 2023 after the expedited review process (Ref. 1689). Informed consent was taken from the patient or the patient's guardian for under age patients. Assent form was taken from patients aged 7- 18 years of age in two subgroups of 7-11 years and 12- 18 years of age.

Patients with best corrected visual acuity of $\geq 20/20$, spherical refractive error with cylindrical error of more than and equal to -0.75 and no pathology detected on slit lamp examination were included in this study. All age groups who were co-operative for the examination were included. Cyclorefraction was done in paediatric patients below 15 years of age where indicated. Patients with corneal scars, recent history of eye surgery and any other ocular pathology other than refractive error at the time of examination were excluded. Patients with disorders that would affect the measurements, such as pterygium, cataract, strabismus, nystagmus or unco-operative patients were excluded.

A total sample of 200 eyes from 100 patients was used for the comparison. Consecutive sampling was done. As refractive error is an asymmetric eye condition, the data from a pair of eyes of an individual are less likely to be correlated and therefore, data from both eyes can be used as a

sample. With rapidly developing new technology and varied instruments in ophthalmic practice, McAlinden et al. developed an appropriate statistical method to apply in agreement studies between two sets of quantitative data. The statistical formula used in that method for sample size calculation requires at least 100 samples for the confidence interval to be 0.05 which increases the validity of results. Thus, a sample size of 100 was taken as recommended by McAlinden for studies in ophthalmology (McAlinden, Khadka, and Pesudovs, 2011).

The keratometer/Autorefractor used in this study is the Unicos URK-800f that has a seven inch colour touch screen giving a clearer and wider graphic user interface (GUI). It gives enhanced measurement speed for more accurate measurement data. It is based on the principle of keratometry. It measures on the fact that the anterior surface of the cornea acts as a convex mirror and the size of the image formed varies with its curvature. Using complex formulae, the radius of curvature is determined by the apparent size of the image of bright object (mires) viewed by the reflection from the anterior corneal surface which acts as a convex mirror (Khurana and Khurana, 2013). It gives corneal power between 33.00 to 67.50 D and corneal astigmatism from 0.00 to +/-15.00 D for corneal diameter between 2.0 to 12.00 mm.

The MS-39 AS- OCT is the gold standard for analysis of the anterior segment of the eye. It combines Placido disk corneal topography, with high resolution OCT-based anterior segment tomography. It is based on the similar principle as of keratometry, except it scans corneal surface larger than 3 mm as compared to the keratometer (Pateras and Konstantinos, 2020).

It has 22 placido disk rings that gives 10 mm covering of the corneal surface that provides dioptric measurement range from 1 D to 100 D giving measurement accuracy of class A according to the UNI EN ISO 19980-2012 (Standards, 2012).

Moreover, a structured data collection form was prepared for the study to collect all the background variables and vision- related variables. Data on socio-demographic variables like age and sex were collected using structured data collection forms by trained optometrists.

Similarly, the keratometry reading, the spherical equivalent error, cylinder power and cylinder axis were obtained on URK- 800f refracto-meter and Keratometry reading and cylindrical power and cylindrical axis was measured by MS-39 AS-OCT topographer in non-cycloplegic eyes. Both instruments were operated by trained optometrists. Each measurement was repeated three times in each eye and the average value was used in the final analysis. The data capture procedure for both devices were as follows: the patient was seated comfortably in front of the instrument and the subject's chin placed on the chin rest, the subject's forehead pressed against the forehead strap and the subject's eye would be aligned to the visual axis by a central fixation light or target.

All three images captured with MS-39 AS-OCT are digitised and processed. Absolute scale topographic maps were obtained for each eye and the non-orthogonal simulated keratometric (Simk) readings (power and axis) for all patients were obtained. The Simk reading of the MS-39 represents proximate points of the cornea to the location at which the auto-keratometer measures corneal curvature (central 3 mm of the cornea)

The collected data were entered into MS Excel Version 16 and cleaned. Frequency and percentages for categorical variables and Mean (standard deviation) or Median (Interquartile-range) were calculated for numerical variables. For assessing the agreement between measurements taken by the two instruments, Bland-Altman analysis (Altman and Bland, 1983) was done using BlandAltmanLeh package (version 0.3.1) of R-software. Limits of Agreement (LoA) between the two devices was assessed and whether the agreement is clinically acceptable was decided by clinical significance based on the mean difference, LoA and its corresponding 95% Confidence interval. The circular statistics were utilised to analyse the cylindrical axis given their cyclic angular nature (Jammalamadaka and Sengupta, 2001; Fisher, 1993). The angles (0-180 degrees) were converted unto circular data using the circular (Axis) function in R to map onto the unit circle. Circular means and corresponding standard deviations were calculated using the converted

dataset. Circular methods avoid distortions in linear techniques and account for the periodicity in angular data. The R circular package enabled appropriate circular analysis of the orientation variables.

RESULTS

The mean age of participants was 17 years (range of 4-47 years) with a standard deviation of 9 years. Of the 100 participants, 57 were male and 43 were female. The descriptive characteristics of the study participants, including spherical error, average K, cylindrical power, and cylindrical axis for both the right and left eyes separately is displayed in the table (Table 1).

The Bland-Altman plot demonstrated a good agreement between the two methods for measuring cylindrical power for both left eye (Figure 1) and right eye (Figure 2). The mean difference between the two measurement methods for cylindrical power of left eye was -0.05D with 95% limits of agreement (LoA)

Table 1. Descriptive characteristics of study participants (n = 100).

Characteristic	MS-39 AS- OCT	URK 800-F Auto-refractometer Keratometer
Myopic error (RE) Mean (SD)	-	-3.00 (2.69),
Myopic error (LE) Mean (SD)	-	-2.87 (2.51)
Hyperopic error (RE) Mean (SD)	-	+1.43 (1.41)
Hyperopic error (LE) Mean (SD)	-	+1.59 (1.74)
Average K (RE) Mean (SD)	43.92 (1.45)	43.70 (1.42)
Average K (LE) Mean (SD)	43.91 (1.40)	43.69 (1.39)
Cylindrical power (RE) Mean (SD)	-2.33 (0.88)	-2.31 (0.87)
Cylindrical power (LE) Mean (SD)	-2.32 (0.87)	-2.27 (0.85)
Cylindrical axis (RE) Mean (SD)	75.86 (1.82)	84.33 (1.81)
Cylindrical axis (LE) Mean (SD)	153.66 (1.37)	158.26 (1.31)

RE: Right eye, LE: Left eye, -: Data not available

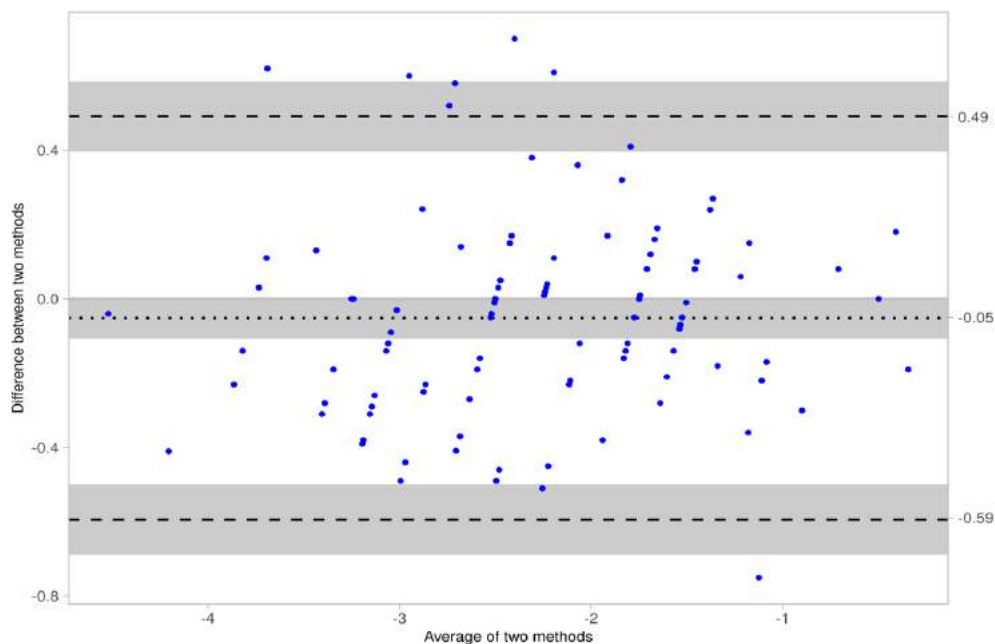


Figure 1: Comparability of cylindrical power measurement between MS-39 AS-OCT and URK 800-F Auto-refractometer for left eye.

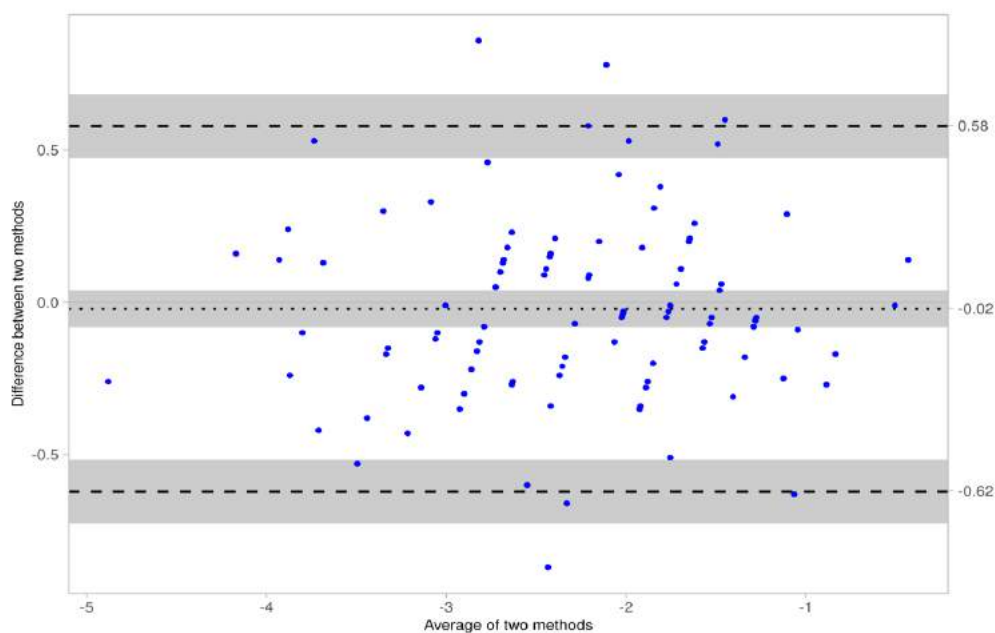


Figure 2: Comparability of cylindrical power measurement between MS-39 AS-OCT and URK 800-F Auto-refractometer for right eye.

between -0.59 and 0.49 D. Similarly, the mean difference between the two measurement methods for cylindrical power of right eye was -0.02D with 95% limits of agreement (LoA)

between -0.62 and 0.58 D. Five observations were beyond the LoA for the left eye (Figure 1) and three observations were beyond the LoA for the right eye (Figure 2).

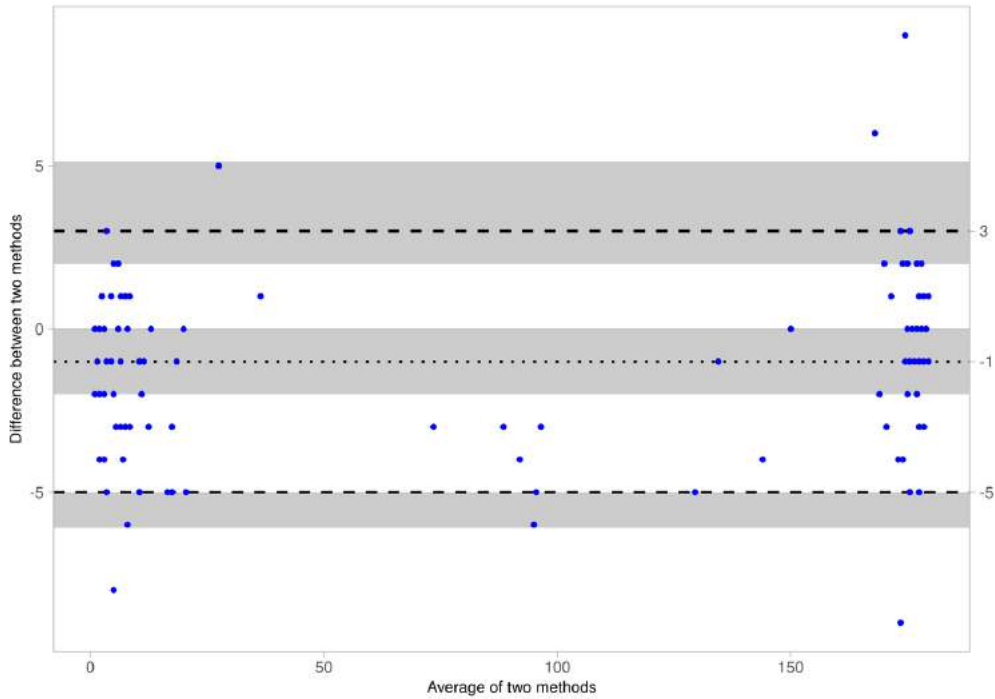


Figure 3: Comparability of cylindrical axis measurement between MS-39 AS-OCT and URK 800-F Auto-refractometer for right eye

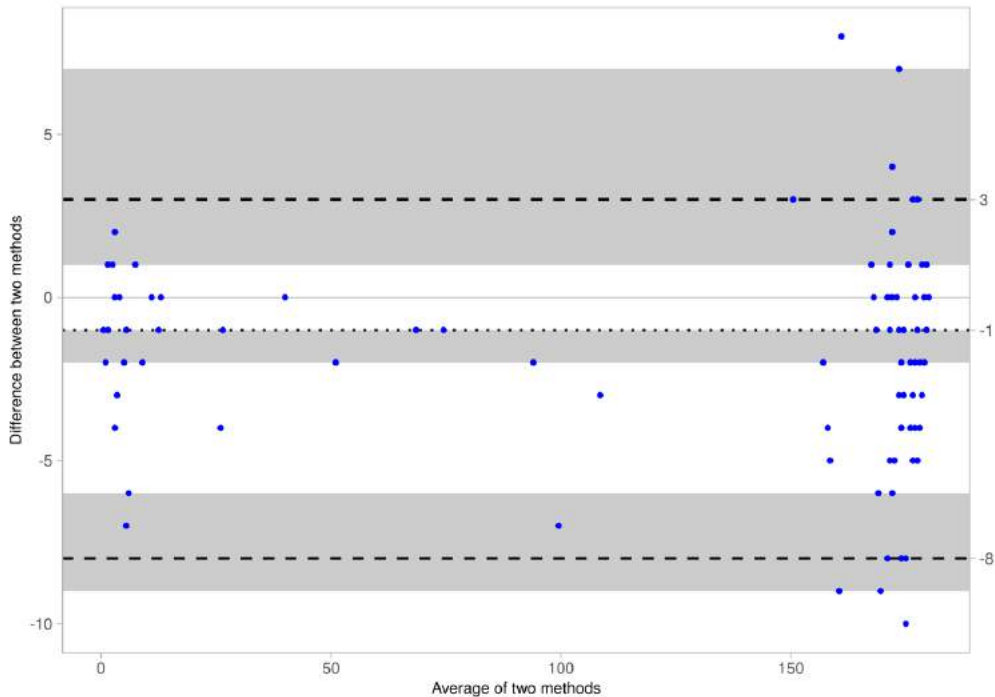


Figure 4: Comparability of cylindrical axis measurement between MS-39 AS-OCT and URK 800-F Auto-refractometer for left eye

The mean difference between the two measurement methods for cylindrical axis of right eye was 1 degree with 95% limits of

agreement (LoA) between 3 and -5. Similarly, the mean difference between the two measurement methods for cylindrical power of left eye was

2 degrees with 95% limits of agreement (LoA) between 3 and -8. Three observations were beyond the LoA for the right eye (Figure 3) and five observations were beyond the LoA for the right eye (Figure 4).

DISCUSSION

To our knowledge, this study is first of its kind in our country. The availability of the most reliable instrument is not possible in every ophthalmic setup owing to the huge cost and lack of skilled personnel. Auto-refractometer is a relatively affordable diagnostic tool and has a quick learning curve. Although the refractive error estimate cannot be solely relied on auto-refractometer, it does aid in comparing its values with that of the objective retinoscopy and cross check the values subjectively. In a study was done by Karabatsas et al. to evaluate agreement in measurement of astigmatic axis power and location between keratometry and corneal topography on normal corneas with less than -1.50 D of astigmatism, the differences in measurements between keratometry and corneal topography was not clinically significant. Thus, it was concluded that two instruments can be used interchangeably in measuring only the magnitude of astigmatism on normal corneas

(Karabatsas et al., 2005).

The observations in our study indicate that the cylindrical refractive error measurement by auto-refractometer was comparable to the measurements made from MS-39 AS-OCT. Thus, the auto-refractometer can be taken as a reliable method of refractive error measurement.

The finding in our study is similar to the study by Galindo-Ferreiro et al. where they found that a conventional auto-refractometer can be effective as a first level screening method to detect irregular corneal astigmatism in places where corneal topography facilities are not available.

CONCLUSION

The findings of this study conclude that an auto-refractometer can be used as an effective tool for identification of spherical refractive error as well as accurate cylindrical power and cylindrical axis for screening and management purposes in centres that lack the standard corneal topography based instruments.



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