COMPARISION OF ASTIGMATIC REFRACTIVE ERROR AND CORNEAL CURVATURE MEASURES USING THE RETINOMAX K-PLUS 2 AUTOREFRACTOR/KERATOMETER TO THE GRAND SEIKO AUTOREFRACTOR/KERATOMETER, MANUAL CORNEAL REFLEX KERATOMETR, AND SUBJECTIVE REFRACTION

by

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and
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We, Tamara Balentine and Katie Bigari, hereby release this Paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

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ABSTACT

Purpose: To compare the inter-instrument repeatability of refractive and corneal curvature measures on a population of patients with mild to moderate magnitude of astigmatism. **Methods:** Readings will be acquired on thirty people (60 eyes). Subjective refractive sphere power, cylinder power and axis will be compared to the automated instruments. Front surface corneal power and axis for each meridian will be compared between the automated instruments and the manual corneal reflex keratometer. **Results:** The difference in raw data for each method will be calculated for each parameter of every eye. The difference for each parameter will be evaluated statistically to assess repeatability. **Conclusion:** The data will be summarized and compared to the ANSI Z80.1 standard to demonstrate if each of the methods provides the practitioner with clinically equivalent values.

Key words, subjective refraction, autorefractor, autokeratometer, manual keratometer

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Introduction

Auto-refractors provide a reasonable level of accuracy in the measurement of refractive error[1]. However, the variability found when comparing auto-refractor and subjective measurements is greater than the variability found when comparing the subjective prescriptions of different optometrists[1]. Also, auto-refractor measurements produce a wider variation of refractive error distributions in human than in model eyes[1]. This result is attributed to accommodation and fixation instabilities in human eyes. While small fixation instabilities are difficult to control, auto-refractor manufacturers have attempted to control accommodation with the use of fogging techniques and distance scenes as targets[1]. Retino-Max K-Plus 2 auto-refractor uses a distant tree in attempt to control accommodation. The Grand Seiko uses a viewing section that is transparent so the patient can look beyond the machine and at a target on the other side of the room.

One is to also wonder what the variability is when comparing these same instruments as autokeratometers to manual keratometry readings. If a patient has to undergo refractive or cataract surgery, is it safe to rely on measurements from autokeratometers or is it best to measure the corneal curvatures manually to get the most accurate results? The purpose of this study is to compare the difference of refractions and corneal curvature measures recorded with manual subjective refractions and keratometry readings to the Retino-Max K-Plus 2 auto-refractor/auto-keratometer, and Grand Seiko 2100 auto-refractor/auto-keratometer.

Methods

The study consisted of 30 subjects (60 eyes), who volunteered to participate and were over the age of 18 years. Each subject was informed of all aspects of the study and

was asked to read and sign the consent form provided. Once the consent was signed, the collection of data began and all measurements were completed within thirty minutes.

Pre-test activities for this study involved a brief questionnaire to determine subject eligibility, regarding ocular health and vision. Provided all preliminary criteria are met, each subject was assigned a random number which was used to record and compare all examination data. The questionnaire revealed sixty-three percent (19 subjects) have been prescribed a spectacle correction. Sixty percent (18 subjects) are current contact lens wearers. Of the 18 subjects, one currently wears gas permeable lenses, 13 subjects wear soft contact lenses, and four subjects did not specify gas permeable or soft contact lenses. Two subjects reported corneal conditions; one subject with dry eyes and one subject in corneal refractive therapy (whose lenses were removed 3.5 hours prior to participation). One subject reported a history of a retinal condition - photocoagulated retinal tear 17 years prior. The sample population consisted of 47 myopic eyes (mean refractive error = -3.50 D +/- 3), six hyperopic eyes (mean refractive error = +2.00D +/- 2.50), 6 plano-spherical eyes, and 23 with an astigmatic component (mean refractive error = -0.75 +/-0.25), based on the subjective refraction.

The study was conducted in a typical exam room using routine clinical instruments and following instrument manufacturer procedures. The study required subjects to sit in a typical examination chair or stool and place their chin and forehead against a cleaned stabilization rest so that recordings could be taken. All tests were performed on both eyes of each subject within thirty minutes. There was no use of ophthalmic drops used for this study.

The first station required the subject to sit behind a phoropter to obtain maximum

plus subjective refraction. Next, using the manual corneal reflex keratometer, Topcon OM-4 keratometry, corneal curvature measurements were taken. The subjects than proceeded on to have their corneal curvature measurements and their refraction measurements taken with the Retino-Max K-Plus 2 auto-refractor/keratometer and the Grand Seiko 2100 auto-refractor/keratometer. One measurement was taken on each eye with each instrument. All subjects were corrected to Snellen 20/20. Subjective refraction values were rounded to the most plus +/-0.25D. The Retino-Max K-Plus auto-refractor/keratometer rounds its data to +/-0.25D, whereas the Grand Seiko 2100 auto-refractor/keratometer rounds its data to the nearest 0.12D along with the manual Topcon OM-4 keratometer.

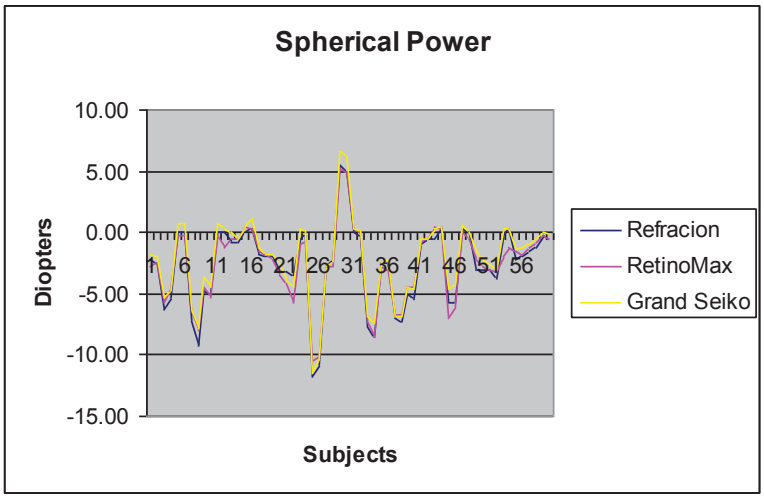
The data recorded will be analyzed in the following manner.

1) Auto-refraction measurements taken with the Retino-Max K-Plus 2 and the Grand Seiko 2100 Auto Refractors will be compared to maximum plus best corrected visual acuity.
2) The corneal curvature measurements taken with the manual keratometer will also be compared to the measurements taken with the Retinomax K-Plus 2 Auto Keratometer and the Grand Sieko 2100 Auto Keratometer.

Results

Each component of refractive error from each method was compared. The spherical components of the study are outlined in Graph 1: Spherical Components. For subjective refraction, the spherical powers averaged -2.61D, with a standard deviation (SD) of 3.13D. Averages for spherical powers measured by the RetinoMax K-Plus 2 and

Grand Seiko 2100 were -2.62D (SD 3.13D) and -2.07D (SD 3.29D), respectively. The average difference between subjective refraction and the Retino-Max K-Plus 2 was 0.00D (SD 0.67D). The average difference between subjective refraction and the Grand Seiko 2100 was +0.54D (SD 0.46D). The average difference between the Retino-Max K-Plus 2 and the Grand Seiko 2100 was 0.54D (SD 0.62D).



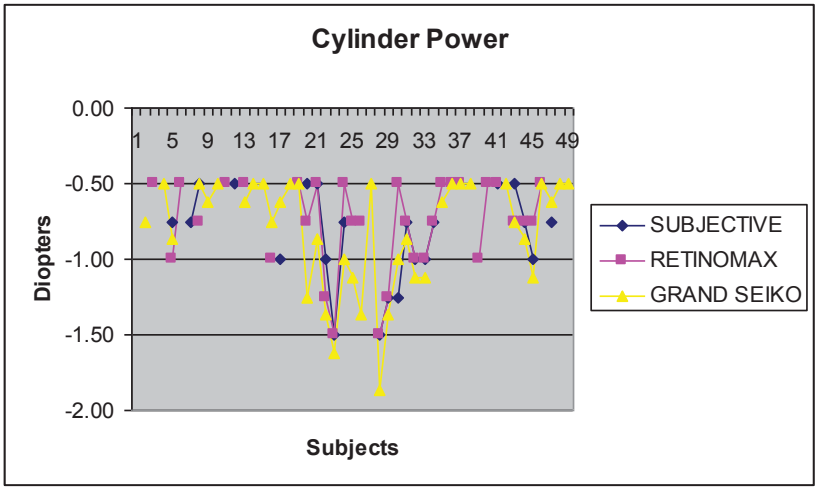
Graph 1: Spherical Components

The following averages include all cylindrical powers and their axis measured during the entire study. The average cylindrical power was -0.32D (SD 0.45D) for subjective refraction. Cylindrical power averages for Retino-Max K-Plus 2 and Grand Seiko 2100 were -0.47D (SD 0.39D) and -0.60D (SD 0.42D), respectively. The average difference between subjective refraction and the Retino-Max K-Plus 2 was -0.15D (SD 0.34D). The average difference between subjective refraction and Grand Seiko 2100 was -0.28D (SD 0.35D). The average difference between the Retino-Max K-Plus 2 and the Grand Seiko 2100 cylindrical powers was -0.13D (SD 0.32).

The average cylindrical axis for subjective refraction was 37.62 (SD 64.68). Averages of cylindrical axis for the Retino-Max K-Plus 2 and Grand Seiko 2100 was

77.18 (SD 71.07) and 105.55 (SD 69.04), respectively. The average difference between subjective refraction and the Retino-Max K-Plus 2 was 39.57 (SD 85.73). The average difference between subjective refraction and the Grand Seiko 2100 was 67.93 (SD 96.15). The average difference between the Retino-Max K-Plus 2 and the Grand Seiko 2100 was 28.37 (SD 90.71).

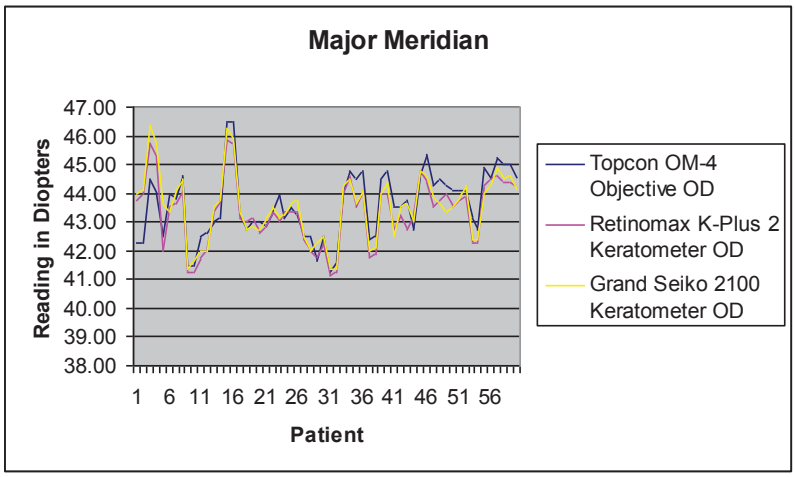
To look at cylindrical powers and axis on a more clinical level, all powers and respective axis less than -0.50D have been excluded. The cylinder powers are outlined in Graph 2: Cylindrical Component. The subjective refraction had 22 eyes remaining in this set of data for average cylindrical powers and axis. The Retino-Max K-Plus 2 had 32 eyes remaining, and the Grand Seiko 2100 had 39 eyes remaining in the set. Subjective refraction data revealed an average of -0.85D cylinder (SD 0.31D). The Retino-Max K-Plus 2 and the Grand Seiko 2100 revealed an average of -0.76D cylinder (SD 0.30) and -0.80D cylinder (SD 0.36D), respectively. The average axis found during subjective refraction was 98.50. The Retino-Max K-Plus 2 and Grand Seiko 2100 revealed average axis of 103.84 and 115.82, respectively.



Graph 2: Cylindrical Component

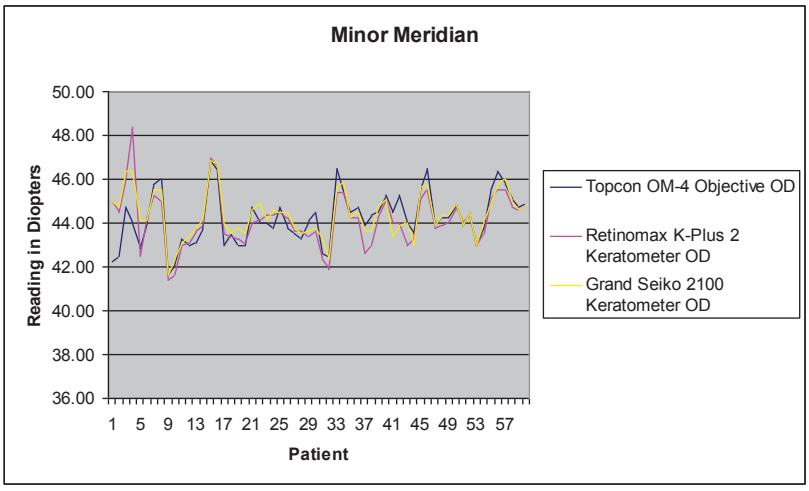
Subjective refractions of the remaining 22 clinically significant cylindrical powers revealed 3 eyes with against-the-rule astigmatism, three oblique-astigmatisms, and 16 with-the-rule-astigmatisms. The Retino-Max K-Plus 2 revealed 4 eyes with against-the rule astigmatism, 6 oblique, and 22 with-the-rule astigmatism of the remaining 32 significant cylindrical powers. The Grand Seiko 2100, with 39 eyes remaining, revealed 6 with against-the-rule astigmatism, 2 oblique astigmatism, and 31 with-the rule astigmatism.

To make the keratometry readings easy to understand, we categorized the data into major meridian, minor meridian, and axis. The major meridian is the steepest meridian, the minor meridian is the flattest meridian, and the axis is the power axis of the major meridian. The measurements taken from the Topcon OM-4 manual keratometer was used as the standard measurement. For the major meridian, the average measurement taken from the Topcon OM-4 was 43.59D with a standard deviation of 1.18. The Retinomax K-Plus 2 gave an average measurement of 43.35D (SD 1.14) while the Grand Seiko 2100 average given was 43.51 SD 1.15). The difference of the averages between the standard Topcon OM-4 and the Retinomax K-Plus 2 was 0.16D (SD 0.04). The average difference of the averages between the Topcon OM-4 and the Grand Seiko 2100 was 0.08D (SD 0.01). The data can be compared more closely by looking at graph 3 below.



Graph 3: Major Meridian

The data from the minor meridian was also close together as seen in graph 4 below. The average measurement taken from the Topcon OM-4 was 44.22D with a standard deviation of 1.18. The Retinomax K-Plus 2 gave an average measurement of 44.15D (SD 1.23) while the Grand Seiko 2100 average given was 44.38 (SD 1.07). The difference of the averages between the standard Topcon OM-4 and the Retinomax K-Plus 2 was 0.07D (SD 0.00). The average difference of the averages between the Topcon OM-4 and the Grand Seiko 2100 was 0.16D (SD 0.11).



Graph 4: Minor Meridian

The average of the power axis given by the Topcon OM-4 was 082 degrees with 26 being with-the-rule, 2 against-the-rule and 2 spherical. The Retinomax K-Plus 2 gave an average of 085 degrees, 23 with-the-rule, 2 against-the-rule and 5 obliques. The average from the Grand Seiko 2100 was 086 degrees, 24 with-the-rule, 1 against-the-rule, 2 oblique and 3 spherical. The difference of the averages given by the Topcon OM-4 and the Retinomax K-Plus 2 is 003 degrees while the difference in averages given by the Topcon OM-4 and the Grand Seiko 2100 is 004 degrees.

Discussion

We analyzed the data to look at the variation of refraction components between techniques performed within minutes. First, we looked at what percent of the data from each automated technique showed over +/-0.50D when compared to the maximum plus best corrected subjective refraction. The Retino-Max K-Plus 2 showed 21.67% and the Grand Seiko 2100 showed 43.33% of the subject's spherical component was over +/-0.50D. The average difference of the spherical component between subjective refraction and the Retino-Max K-Plus 2 was zero. Therefore comparing well on average, but with a good chance the Retino-Max K-Plus 2 could error over a half-diopter at any time. The average difference between subjective refraction and the Grand Seiko 2100 was +0.54D. On average the Grand Seiko 2100 found +0.50D more than with maximum plus best corrected subjective refraction, and could error up to a half-diopter at any time.

The average difference of the cylindrical component between subjective refraction and the Retino-Max K-Plus 2 was -0.10D, with possibility of up to 0.40D of error. The average difference between subjective refraction and the Grand Seiko 2100

was -0.24D. This difference can be viewed as clinically significant with possible error of 0.41D.

The cylindrical axis component of subjects that remain once the data was reduced to clinically significant cylindrical refractive error, revealed all techniques on average to show against-the rule-astigmatism. The average difference showed 19.27 degrees between subjective refraction axis and the Retino-Max K-Plus 2 and possible error of 85.94 degrees. The average difference between subjective refraction and the Grand Seiko 2100 was 39.17 degrees and possible error of 97.40 degrees.

Most of the variation between techniques appeared in the cylindrical axis component and was greater with the Grand Seiko 2100. The least variation between techniques was the spherical component found in subjective refraction and the Retino-Max K-Plus 2. Further studies that would indicate repeatability of automated techniques on the same subject may supplement the results of this study.

A question was asked earlier about if taking manual keratometry readings would be just as clinically significant as taking autokeratometry readings for a refractive surgery patient or cataract surgery patient, for example. The data shows that taking the corneal curvature measurements using one the autokeratometer instruments in the study would be just as acceptable as taking them manually. The difference in the averages in the measurements taken by the instruments in the major and minor meridians are close; however, it also shows through the standard deviations that an error could take place at any given time by 1.00D or more. The data is also showing that the minor meridian values were more variable than the major meridian values. Furthermore, the data is also revealing that the variation of measurements between the gold standard Topcon OM-4

and the Retinomax K-Plus 2 were more for the major meridian, less for the minor meridian, and vice versa between the Topcon OM-4 and the Grand Seiko 2100.

In conclusion, refractions and keratometry readings taken within a few minutes of each other are likely to be quite different. Hence, more research needs to be conducted to determine the repeatability of the techniques on the same individual, before conclusion can be made between instruments or between instruments and traditional methods.

REFERENCES

[1.] Strang, Niall, et al. Clinical Evaluation of patient tolerance to autorefractor prescriptions. Clinical and Experimental Optometry 81:3 May–June 1998. Site: http://www.opto.ca/en/bc_cd/PDFs/autorefractor%20study.pdf

APPENDIX A

CONSENT FORM

Agreement To Participate

Title: Comparison of astigmatic refractive error and corneal curvature measures using the Retinomax K-Plus 2 auto refractor/keratometer to the Grand Sieko 2100 auto refractor/keratometer, manual corneal reflex keratometer, and subjective refraction.

Investigators: Mark Swan, OD, MEd, Tamara Balentine, Student Intern, and Katie Bigari, Student Intern.

This study is being conducted at the Michigan College of Optometry at Ferris State University and is designed to determine if different automated instruments used to measure the refractive power of the eye provide equally reliable values. It will need 50 participants in order to complete this study.

Pre-test activities for this study involve a brief questionnaire to determine subject eligibility. Provided all preliminary criteria are met, the subject will be assigned a random number which will be used to record and compare all examination data.

The study will be conducted in a typical exam room using routine clinical instruments and following instrument manufacturer procedures. The study requires subjects to sit in a typical examination chair or stool and place their chin and forehead against a cleaned stabilization rest so that recordings can be taken. The entire testing time will take less than 30 minutes. There will be no use of ophthalmic drops used for this research project.

Participation in this study is strictly voluntary and you may chose to discontinue at any time. If you choose to withdraw from the study, it will not affect your status as a student at Ferris State University. Additionally, it will not affect your future eye care at the University Eye Center at Ferris State University. All finding are confidential and any results used in publication will be coded to protect your privacy. Although there is no benefit to you for taking part in this study, your participation will contribute to the general body of scientific knowledge.

If you have any questions regarding this study, contact the responsible investigator – Dr. Mark Swan, Michigan College of Optometry at Ferris State University, (231) 591-2184.

ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH SUBJECT MAY BE ADDRESSED TO THE FERRIS STATE UNIVERSITY COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (231.591.2177). ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT FERRIS STATE UNIVERSITY ARE GOVERNED BY REQUIREMENTS OF THE UNIVERSITY AND FEDERAL GOVERNMENT.

I have read the information in this statement and agree to participate. I understand that this decision is voluntary and will not provide any favored consideration to my status as a student or applicant at the Michigan College of Optometry or Ferris State University, or any other advantage that could be offered by the investigators.

_____ _____ ___ I am at least
Signature of Participant Date 18 years of age

_____ _____
Signature of Investigator Date

APPENDIX B

DATA RECORDING SHEET

Questionnaire **(please circle correct answer)**

1. Do you wear glasses? Y N

2. Do you wear contacts? Y N If yes, soft RGP

3. Do you have any corneal conditions? Y N

If yes, please explain _____

4. Do you have any retinal conditions? Y N

If yes, please explain _____

REFRACTIONS

Manual Subjective Refraction

OD _____ - _____ x ____ 20/

OS _____ - _____ x ____ 20/

Retinomax K-Plus 2 Auto refractor

OD _____ - _____ x ____

OS _____ - _____ x ____

Grand Seiko 2100 Auto refractor

OD _____ - _____ x _____

OS _____ - _____ x _____

KERATOMETERY

Topcon OM-4 Objective

OD _____ - _____ @ _____

OS _____ - _____ @ _____

Retinomax K-Plus 2 Keratometer

OD _____ - _____ @ _____

OS _____ - _____ @ _____

Grand Seiko 2100 Keratometer

OD _____ - _____ @ _____

OS _____ - _____ @ _____