11-1997

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Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Lee Ann Remington

Subject Categories

Optometry

DETERMINATION OF RELIABILITY AND VALIDITY OF THE TWO MODES OF THE NIKON RETINOMAX AUTOREFRACTOR

BY

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AND
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A thesis submitted to the faculty of the
Pacific University
College of Optometry
Forest Grove, Oregon
for the degree of
Doctor of Optometry
November, 1997

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Biographical Sketch

Laurali M. Sime

Laurali M. Sime graduated cum laude from Jamestown College, Jamestown, ND in 1994 with a B.A. in biology and a minor in chemistry. She was also awarded the College Fellow in Biology during her senior year. She entered Pacific University College of Optometry in the fall of 1994. Laurali is a current member of Beta Sigma Kappa honor society and was a local liaison for the American Public Health Association during her second year of optometry school. She will be a graduate of the Pacific University class of 1998 with plans of returning the Midwest to begin her career in optometry.

Dallas C. Wilkinson

Dallas Wilkinson was born in Hot Springs, South Dakota on June 15, 1969. He lived in Custer, South Dakota throughout high school and for four years following graduation worked for the US Forest Service. In 1991 he moved to Boise, Idaho to attended Boise State University and graduated in 1995 with a Bachelors of Science degree in biology. Entering Pacific University College of Optometry in August of 1995 he has focused his attention to primary care optometry. Upon graduation, Dallas intends to return to Custer, South Dakota to open a private practice.

Abstract

This study was designed to determine the reliability and validity of the two modes of the Nikon Retinomax Autorefractor. Reliability was determined by comparing readings within the regular mode and the quick mode. Ten consecutive readings, in each mode, were taken on 14 subjects ranging in age from 22 to 50. Validity of the quick mode was determined by comparing the readings of the quick mode to readings taken with the regular mode, 119 subjects between the ages of 5 and 88 participated. Results indicated that the findings are quite variable. Twenty five percent of the readings in the regular mode and 34% of the quick mode readings differed from the mean reading to a clinically significant degree using ANSI standards. However, when the data was compared using a less restrictive increment of +/- .25D, the reliability was greatly improved. In the validity analysis, the only significant difference between the modes was in the axis findings (p=.0264).

Introduction

The Nikon Retinomax Autorefractor is a hand-held, portable instrument. It is convenient for out-of-office uses or for patients with mobility problems who are unable to place their head comfortably in the traditional type of chin and forehead rest of a non portable autorefractor.

The Retinomax projects infrared light into the patient's pupil in a "manner derived from streak retinoscopy. The light from the fundus is observed by a photodetector which is optically conjugate to the pupil plane. The ametropia in the meridian under test is determined from the time delay of the fundus reflex in the pupil. Astigmatism is determined with the help of a rotating prism, which changes the orientation of the illuminating beam."[1] A single "reading" is an average of 8 consecutive measurements taken automatically by the instrument.

The autorefractor has two modes of operation, regular and quick. The regular mode is used most commonly. It has an automatic fogging mechanism to help prevent the patient from accommodating.

The quick mode overrides the fogging mechanism to aid the user in obtaining readings in otherwise difficult situations. It would be difficult to obtain readings on patients with nystagmus or a child with quick eye movements without a clear target for them to attend.

The goals of this project are to determine the reliability of the regular and quick modes and to test the validity of the quick mode as compared to the regular mode of the Nikon Retinomax Autorefractor.

Subjects

Reliability data was collected on 14 optometry students. Ages ranged from 22 to 50 years (mean=31.4, SD=9.26). Refractive errors ranged from +0.25 to -3.25. No pathology or amblyopia was present in any of the subjects.

Validity data was collected during a goodwill eyecare mission to San Jose del Cabo, Mexico. The 119 subjects ranged in age from 5 to 88 years (mean=37.2, SD=19.5). Refractive errors ranged from +4.75D to -6.00D. Persons with any significant ocular pathology were not included in this study.

Methods

Data was collected to compare consecutive readings in both the regular mode and the quick mode on the same subject. On the first subject, 10 consecutive readings in the regular mode were collected on the right eye. The mode was then switched to the quick mode and another 10 consecutive readings were taken on the right eye. The same procedure was used to collect data on the second subject except that the quick mode was used first. On each subsequent subject, the order of the modes was opposite that of the previous subject.

To compare the quick mode to the regular mode, measurements were taken on the same subject and the same person collected all of the data on each of the subjects. To randomize the data collection, the collector looked at the second hand on his watch before each subject. If the second hand was on an even number, the regular mode readings were taken first. If the second hand was on an odd number, the quick mode readings were taken first.

Once it was determined which mode would be used first, one reading on each eye was taken, first the right eye then the left eye. The mode of the instrument was switched and an additional reading on each eye was immediately taken in the same manner as the first reading.

The manufacturer's recommended procedure was followed to maintain stability of the instrument and to minimize leveling errors during all readings in both test groups. Patients were instructed to look at the tree on the horizon in a relaxed manner and to keep their eye open as long as possible.[2]

Subjects were broken down into age groups and the validity data was analyzed within these groups. The age groups were broken down as follows:

Group A - 0-10 years (n=10)
Group B - 11-20 years (n=21)
Group C - 21-30 years (n=19)
Group D - 31-40 years (n=12)
Group E - 41-50 years (n=26)
Group F - 51-60 years (n=16)
Group G - 61-70 years (n=10)
Group H - 71-90 years (n=4)

Only the data collected from the right eye of each subject was used for statistical analysis in this project.

To analyze the reliability, the mean, range and standard deviation was calculated for the ten readings collected from each subject. Using ANSI standards each reading was compared to the mean, those which fell outside of the error range were considered clinically significant. For instance, if the mean were -3.00 D, the acceptable error by ANSI standards is $\pm$ 0.13 D. A reading of -3.25 D would therefore be considered clinically significant. Then each reading was compared to the mean using +/- 0.25D difference on all data except the axis data. This comparison may be more applicable because the instrument only measures in 0.25D increments.

Validity was determined using the paired t-test to compare sphere, cylinder, axis and equivalent sphere readings of the quick mode to the regular mode. The astigmatic errors were divided into two groups and analyzed separately. Those with cylinder errors greater than or equal to -1.00D were in one group and those with less than -1.00D of cylinder error were in the other group. The p-value was set at ≤ 0.05.

Results

The reliability data, when compared to ANSI standards, showed a large number of clinically significant deviations. In the spherical equivalent data, the average number of deviations from the mean per subject was 2.5 or 25% for the regular mode, and for the quick mode readings was 3.4 or 34% (tables 1 & 2). The sphere, cylinder and axis reading also showed large numbers of significant deviations. See appendix for that data.

Analyzing the reliability data using +/- 0.25D increments showed fewer clinical significant deviations. The average number of deviations from the mean per subject for the regular and quick modes, for the spherical equivalent data, were .1428 and .214 respectively (tables 1 & 2).

S.Eq. Reg. Subject	Mean	Range	Standard Deviation	Clinically Sig. Dev. (ANSI)	Clinically Sig. Dev. (+/- 0.25D)
1	-3.224	0.37	0.12781932	4	0
2	-0.26	0.38	0.12516656	4	0
3	-2.108	0.12	0.03794733	0	0
4	0.25	0	0	0	0
5	-1.884	0.25	0.07167829	1	0
6	-2.448	0.37	0.13356646	2	0
7	-2.558	0.38	0.13579396	4	0
8	-1.87	0.38	0.14787758	3	0
9	-2.358	0.38	0.09307106	2	0
10	-1.096	0.38	0.13040109	4	0
11	-1.375	0.5	0.1767767	1	1
12	-0.797	0.62	0.18761959	5	1
13	-4.534	0.38	0.13301629	3	0
14	-1.45	0.25	01.540926	2	0
				m=2.5	m=.1428

Table 1. Spherical equivalent data collected in the regular mode.

S.Eq Quick Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)	Clinically Sig. Dev. (+/- 0.25D)
1	-3.023	0.38	0.16660332	7	0
2	-0.323	0.38	0.14787758	5	0
3	-2.097	0.25	0.07803845	1	0
4	0.236	0.25	0.07167829	1	0
5	-1.958	0.25	0.11877149	3	0
6	-2.411	0.38	0.13395273	2	1
7	-2.558	0.25	0.10591401	2	0
8	-2.01	0.5	0.14944341	4	1
9	-2.296	0.25	0.10490207	2	0
10	-1.083	0.25	0.08380533	1	0
11	-1.515	0.38	0.13091558	4	0
12	-0.922	0.37	0.17655972	8	0
13	-4.761	0.5	0.16141389	5	1
14	-1.473	0.37	0.11441154	3	0
				m=3.4	m=.214

Table 2. Spherical equivalent data collected from the quick mode.

Considering the validity, the only significant difference found was between the axis readings determined by the regular and the quick modes.(p=0.0264) But when the subjects were broken down into age groups there was no significant difference found in this data set. When the astigmatic error groups were analyzed, those with less than 1.00D of cylinder showed a significant difference (p=.497) while those with 1.00D of cylinder or greater (p=.0197) did not.

Discussion

The reliability of the autorefractor was determined by taking ten consecutive readings in both the regular mode and the quick mode on each of 14 individuals. Within the spherical equivalent data when compared to ANSI standards, some subjects had high variability with large numbers of clinically significant deviations. Others had little or no variability with no clinically significant deviations. However, 25% of the regular mode findings and 35% of the quick mode findings differed from the mean by a value greater than that allowed by ANSI. Using this stringent criteria it would appear that the instrument did not give reliable readings.

However, when the spherical equivalent data was compared using +/-.25D increments, the number of clinical significant deviations was much less. It was found that in the regular mode and the quick mode the mean deviations per subject were only .1428 and .214 respectively. Utilizing this criteria, which seems to be more clinically relevant, the Retinomax does give reliable readings. Similar results were found when comparing the sphere and cylinder data (see appendix).

The quick mode was compared to the regular mode of the Nikon Retinomax Autorefractor to determine the validity of the quick mode. A significant difference existed in the axis readings of the entire study population. However, when the population was split into age groups there were no significant differences found. The differences of the subgroups were not significant perhaps due to the smaller sample size. But considering the whole group, the larger sample size makes the differences significant. A significant difference was also found when only comparing those with cylinder values less than 1.00D.

The significant differences could be attributed to three possible causes. One, any tilting of the patient's head or of the autorefractor could induce aberrant axis findings. Two, low cylinder powers have a high variability of axis position. Three, this study found poor reliability when compared to ANSI standards in both modes and findings are therefore inconsistent.

One method to improve this study would be to compare the validity readings of the autorefractor to static retinoscopy findings of each subject.

In conclusion, the Nikon Retinomax Autorefractor gives consistent readings between modes but has high variability within each mode when compared to ANSI standards. This lack of reliability may not provide a solid foundation on which to analyze validity data. However, the variability is greatly decreased when the clinical significant deviations are determined using +/- .25D increments.

Due to some unreliability, this instrument may be a good screening tool but may not be precise enough nor reliable enough to prescribe lenses from. In the authors' opinion a larger population should be used to verify the poor reliability determined in this study when compared to ANSI standards.

References

1. Wesemann, W, Rassow, B, Automatic Infrared Refractors- A Comparative Study, Am J Optom. & Phys. Optics. 64(8), 627-638. 1987.

2. Nikon Hand-Held Ref. Retinomax Instructions, Nikon Corporation, Tokyo, Japan.

Appendix

Sph. Reg. Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)	Clinically Sig.Dev. (+/- 0.25D)
1	-3.025	.5	.184462	5	2
2	-0.05	.5	0.15811388	4	0
3	-1.725	.25	0.07905694	0	0
4	0.25	0	0	0	0
5	-1.725	.25	0.07905694	1	0
6	-1.9	.25	0.12909944	4	0
7	-2.175	.25	0.12076147	3	0
8	-1.475	.5	0.1844662	5	2
9	-1.975	.25	0.07905694	1	0
10	-1	.25	0.12076147	3	0
11	-1.325	1	0.31291639	7	1
12	-0.475	.5	0.1844662	5	2
13	-4.225	.75	0.24860723	6	4
14	-1.2	.25	0.10540926	2	0

Table 1. Sphere data collected in the regular mode

Cyl Reg. Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)	Clinically Sig.Dev. (+/- 0.25D)
1	-0.45	0.25	0.10540926	2	0
2	-0.375	0.25	0.13176157	5	0
3	-0.775	0.25	0.07905694	1	0
4	0	0	0	0	0
5	-0.325	0.25	0.12076147	3	0
6	-1.1	0.25	0.12909944	4	0
7	-0.725	0.25	0.07905694	1	0
8	-0.65	0.25	0.12909944	4	0
9	-0.775	0.25	0.07905694	0	0
10	-0.25	0.25	0.10540926	2	0
11	-0.1	1	0.31622777	1	0
12	-0.65	0.25	0.12909944	4	0
13	-0.625	1.5	0.4487826	2	1
14	-0.5	0	0	0	0

Table 2. Cylinder data collected in the regular mode.

Axis Reg. Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)
1	114.4	52	14.2532647	6
2	90.5	11	3.68932394	0
3	99.2	8	2.34757558	0
4		0		0
5	86.3	24	6.97694616	1
6	101.9	6	1.79195734	1
7	115.9	12	3.81371793	3
8	82.4	10	3.80642731	3
9	113.1	8	2.02484567	2
10	99	18	6.4152559	5
11	13	0		0
12	106.7	15	4.32177947	1
13	75.4	78	21.5947263	8
14	137.5	28	7.32196088	3

Table 3. Axis data collected in the regular mode

Sph. Quick Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)	Clinically Sig.Dev. (+/- 0.25D)
1	-2.825	0.25	0.12076147	3	0
2	-0.125	0.25	0.13176157	0	0
3	-1.675	0.25	0.12076147	3	0
4	0.275	0.25	0.07905694	1	0
5	-1.825	0.25	0.12076147	3	0
6	-1.925	0.25	0.12076147	3	0
7	-2.175	0.25	0.12076147	3	0
8	-1.675	0.75	0.20581815	3	2
9	-1.9	0.25	0.12909944	4	0
10	-0.975	0.25	0.07905694	1	0
11	-1.45	0.5	0.15811388	4	1
12	0.6	0.25	0.12909944	4	0
13	-4.575	0.5	0.1844662	5	0
14	-1.225	0.5	0.14191155	3	1

Table 4. Sphere data collected in the quick mode.

Cyl. Quick Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)	Clinically Sig.Dev. (+/- 0.250)
1	-0.4	0.25	0.12909944	4	0
2	-0.4	0.25	0.12909944	4	0
3	-0.85	0.25	0.12909944	4	0
4	-0.075	0.25	0.12076147	3	0
5	-0.275	0.25	0.07905694	1	0
6	-0.975	0.5	0.14191155	3	1
7	-0.725	0.25	0.07905694	1	0
8	-0.675	0.5	0.16873714	5	0
9	0.8	0.25	0.10540926	2	0
10	-0.225	0.25	0.07905694	1	0
11	-0.125	0.25	0.13176157	0	0
12	-0.65	0.25	0.12909944	4	0
13	-0.475	0.5	0.14191155	3	1
14	-0.5	0.5	0.16666667	4	0

Table 5. Cylinder data collected in the quick mode

Axis Quick Subject	Mean	Range	Standard Deviation	Clinically Sig.Dev. (ANSI)
1	115.1	11	3.10733898	0
2	99.8	11	3.765339	0
3	99.8	6	1.68654809	1
4	107.333	15	7.76745347	1
5	83.2	40	11.6313752	4
6	103.7	9	2.83039063	3
7	116.7	9	3.0568684	1
8	84.9	10	3.07668674	1
9	113.4	9	2.54732976	1
10	98.4444	17	5.74697988	3
11	181.2	73	31.4117812	5
12	107.2	10	2.89427535	1
13	33.3	56	17.1855883	7
14	137	24	6.91214712	1

Table 6. Axis data collected in the quick mode.

PACIFIC UNIVERSITY FAMILY VISION CENTERS

SPECTACLE VERIFICATION INSTRUCTIONS

BEFORE VERIFYING ANY LENSES ADJUST LENSOMETER OCULAR FOR YOUR EYE AND ADJUST PRISM TO CENTER TARGET

NAME: Be sure patient's name on lab envelope matches name on our prescription order.

TINTS AND COATS: Verify tints and coats if ordered.

LENS MATERIAL: Verify if appropriate materials were used.

MULTIFOCAL STYLE: Check shape and size.

FRAMES: Check frame style and name, size, DBL, temple length, and color.

SPHERE POWER:	Plano to 6.50 D	- ±0.13 D.
	Over 6.50 D.	- ±2% of power
CYLINDER POWER:	Plano to 2.00 D.	- ±0.13 D
	2.12 to 4.50 D.	- ±0.15 D
	Above 4.50	- ±4% of power
CYLINDER AXIS:	0.125 to 0.375 D.	- ±7°
	0.50 to 0.75 D.	- ±5°
	0.875 to 1.50 D.	- ±3°
	Above 1.50 D.	- ±2°
VERTICAL PRISM:	1/3 Δ or O.C.'s within 1 mm if greater than 1/3 Δ	
LATERAL PRISM:	2/3 Δ or O.C.'s within 2.5 mm if greater than 2/3 Δ	
MULTIFOCAL POWER:	0.00 to 8.00 D.	- ±0.13 D.
	Above 8.00 D.	- ±0.18 D.
MULTIFOCAL LOCATION:	Vertical	- ±1.0 mm
	Horizontal	- ±2.5 mm of specified NEAR PD
	Segment top lines must be horizontal. Segments should appear symmetrical and balanced.	
M.R.P. HEIGHT:	Within ±1.0 mm of specifications.	
BASE CURVES:	Within ±0.75 D. of specified base curve.	
THICKNESS:	±0.3 mm of specified.	
SURFACE IMPERFECTIONS:	Pits, scratches, grayness, bubbles, checks, striae, or water marks which are visible and would impair the function of the lens should be rejected.	
SPECIAL INSTRUCTIONS:	See that all special instructions and notes have been complied with.	

From ANSI Standard Z80.1 - 1987

PRESCRIPTION ORDERS THAT DO NOT MEET SPECIFICATIONS MUST BE RE-VERIFIED BY THE DISPENSER ON DUTY OR YOUR ASSIGNED STAFF OPTOMETRIST BEFORE A REJECT FORM IS PREPARED.

Paired t-test
Split By: Age
Hypothesized Difference = 0

	Mean Diff.	DF	t-Value	P-Value
OD Eq Sph Regular, OD Eq Sph Quick: Total	-.021	118	-.498	.6192
OD Eq Sph Regular, OD Eq Sph Quick: A	-.013	9	-.095	.9268
OD Eq Sph Regular, OD Eq Sph Quick: B	.098	20	.756	.4587
OD Eq Sph Regular, OD Eq Sph Quick: C	.018	18	.225	.8248
OD Eq Sph Regular, OD Eq Sph Quick: D	-.038	12	-.492	.6318
OD Eq Sph Regular, OD Eq Sph Quick: E	-.158	25	-1.828	.0795
OD Eq Sph Regular, OD Eq Sph Quick: F	.071	15	.861	.4026
OD Eq Sph Regular, OD Eq Sph Quick: G	-.050	9	-.448	.6648
OD Eq Sph Regular, OD Eq Sph Quick: H	-.185	3	-.346	.7524

Cylinder powers less than 1.00D.

Paired t-test
Hypothesized Difference = 0
Row exclusion: Mexico Data

	Mean Diff.	DF	t-Value	P-Value
OD Axis Regular, OD Axis Quick	-9.086	69	-2.389	.0197

Cylinder powers greater than or equal to 1.00D.

Paired t-test
Hypothesized Difference = 0
Row exclusion: Mexico Data

	Mean Diff.	DF	t-Value	P-Value
OD Axis Regular, OD Axis Quick	1.200	19	.692	.4970

Paired t-test
Split By: Age
Hypothesized Difference = 0

	Mean Diff.	DF	t-Value	P-Value
OD Sphere Regular, OD Sphere Quick: Total	-.021	118	-.471	.6386
OD Sphere Regular, OD Sphere Quick: A	0.000	9	0.000	•
OD Sphere Regular, OD Sphere Quick: B	.036	20	.274	.7873
OD Sphere Regular, OD Sphere Quick: C	.039	18	.459	.6520
OD Sphere Regular, OD Sphere Quick: D	.058	12	.822	.4273
OD Sphere Regular, OD Sphere Quick: E	-.221	25	-2.020	.0542
OD Sphere Regular, OD Sphere Quick: F	.078	15	.662	.5178
OD Sphere Regular, OD Sphere Quick: G	-.050	9	-.612	.5554
OD Sphere Regular, OD Sphere Quick: H	.062	3	.124	.9091

Paired t-test
Split By: Age
Hypothesized Difference = 0

	Mean Diff.	DF	t-Value	P-Value
OD Cyl Regular, OD Cyl Quick: Total	-.019	118	-.564	.5737
OD Cyl Regular, OD Cyl Quick: A	.075	9	1.406	.1934
OD Cyl Regular, OD Cyl Quick: B	-.024	20	-.525	.6052
OD Cyl Regular, OD Cyl Quick: C	-.026	18	-.490	.6301
OD Cyl Regular, OD Cyl Quick: D	-.192	12	-1.873	.0856
OD Cyl Regular, OD Cyl Quick: E	.115	25	1.539	.1364
OD Cyl Regular, OD Cyl Quick: F	-.031	15	-.344	.7359
OD Cyl Regular, OD Cyl Quick: G	0.000	9	0.000	•
OD Cyl Regular, OD Cyl Quick: H	-.500	3	-.980	.3994

Paired t-test
Split By: Age
Hypothesized Difference = 0
Row exclusion: Mexico Data

	Mean Diff.	DF	t-Value	P-Value
OD Axis Regular, OD Axis Quick: Total	-6.758	90	-2.269	.0257
OD Axis Regular, OD Axis Quick: A	-6.167	5	-.753	.4852
OD Axis Regular, OD Axis Quick: B	-11.714	13	-1.364	.1957
OD Axis Regular, OD Axis Quick: C	-3.923	12	-.496	.6285
OD Axis Regular, OD Axis Quick: D	-.444	8	-.201	.8458
OD Axis Regular, OD Axis Quick: E	-4.045	21	-.762	.4548
OD Axis Regular, OD Axis Quick: F	-.231	12	-.033	.9739
OD Axis Regular, OD Axis Quick: G	-27.900	9	-1.892	.0911
OD Axis Regular, OD Axis Quick: H	3.000	3	.387	.7247