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The reliability of the Nikon Retinomax K-Plus

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THE RELIABILITY

OF THE

NIKON RETINOMAX K-PLUS

By

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Signature Page

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Bio-page

Nancy Ngo is a fun loving gal who enjoys the outdoors, travel, and nice people. She looks forward to an adventurous life in the near future. She hopes to see all that there is to see before she rests in peace.

Flete C. Newby received his undergraduate degree in zoology from Brigham Young University in 1994. After a year of odd jobs, he began optometry school at Pacific University where he plans to graduate in May of 1999. Immediate plans for the future include finding a job and a place to live. He hopes to remain in the southwest where he can participate in the many outdoor activities that he enjoys.

Abstract

The Nikon Retinomax K-Plus combines an autorefractor and an autokeratometer into a single handheld, portable unit. This study assesses both the repeatability and the interexaminer variability of the keratometric measurements taken by the Retinomax K-Plus. Six keratometric readings were taken on 75 subjects by two different examiners and compared using ANOVA analysis and a paired t-test. The results of the analysis showed no clinically significant difference between repeated measurements nor between examiners for either the horizontal or vertical powers. Axis measurements were also very repeatable with 89% of the subjects having a mean axis difference between 0° and 10°. The results of this study show the Nikon Retinomax K-Plus to be a very reliable instrument yielding consistent and repeatable measurements.

Reliability of the Nikon Retinomax K-Plus

INTRODUCTION

Keratometry is the measurement of the anterior curvatures of the cornea. The keratometer is primarily utilized for measuring corneal astigmatism used in determining refractive error and in contact lens fitting. Other uses include the evaluation of corneal integrity and tear film quality. The standard of care currently employs the use of the Bausch and Lomb Keratometer, which is not a portable unit. The use of a hand-held, portable keratometer would be advantageous for vision screenings away from the office, for examining bed-ridden patients, and for taking measurements in a busy practice where one instrument can be moved from room to room. The most recent addition to the portable unit market is the Nikon Retinomax K-Plus, which is a combination of the previously released Nikon Retinomax autorefractor with a new built in autokeratometer. While performance studies have been done on the Retinomax autorefractor, there are no published performance studies on this newest addition to the family of optometric high-tech equipment. This study assesses both the repeatability and the inter-examiner variability of the keratometric measurements taken by the Nikon Retinomax K-Plus.

While the Retinomax K-Plus is the newest of the autokeratometers, it was not the first. Alcon introduced the Renaissance Hand-held Keratometer in 1993 claiming accuracy comparable to traditional keratometers. Studies were performed to assess its accuracy and reliability as an autokeratometer by comparing it to the industry standard, the B&L Keratometer. In a study conducted with one-hundred adult subjects with cylinder greater than one diopter, Travis et al found a high correlation between measurements taken with the Renaissance Series Handheld Keratometer and the B&L Keratometer. In a study performed with sixty children between the ages of two and six, Anderson et al concluded that the Alcon Renaissance Series Keratometer was very repeatable with high a correlation between measurements. Additionally, separate studies done by Harvey and Lam concluded that the Alcon autokeratometer is an accurate and reliable instrument and useful for screening young children.

As noted earlier, the Nikon Retinomax K-Plus is both an autokeratometer and autorefractor. The keratometric component was simply added to the already well known

Nikon Retinomax autorefractor. A study conducted by Colby demonstrated that the portable Retinomax autorefractor was accurate and reliable when compared to the tablemounted Nikon NR-5500 autorefractor.

SUBJECTS

Keratometric measurements were taken on seventy-five subjects consisting primarily of optometry students. Subjects included both non-contact and contact lens wearers. No criteria based on the subjects' sex, age, or refractive error was used for determining participation. Subjects were, however, screened for any history of corneal trauma or corneal pathology. The subjects were given a brief explanation of the study and signed an informed consent before participating. The two examiners in the study were third year optometry students. Both examiners were trained to operate the instrument and allowed time to practice before beginning the experiment.

METHODS

Each subject had keratometric measurements taken on either the left or right eye. The subjects were asked to sit in the exam chair in a normal upright position keeping the head held straight with no tilt. The examiner was seated on the side corresponding to the eye being tested. The autokeratometer was held with the hand of the examiner's choice while his or her free hand was placed on the subject's forehead to steady the instrument. The examiner then aligned the instrument with the subject's eye using the target lines on the outside of the instrument. Finer alignment was achieved by looking through the instrument and centering the target mire over the subject's pupil.

With the autokeratometer properly aligned, the subjects were asked to look at the Christmas tree target in the center of a green field and to continue looking there throughout the measurement process. The examiner then pressed the Ready key to enter the instrument's measurement mode. To obtain a reading, the examiner moved the instrument in and out until the target mire or the circle of white dots was clearly focused. The instrument automatically took readings whenever it was in focus always keeping track of the last eight measurements taken. After eight or more readings were taken, the instrument was removed from in front of the subject and the average of the eight readings

printed. The instrument was then realigned with the subject's eye and the measuring process repeated. This procedure was performed three times by each examiner with each subject having been measured a total of six times.

RESULTS

The horizontal power measurements were divided into six groups for the purpose of analysis. Groups 1 to 3 contain the repeated measurements made by examiner one, and groups 4 to 6 contain the repeated measurements made by examiner two. For example, group 1 contains the first horizontal power measurement for each subject made by examiner one while groups 2 and 3 contain the second and third measurements. Each group of power measurements was then compared to the others using one factor ANOVA for repeated measures to determine if a significant difference existed between findings. The significance level was set at 90%. The only measurements that were significantly different from the others using the Scheffe F-test were the measurements of group 1 of examiner one when compared to groups 4, 5, and 6 of examiner two. While the difference was statistically significant, it was not, however, clinically significant. The statistical difference found was the result of the low standard deviations of each group. It should be noted that the largest mean difference between any of the six groups of power measurements was 0.083 D, a difference clinically insignificant. The results of the ANOVA analysis for the horizontal powers are shown in table 1.

Table 1 Horizontal Powers

Group	Mean Diff.	Scheffe F-test
1 vs. 2	0.038	0.845
1 vs. 3	0.041	1.004
1 vs. 4	0.061	2.204
1 vs. 5	0.080	3.819
1 vs. 6	0.083	4.162
2 vs. 3	0.003	0.007
2 vs. 4	0.023	0.320
2 vs. 5	0.042	1.071
2 vs. 6	0.046	1.257
3 vs. 4	0.020	0.233
3 vs. 5	0.039	0.907
3 vs. 6	0.042	1.078
4 vs. 5	0.019	0.220
4 vs. 6	0.023	0.309
5 vs. 6	0.004	0.007

The horizontal powers obtained by examiner one were also compared to those of examiner two using a Paired t-Test. This required obtaining an average of the three repeated power measurements for each subject. These averages were then divided into two groups - one set of averages for examiner one and one set for examiner two as shown in columns 6 and 23 of the data tables. The Paired t-Test showed no significant difference between examiners. The mean difference between the measurements of examiners one and two was 0.049 D with a correlation value at 0.998.

The vertical power measurements were also divided into groups and analyzed in the same manner as the horizontal powers using ANOVA for repeated measures. Analysis showed that none of the measurements differed significantly from the others when performing either an intraexaminer or interexaminer comparison. The Scheffe F-test was used again with the significance level set as 90%. The largest mean difference between any of the groups of power measurements was 0.041 D, a difference considered clinically insignificant. The results of the ANOVA analysis for the vertical powers are shown in table 2.

Table 2 - Vertical Powers

Group	Mean Diff.	Scheffe F-test
1 vs.2	0.004	0.005
1 vs. 3	0.006	0.016
1 vs. 4	0.018	0.125
1 vs. 5	0.037	0.533
1 vs. 6	0.017	0.112
2 vs. 3	0.010	0.038
2 vs. 4	0.022	0.178
2 vs. 5	0.041	0.638
2 vs. 6	0.021	0.163
3 vs. 4	0.012	0.051
3 vs. 5	0.031	0.365
3 vs. 6	0.011	0.043
4 vs. 5	0.019	0.142
4 vs. 6	0.001	0.124
5 vs. 6	0.020	0.156

The vertical powers of the two examiners were also compared to one another using the Paired t-Test in the same manner as the horizontal powers. The Paired t-Test showed no significant difference between examiners. The mean difference between the measurements of examiner one and two was 0.023 D with a correlation value at 0.996.

The axis measurements were analyzed by determining the mean difference in the axis readings of each subject. For the first examiner, 66% of the subjects had a mean axis difference between 0° and 5°, followed by 23% of the subjects with a difference between 5° and 10°, and 11% with a mean difference greater than 10°. It's important to note that as the amount of measured cylinder increased, the mean axis difference decreased. For cylinder powers between 0 and 0.50 D, the average difference was 9°. For cylinder powers between 0.50 and 1.00 D, the average axis difference was 4.7°, and for powers 1.00 D and greater, the average difference was only 2.5°. Similar results were also found with the readings taken by examiner 2. The results for both examiners are summarized in tables 3 and 4.

	Examiner 1	Examiner 2
Mean Axis Difference	% of subjects	% of subjects
0° to 5°	66 %	65 %
0° to 10°	23 %	24 %
> 10°	11 %	11 %

Table 3 showing that 89% of the subjects had a mean axis difference between 0° and 10°.

	Examiner 1	Examiner 2
Cylinder Power	Mean Axis Difference	Mean Axis Difference
0 to 0.50 D	9.0°	9.8°
0.51 to 1.00 D	4.7°	5.4°
> 1.00 D	2.5°	2.1°

Table 4 showing that the mean axis difference decreases as the cylinder power increases.

DISCUSSION

The results of this study suggest that the Nikon Retinomax K-Plus is a very repeatable instrument yielding consistent keratometric readings. The statistical analysis of the horizontal powers showed no clinically significant difference between repeated measurements. This was true for both the intraexaminer and interexaminer comparisons. The analysis of the vertical powers yielded the same favorable results.

The Retinomax K-Plus also proved to be very consistent when taking axis measurements. The analysis indicated that 89% of the subjects had a mean axis difference between 0° and 10°. This result alone is very impressive, but even more so is the fact that as the cylinder power increased, the mean axis difference decreased. For cylinder powers over a diopter, the mean axis difference was only 2.5°.

While this study has shown that the Retinomax K-Plus gives consistent, repeatable readings, it did not address the instrument's accuracy. A separate study comparing the K-Plus to the B&L Keratometer was conducted in conjunction with this study using much of the same data. For further evaluation of this instrument, we refer you to this study.

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DATA TABLES

DATA TABLES

15	16	17	18	19	20	21	22	23	24	25	26	27	28
[illegible]	[illegible]	Num. of Obs	[illegible]	[illegible]	[illegible]	[illegible]	EX 2 - H. power (3)	EX 2 Ave Hor Power	EX 2 - HP Mean Diff	EX 2 - V. power (1)	EX 2 - V. power (2)	EX 2 - V. power (3)	EX 2 - Ave Vert Power
[illegible]	2	0.04	1	H	41.75	41.67	41.75	41.71	0.09	42.25	42.37	42.37	42.33
[illegible]	3	0.12	2	L	44.00	44.00	44.00	44.00	0.00	44.25	44.25	44.12	44.21
[illegible]	4	0.37	3	H	42.83	43.13	43.00	42.91	0.33	43.12	43.25	43.37	43.25
[illegible]	5	0.04	4	L	47.00	46.87	47.00	46.96	0.09	46.75	46.75	46.62	46.71
[illegible]	7	0.05	5	H	43.13	43.00	43.12	43.08	0.08	43.87	44.00	43.87	43.91
81	8	0.07	6	H	42.38	42.25	42.25	42.33	0.17*	43.00	43.75	42.75	42.83
82	9	0.25	7	L	45.75	45.63	45.62	45.67	0.17	45.62	45.62	45.62	45.62
83	1	0.30	8	H	41.75	41.75	41.75	41.75	0.00	41.25	40.25	40.75	40.75
84	2	1.00	9	H	42.37	42.50	42.50	42.50	0.17	42.37	43.25	43.50	43.08
85	4	1.04	10	L	43.63	43.63	43.63	43.63	0.00	43.75	43.75	43.75	43.75
86	4	0.02	11	L	41.87	41.75	41.87	41.83	0.08	42.63	42.63	42.75	42.66
87	4	0.05	12	R	41.75	41.87	41.75	41.79	0.08	41.63	41.63	41.75	41.66
88	5	0.50	13	H	44.87	44.75	44.87	44.83	0.08	44.63	45.00	44.87	44.87
89	5	0.54	14	L	43.87	43.87	43.87	43.87	0.00	43.88	44.00	44.00	43.96
90	5	0.13	15	L	44.87	43.75	43.87	43.83	0.08	42.87	42.87	42.87	42.87
91	16	0.87	16	R	45.50	46.25	45.75	45.83	0.33	45.75	45.50	45.50	45.58
92	8	0.43	17	L	44.25	44.25	44.13	44.21	0.08	44.25	44.88	44.88	44.58
93	9	0.87	18	H	43.62	43.75	43.87	43.75	0.17	43.87	43.50	43.75	43.00
94	11	0.13	19	L	44.37	44.50	44.50	44.46	0.08	44.63	44.50	44.75	44.58
95	9	0.39	20	R	44.87	44.00	44.87	44.58	0.17	44.63	44.50	44.75	44.71
96	11	0.54	21	L	44.62	44.38	44.37	44.46	0.08	44.50	44.63	44.75	44.62
97	9	0.28	22	L	44.87	44.87	44.87	44.87	0.00	44.87	45.00	44.87	44.91
98	7	0.22	23	C	43.00	43.00	43.00	43.00	0.00	43.13	47.25	47.43	47.16
100	7	0.03	24	R	43.13	43.13	43.13	43.13	0.00	43.25	43.37	43.25	43.29
101	14	0.56	25	L	43.63	43.63	43.63	43.63	0.00	43.88	43.75	43.75	43.71
102	1	1.13	26	L	44.13	44.00	44.00	44.04	0.17	43.63	43.50	45.63	45.58
103	9	0.79	27	R	43.75	43.75	43.63	43.71	0.08	44.87	44.62	44.75	44.75
104	4	0.69	28	L	43.00	43.00	43.00	43.00	0.00	42.88	42.38	42.50	42.58
105	3	1.29	29	R	44.62	44.62	44.62	44.62	0.00	46.50	46.25	46.25	46.25
106	8	0.50	30	R	42.13	42.13	42.13	42.13	0.00	42.38	43.63	42.63	42.66
107	7	0.91	31	L	41.50	41.38	41.50	41.46	0.08	41.75	41.50	41.63	41.62
108	8	0.58	32	L	45.00	45.13	45.00	45.04	0.08	45.63	45.63	45.50	45.59
109	20	0.16	33	H	42.62	42.50	42.50	42.54	0.08	42.63	42.63	42.50	42.59
110	8	4.09	34	H	43.13	43.13	43.25	43.17	0.08	44.63	44.25	44.25	44.25
111	20	0.17	35	L	41.13	41.13	41.00	41.08	0.08	41.38	41.63	41.25	41.25
112	3	0.87	36	L	45.00	45.00	44.87	44.96	0.08	44.88	44.75	44.75	44.75
113	3	0.07	37	R	44.75	44.87	44.75	44.79	0.08	43.75	43.50	43.25	43.29
114	8	0.84	38	L	44.13	44.00	44.00	44.04	0.08	45.88	45.75	45.62	45.71
115	3	0.71	39	R	44.37	44.25	44.37	44.33	0.08	45.88	45.75	45.75	45.75
116	8	0.79	40	L	44.13	44.25	44.25	44.21	0.08	44.88	44.87	44.88	44.91
117	3	0.79	41	R	43.37	43.50	43.50	43.46	0.08	43.63	43.75	43.37	43.25
118	8	0.93	42	L	45.00	45.00	44.88	44.96	0.08	45.75	45.63	45.75	45.71
119	3	0.03	43	R	46.88	46.88	46.88	46.88	0.00	47.00	47.00	47.00	47.00
120	3	0.03	44	L	44.25	44.25	44.13	44.21	0.08	45.37	44.88	44.75	45.00
121	8	0.60	45	R	44.88	44.87	44.75	44.83	0.08	42.25	42.25	42.25	42.25
122	8	0.86	46	L	43.37	43.37	43.13	43.29	0.17	44.88	44.87	44.87	44.91
123	2	0.19	47	R	44.63	44.63	44.63	44.63	0.00	44.88	45.00	44.96	44.96
124	1	3.16	48	L	44.00	44.00	44.00	44.00	0.00	46.63	46.50	46.50	46.54
125	1	2.84	49	R	44.37	44.63	44.50	44.50	0.17	45.88	45.75	45.63	45.75
126	9	0.80	50	L	44.63	44.13	44.50	44.42	0.17	46.13	45.88	46.25	46.08
127	7	0.19	51	R	43.63	43.50	43.50	43.54	0.08	46.13	46.25	46.25	46.21
128	9	0.83	52	L	44.50	44.75	44.50	44.58	0.17	40.63	40.88	40.75	40.83
129	3	0.43	53	R	42.63	42.87	41.87	42.46	0.17	42.38	42.50	42.38	42.42
130	6	1.71	54	L	45.50	45.38	45.50	45.46	0.08	45.38	45.38	45.25	45.33
131	1	1.92	55	R	44.00	44.38	44.50	44.29	0.17	44.50	44.63	44.50	44.58
132	1	1.14	56	L	44.37	44.13	44.25	44.25	0.08	45.75	45.88	45.75	45.83
133	9	0.91	57	R	44.63	44.38	44.25	44.42	0.08	44.75	45.00	44.88	44.96
134	9	0.39	58	L	41.87	42.00	41.75	41.87	0.08	42.87	42.63	42.75	42.62
135	8	0.84	59	R	46.87	46.88	46.63	46.79	0.08	46.50	46.38	46.75	46.46
136	9	0.54	60	L	42.87	43.00	42.63	42.83	0.17	43.38	43.38	43.38	43.46
137	5	0.58	61	R	47.00	47.00	47.00	47.00	0.00	46.38	46.38	46.50	46.41
138	8	0.56	62	L	43.50	43.50	43.75	43.58	0.17	42.75	42.88	42.75	42.75
139	1	1.54	63	R	41.75	41.63	41.63	41.67	0.08	42.88	43.00	43.12	42.83
140	3	1.71	64	L	43.25	43.13	43.13	43.17	0.08	43.88	43.88	43.75	43.79
141	1	0.67	65	R	42.37	41.88	41.88	42.04	0.17	42.00	42.00	42.25	42.08
142	8	0.16	66	L	43.75	43.38	43.38	43.50	0.08	44.50	44.50	44.50	44.50
143	1	0.96	67	R	44.00	44.00	44.00	44.00	0.00	44.50	44.50	44.50	44.50
144	5	4.71	68	R	43.00	43.13	43.00	43.04	0.08	44.00	44.00	43.88	43.91
145	9	1.33	69	R	44.25	44.38	44.38	44.33	0.08	45.50	45.63	45.50	45.54
146	11	0.48	70	R	46.25	46.25	46.25	46.25	0.00	46.63	46.50	46.50	46.50
147	2	0.78	71	R	43.25	43.13	43.38	43.25	0.17	43.38	43.50	43.50	43.46
148	4	1.04	72	L	44.88	44.88	44.88	44.88	0.00	45.13	45.13	45.13	45.13
149	3	1.08	73	L	41.75	41.63	41.50	41.63	0.17	42.38	42.63	42.50	42.50
150	4	0.79	74	R	43.75	43.88	43.63	43.75	0.17	43.13	43.13	43.00	43.09
								43.93	0.08				44.20

DATA TABLES

30	31	32	33	34	35		36	37
EX 2 - VP Mean Diff	EX 2 - V. axis (1)	EX 2 - V. axis (2)	EX 2 -V. axis (3)	Axis Mean Diff.	Amt. of Cyl		EX1 AHP - EX2 AHP	EX1 AVP - EX2 AVP
0.08	100	111	99	8	0.62		0.04	0.04
0.09	145	143	135	7	0.21		0.00	0.09
0.17	90	99	100	7	0.33		0.21	0.17
0.09	73	77	75	3	0.25		0.08	0.04
0.09	72	73	78	6	0.83		0.08	0.08
0.17	78	86	81	5	0.50		0.08	0.04
0.00	80	71	76	6	0.75		0.00	0.00
0.00	95	97	93	3	0.54		0.13	0.09
0.75	81	82	85	2	0.58		0.08	0.33
0.00	90	87	88	2	1.17		0.04	0.17
0.09	87	100	88	9	0.83		0.12	0.04
0.09	94	87	99	8	0.33		0.08	0.04
0.17	101	129	89	27	0.33		0.21	0.04
0.09	57	51	56	4	0.54		0.00	0.00
0.00	79	81	84	3	1.04		0.00	0.09
0.17	68	62	58	7	0.33		0.00	0.04
0.08	114	112	117	3	0.37		0.04	0.00
0.17	69	63	75	8	0.75		0.13	0.00
0.17	128	151	90	41	0.13		0.04	0.00
0.09	131	121	127	7	0.79		0.08	0.08
0.17	71	77	67	7	0.42		0.04	0.12
0.09	73	77	77	3	0.42		0.17	0.04
0.09	97	96	97	1	2.16		0.17	0.08
0.08	103	112	113	7	0.21		0.12	0.08
0.09	83	87	87	3	0.46		0.08	0.04
0.08	103	103	102	1	1.08		0.04	0.09
0.17	90	86	87	3	1.37		0.08	0.08
0.08	75	81	78	4	0.62		0.09	0.04
0.00	81	81	83	1	1.55		0.08	0.04
0.09	87	81	95	9	0.50		0.04	0.04
0.17	87	90	83	5	0.62		0.25	0.17
0.33	97	74	92	15	0.67		0.04	0.04
0.17	34	78	83	33	0.17		0.04	0.04
0.00	72	73	75	2	1.09		0.04	0.04
0.00	110	114	127	21	0.17		0.13	0.17
0.00	74	70	76	4	0.41		0.04	0.00
0.08	71	74	73	2	1.58		0.09	0.00
0.09	84	77	83	5	1.67		0.00	0.16
0.00	76	71	69	5	0.58		0.04	0.09
0.09	83	90	86	5	0.71		0.13	0.04
0.17	108	109	111	2	0.79		0.13	0.13
0.09	88	85	84	3	0.71		0.00	0.08
0.00	93	101	95	5	0.83		0.05	0.05
0.41	84	82	78	4	0.87		0.21	0.25
0.00	93	83	94	7	0.50		0.08	0.04
0.09	88	84	88	2	1.67		0.04	0.09
0.75	61	61	62	1	0.38		0.04	0.04
0.08	82	85	85	2	3.58		0.04	0.04
0.17	105	108	103	3	1.42		0.17	0.04
0.25	90	80	87	7	0.67		0.04	0.08
0.09	115	115	112	2	0.67		0.08	0.17
0.08	107	90	89	12	0.21		0.12	0.08
0.41	78	61	74	11	0.38		0.29	0.25
0.08	84	83	88	1	1.79		0.08	0.04
0.08	72	72	74	1	1.96		0.04	0.00
0.17	75	74	75	1	1.50		0.12	0.08
0.25	74	75	74	1	0.79		0.04	0.04
0.33	85	93	100	10	0.71		0.04	0.16
0.09	46	55	52	6	0.54		0.00	0.00
0.09	78	84	78	4	0.67		0.13	0.00
0.09	68	66	83	11	0.67		0.12	0.17
0.00	74	74	63	7	0.58		0.04	0.00
0.58	88	91	86	5	1.12		0.04	0.38
0.08	98	98	97	1	1.63		0.12	0.04
0.17	79	82	82	2	0.67		0.08	0.08
0.17	88	83	83	3	2.08		0.04	0.12
0.00	92	97	93	3	0.54		0.00	0.04
0.09	111	106	110	3	0.87		0.04	0.21
0.08	72	79	75	5	1.37		0.04	0.00
0.17	111	106	106	3	0.25		0.09	0.08
0.09	83	82	83	8	0.58		0.25	0.04
0.00	89	87	87	1	1.08		0.04	0.08
0.17	82	79	81	2	1.12		0.12	0.08
0.09	87	88	77	7	0.38		0.04	0.08
0.13								