Comparison of Simulated K's as measured by the B&L Keratometer to the EyeSys Corneal Analysis System and the Alcon Hand-Held Keratometer.

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INTRODUCTION

Reliance on the reproducibility of corneal measurements is very important to the success and satisfaction patients experience with their eye care providers. The procedures most reliant upon corneal measurements include the fitting of rigid gas permeable lenses and surgical alteration of the cornea to correct refractive errors. Several systems are available to assist in the measurement of corneal curvature. The standard is the keratometer, but as we have become more technologically advanced, sophisticated computerized videokeratographers (CVK's) have made their way onto the market and into the office of practicing optometrists and ophthalmologists. Companies who manufacture and market CVK's claim they provide more information, are more reliable and give more accurate measurements of toric surfaces than the standard keratometer.

The commonly used manual keratometer observes the first Purkinje image reflected from the cornea and relates the size of the corneal reflections from a collimated source to the cornea's radius of curvature.[1] It assumes a spherocylindrical shape and measures the image at two or four points around a circle that is 2.8 to 4.0 mm in diameter depending on the corneal power.[1-3] The portable hand held Alcon keratometer interprets corneal curvature by interpreting the distance between reflected images of a projected beam onto the cornea. The distance between images is converted into steepest and flattest images using vergence relationships.[4] The EyeSys system, as with most other CVK's, measures corneal curvature by reflecting a Placido disk onto the cornea. Distortions in the rings that are reflected from the corneal surface are analyzed using algorithms that are based on tested calibration spheres and maintained in look-up tables within the computer's memory.[3-6]

In this study we compare the measurements of three PMMA toric lenses of known toricity and ten human corneal surfaces using the manual B&L keratometer, Alcon hand-held keratometer and the EyeSys II system. With this data we have attempted to see if there are any significant differences between measurements taken by the manual keratometer, which is our standard instrument for comparison, versus the Alcon and the EyeSys units.

METHODS

Three front toric, spherical back surface PMMA lenses were ordered from Art Optical Laboratories. The mean front surface toricities (of three measurements) were measured with a B&L keratometer, an Alcon hand-held keratometer and an EyeSys II corneal analysis system at the Michigan College of Optometry at Ferris State University in Big Rapids, Michigan.

All instruments were calibrated according to the manufacturers directions. The mean measurements from the B&L keratometer were as follows:

(1) 9.13 / 8.27 mm (equivalent to a 36.95 / 49.79 D cornea), or 3.84 D toricity, (2) 8.77 / 8.29 mm (equivalent to a 38.48 / 40.71 D cornea), or 2.23 D toricity and (3) 8.54 / 8.31 mm (equivalent to a 39.52 / 40.63 D cornea), or 1.11 D toricity.

When measuring the lenses with the EyeSys II system, the buttons were mounted on the 42.51 D steel test surface of the calibration device using a drop of water to hold it in place. They were then placed in front of the machine and measured three times. Measurements that were not well focused, well centered, and/or containing a good "bow-tie" pattern were not considered as one of the three readings. The mean was calculated and statistically compared to the B&L keratometer results.

When measuring the buttons with the Alcon hand-held keratometer, the lenses were floated in saline to minimize back surface reflections. Again, three readings were taken, the mean calculated, and then statistically compared to the B&L keratometer values.

Ten patient eyes (with verbal informed consent) were analyzed on the same three instruments as the PMMA button lenses. In order for a patient to qualify for the study, the toricity as measured with the B&L keratometer had to be $\geq$ 0.75 D. Just as with the toric button lenses, three measurements were taken, the mean calculated and statistically compared to the B&L keratometer results. The purpose of including human corneas was to evaluate if similar results of the consistency among the keratometers could be correlated between a known toric surface (PMMA buttons) and a toric surface in which there are several unknown variables involved (human corneas).

RESULTS

Charts 1-3 show the mean amount of toricity in diopters of the three manufactured button lenses as determined by the three different instruments. Similarly, chart 4 shows the comparative mean amounts of toricity in diopters of the ten patient eyes. Table 1 shows the statistically significant differences between the B&L keratometer (referred to as the standard instrument) and the remaining two instruments by applying the 95% confidence interval (using the 97.5 percentile of the Student's t distribution). In order to increase the degrees of freedom for statistical purposes, all data was used twice (as if three more trials were recorded and the same results obtained). This, of course, assumes the initial data is an accurate representation of the normal distribution. Table 2 similarly shows the statistical significance of the ten human corneas by applying the same statistical method as was used with the button lenses.

Chart 1

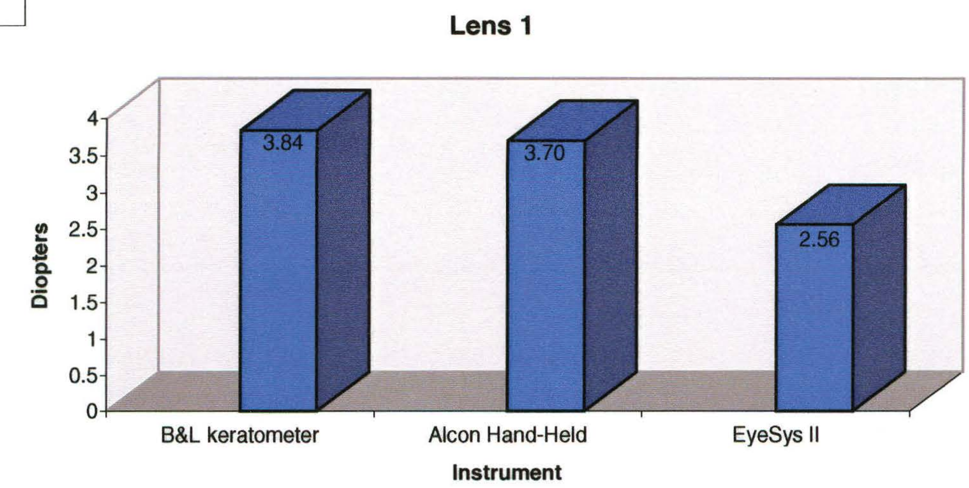


Chart 2

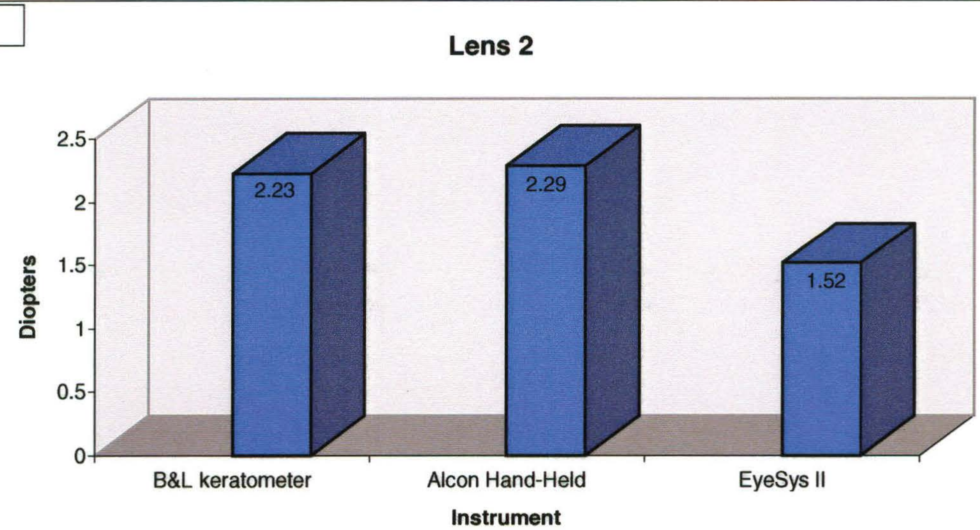


Chart 3

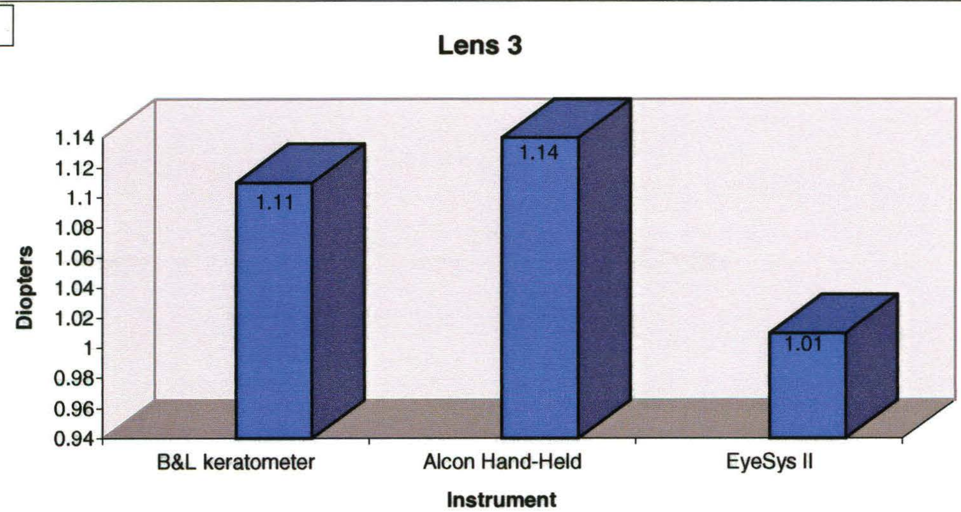
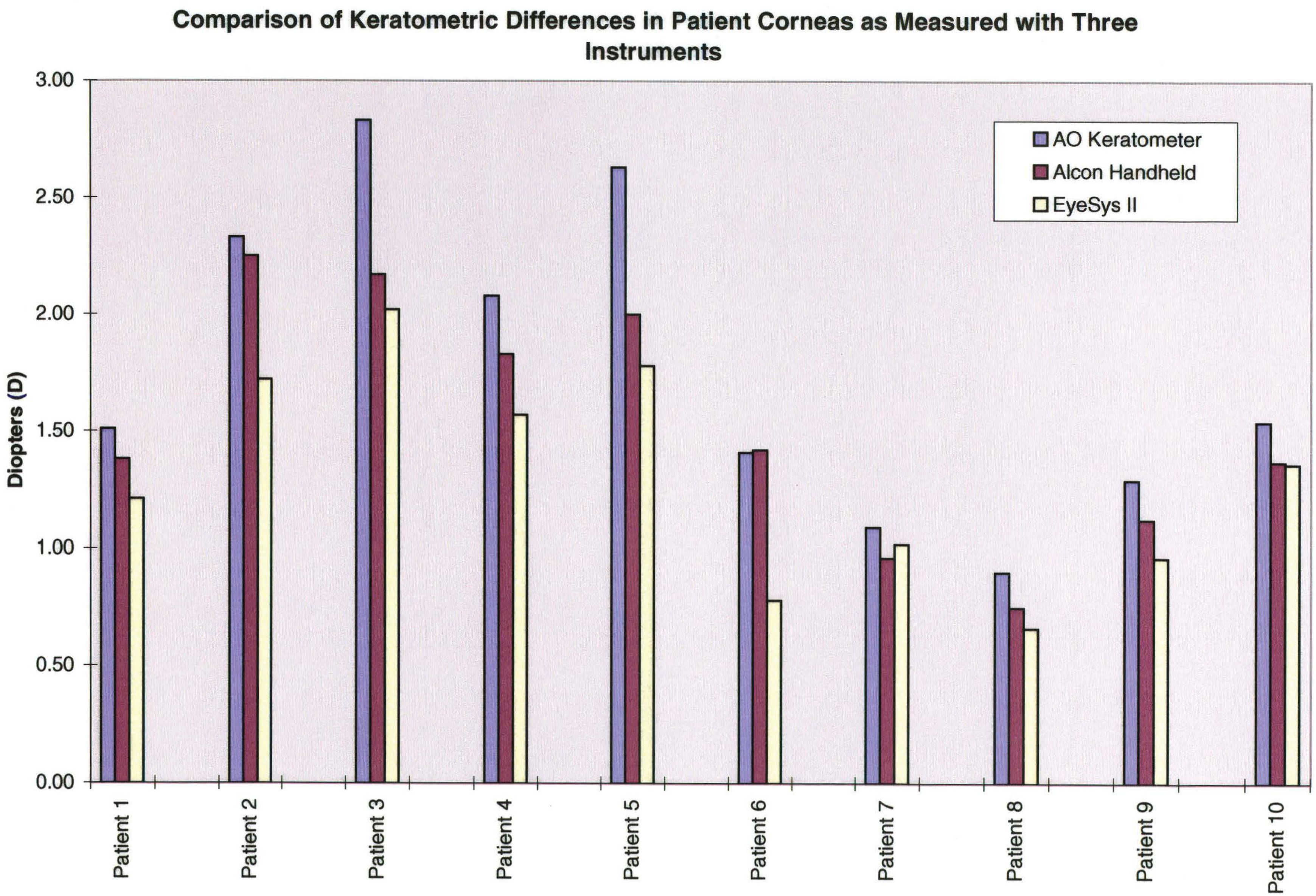


Chart 4



Comparison of Keratometric Differences in Patient Corneas as Measured with Three Instruments
3.00
2.50
2.00
1.50
1.00
0.50
0.00
Diopters (D)
AO Keratometer
Alcon Handheld
EyeSys II
Patient 1
Patient 2
Patient 3
Patient 4
Patient 5
Patient 6
Patient 7
Patient 8
Patient 9
Patient 10

Table 1: Comparison of the Statistical Significance of the Ten Patient Corneas to the B&L Keratometer.

	Alcon Handheld	EyeSys II
Patient 1	NO	YES
Patient 2	NO	YES
Patient 3	YES	YES
Patient 4	NO	YES
Patient 5	YES	YES
Patient 6	NO	YES
Patient 7	NO	NO
Patient 8	NO	YES
Patient 9	NO	YES
Patient 10	NO	NO

NO indicates that there is no statistical significance between the two instruments.
YES indicates that there exists a statistical significance between the two instruments.

Table 2: Comparison of the Statistical Significance of the Toric Button Lenses to the B&L Keratometer.

	Alcon Handheld	EyeSys II
Lens 1	NO	YES
Lens 2	NO	YES
Lens 3	NO	YES

NO indicates that there is no statistical significance between the two instruments.
YES indicates that there exists a statistical significance between the two instruments.

SUMMARY

There was no significant difference in measurements of the three PMMA toric buttons when comparing the B&L keratometer to the Alcon hand-held keratometer whereas the measurements from the EyeSys II system differed significantly from the B&L keratometer. In all cases the EyeSys II system gave the lowest toric readings. In comparing the ten human corneas as measured by the three devices, the Alcon hand-held keratometer gave readings that were not significantly different from the B&L keratometer for eight of the ten corneas, thus showing statistically significant differences in measurements of only 20% of the corneas. On the other hand, when comparing the human corneas the EyeSys II system produced statistically significant readings from the keratometer 80% of the time (eight of the ten corneas), leaving only two of the corneas to show readings that did not vary significantly from the B&L keratometer. A previous study showed the greatest deviation in toric measurements to be between the keratometer and the EyeSys system as opposed to other CVK's, with the EyeSys system giving significantly lower readings than the other techniques.[6,7] Another investigator found a significant difference between corneal cylinder measured with a manual keratometer and one CVK (EyeSys) but not another (TMS-1).[5] Although the EyeSys system appears to have consistently shown significantly lower readings than the B&L keratometer in several studies it does maintain fairly consistent readings within itself even when slightly misaligned or decentered by less than 1 mm.[3,8] The Alcon hand-held keratometer has not been studied extensively but one study found it to be reliable and effective in reproducing measurements of corneal curvature.[4]

Keratometry has long been the standard method of obtaining corneal curvature for fitting rigid gas permeable lenses. According to this and several studies this need not change.[2,4,7] Measurements with this instrument are more reproducible than many other devices when taken by the same person.[2] Several studies have shown significant differences in measurements of the same test subject when different clinicians take readings with the keratometer.[2,6,9] This is probably because there is a higher degree of variable interpretation among clinicians with respect to the vernier alignment of the reticles seen reflected off the cornea. The test surface seems to make some difference in certain studies too. Binder[3] and coworkers found keratometer readings to be much more reproducible for test spheres than actual live human corneas when the same individual does the testing as opposed to multiple observer testing. The small area assessed by the keratometer is assumed to be spherocylindrical and accurately evaluates the power of the cornea.[2] When this is the case the mires are not distorted. Even though the cornea in its entirety is aspheric we assume the central portion is not. Keratometry has remained the mainstay for contact lens fittings due to the awareness that keratometric readings in a small region of any surface closely approximates a toric surface. This is clinically valid for the small central region of the cornea considered in contact lens fitting and thus continues to be widely used.[3]

Areas where the keratometer is less than ideal for corneal evaluation are in the early detection of keratoconus and in amassing data for refractive surgery.[5] CVK's have gained broad acceptance and are heavily relied upon especially by ophthalmologic practitioners because they provide an assessment of a much greater area of the cornea. This is essential in preparing for refractive surgery because CVK's can quantitatively assess an irregular cornea where a manual keratometer cannot. Surgeons must be aware of the limitations of CVK's. One such limitation is that their repeatability is worse toward the periphery.[1] The underestimation of corneal curvature seems to be the most troublesome to clinicians who attempt to fit contact lenses from the data obtained by CVK's. Certain autokeratometers have the most difficulty assessing low or no cylinder powers.[3] These problems may stem from the computer's algorithms which are programmed to assign a single radius of curvature to a large surface that is actually the equivalent of several different radii of curvatures that progressively flatten towards the periphery. This makes most CVK's useless for fitting contact lenses but if only the central region equivalent to approximately 3 mm as with the manual keratometer were considered the corneal curvature may be a better representation of that required to successfully fit contact lenses. Of course some CVK's offer programs specifically designed for fitting contact lenses, whether they work or not was not within the scope of this study.

Limitations of this study consist of the obvious lack of abundant data which is essential in providing a truly random distribution of readings for statistical analysis. This can be achieved by having more time with each subject and taking more readings. More subjects would also increase the reliability of this study. Broadening the study by adding a temporal component to judge if measurements vary over time would provide information on the repeatability of measurements taken on different occasions. Using different operators to assess the variation in measurements is also of benefit when deciding how much reliability should be placed on any one operator's findings. Other limitations include focusing and alignment errors which although carefully watched for may have caused some inaccurate readings. Expanding this study to include several observers taking data over time would provide beneficial data pertaining to both repeatability and interobserver reliability and is a possible next step.

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