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# Clinical comparison of the Bausch & Lomb keratometer to the Alcon Renaissance series handheld keratometer

## Abstract

The newly introduced Renaissance Handheld keratometer from Alcon was compared for accuracy and ease of use with the B&L keratometer. Keratometer readings were obtained from 200 eyes (100 subjects), as well as 4 steel balls and a contactometer. A high correlation between the two instruments was found on patients with clinically significant cylinder ( $>1.0D$ ), with respect to both power and axis determination. A significant difference was found between the two instruments for both axis and power.

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## Committee Chair

Paul Kohl

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keratometry, keratometer, ophthalmometry, automated keratometry, renaissance series, astigmatism

## Subject Categories

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CLINICAL COMPARISON OF THE  
BAUSCH & LOMB KERATOMETER  
TO THE  
ALCON RENAISSANCE SERIES  
HANDHELD KERATOMETER

BY

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A thesis submitted to the faculty of the  
College of Optometry  
Pacific University  
Forest Grove, Oregon  
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Doctor of Optometry  
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**Abstract**

The newly introduced Renaissance Handheld keratometer from Alcon was compared for accuracy and ease of use with the B&L keratometer. Keratometer readings were obtained from 200 eyes (100 subjects), as well as 4 steel balls and a contactometer. A high correlation between the two instruments was found on patients with clinically significant cylinder ( $>1.0D$ ), with respect to both power and axis determination. A significant difference was found between the two instruments for both axis and power.

**Key Words**

Keratometry, keratometer, ophthalmometry, automated keratometry, Renaissance Series, astigmatism

## Introduction

Accurate and reliable keratometer measurements of the anterior corneal surface are essential components of every first time vision examination, contact lens fitting, optical and surgical correction of astigmatism, refractive surgery, and intraocular lens power determination<sup>1</sup>. Hence there exists a need for accurate and reliable keratometric measurements.

Mention the word "keratometry", and we all think of the Bausch & Lomb keratometer (Rochester, NY). Not only has it been considered the standard in optometric practices since its introduction in the 1940's, it has generally been the standard to which other keratometers are compared to when evaluating them for accuracy<sup>2</sup>.

In what some consider a landmark study on the reliability of the keratometer, Brungardt randomly measured three steel balls on 11 different sessions over a 30-day period and found that a single reading could be in error by .37D due to operator and/or instrument<sup>3</sup>. In a second experiment, Brungardt used a human subject on which keratometer readings were made on each eye immediately following the first experiment, on each of the 11 sessions and one extra session. He found that the total range that any one reading may be in error in the vertical meridian was .75D, and the range for the horizontal meridian was limited to .37D. Lusby et al., compared the Humphrey Auto Keratometer to the B&L keratometer on 497 eyes prior to cataract surgery, the automated keratometers consistently measured both the steeper and flatter meridians steeper than the B&L,(steeper:-0.26± 0.12D steeper than the B&L; flatter: -0.01±0.68D steeper than the B&L).<sup>2</sup> In a study by Hannush et al., the B&L keratometer, Kera Corneascope, and the Computed Anatomy Corneal Modeling system, were evaluated for accuracy and precision. They found no statistically significant difference between the B&L keratometer and the Corneal Modeling System with respect to accuracy or precision and that these two instruments were more accurate than the Corneascope<sup>4</sup>. Hannush et al., also found that when measuring four calibrated steel balls, the B&L keratometer generally produced lower values and the Corneal Modeling System generally produced higher values than the calibrated value.

With it's recent introduction of the Renaissance Handheld keratometer, Alcon claims that it's accuracy is comparable to traditional keratometers but with greater flexibility. We

felt that if this were the case, the general practitioner could stand to benefit from such an instrument.

In keeping with tradition, a clinical comparison of the accuracy, reliability, and ease of use of the newly introduced Alcon Renaissance Series Handheld Keratometer (St. Louis, MO) as compared to the B&L keratometer, is undertaken here.

If the Alcon Handheld Keratometer is determined to be user friendly and produces accurate measurements, it would not only be useful to the general practitioner, but also to the practitioner who cares for special patients who have, in the past, proven to be a challenge. Such patients include the pediatric and physically disabled populations. It would also provide a handheld instrument that can be easily used in the surgical suite.

### *The B&L*

The B&L keratometer uses a measuring system in which a light beam is reflected off the cornea and passes through four apertures. The left and right apertures use horizontal and vertical prisms respectively to deviate the light beam. The light beam passes through the upper and lower apertures undeviated, and allows the operator to focus the instrument by creating a Scheiner disc. The light reflection off the patient's cornea will be seen singly when in focus, and double when out of focus. Focusing is achieved by turning the focusing knob until the mires are seen singly. Once the instrument is in focus, cylinder axis is determined by rotating the barrel of the instrument to align the horizontal limbs. At this point, the base-apex lines of the prisms will be aligned with the principle meridians of the cornea. Powers of the principle meridians are determined by aligning the plus signs for the horizontal and the minus signs for the vertical. Measurements are dynamically refined until the appropriate endpoint is reached. Corneal topography and tear film stability can be assessed by inspecting the mire reflection for any distortion, waviness, doubling, or missing parts.<sup>6</sup>

### *Alcon Handheld Keratometer*

The Alcon handheld keratometer uses four projectors positioned behind the projection window around the central aperture of the instrument. These projectors shine a pattern of eight green lights onto the cornea. The lights are used by the operator to determine if he/she is holding the keratometer at a proper distance from the patient's cornea. Fixation



is maintained by a red light that projects along the optic axis and onto the center of the cornea. Proper positioning and alignment are indicated when the operator sees the eight green lights form an "X" with the fixation light in the center of the cornea. Upon proper alignment, a measurement is automatically taken, computed and displayed in the display window of the instrument. Care must be taken to maintain head and instrument verticality since no head rest is used. The Alcon keratometer has the capability of calculating the cylinder in plus or minus cylinder form while in the sphere/cylinder setting or the base curve in diopters and millimeters while in the base curve setting. In addition, it can produce a hard copy of the results and the data can be downloaded into IVY System Medical Records. A ring of green lights along the edge of the projection window is used to analyze the topography of the cornea.<sup>7</sup>

## **Subjects and Methods**

### **Subjects**

The 100 subjects (200 eyes) were Pacific University College of Optometry students and faculty and also friends and family of the students (mean age 27; SD 7; range 4-55; 58 males and 42 females). Individuals currently wearing rigid contact lenses were screened from this study. Of the 100 subjects that did participate, none had any corneal diseases. Prior to participation, a brief explanation of the study was presented to each subject and informed consent was obtained.

### **Methods**

Before subject examinations were performed, the B&L keratometer and the Alcon autokeratometer were used to measure spherical surfaces of known values to ensure reliability when comparing the measurements from the two instruments. Both instruments were used to measure the radii of four steel balls and a contactometer. Three measurements were obtained from each surface by each instrument. Conversion from sphere radius to diopters was made using the formula  $D = 0.3375/R$  (where  $D$  = diopters, and  $R$  = radius of sphere) for both instruments. Averages of these readings were calculated and compared against the true values of the spheres.

The examiners involved in the study consisted of two third year optometry interns and one second year optometry intern. All examiners were trained and allowed adequate time

to practice using the instruments thus being able to obtain measurements accurately and efficiently throughout examination of subjects.

Approximately equal time was allocated to each of the examiners in operating each of the keratometers. To begin, the subjects were seated at one of the two keratometer locations where three measurements were taken from each eye before they moved to the second instrument location. Three measurements per eye from each instrument (12 total measurements) were obtained. Examiners rotated from one instrument to the other and then served as the recorder at the B&L keratometer location.

At the B&L keratometer station, examiner bias was eliminated by placing wide rubber bands around each power drum scale so as to conceal the power readings from the operating examiner. A second examiner (the recorder) was responsible for recording power and axis measurements, returning the power drums to a different starting position, and shifting axis adjustment to a different starting position before each subsequent measurement. Since measurements obtained by the Alcon autokeratometer are not dependent upon manual manipulations by the operator, bias was not a concern.

Upon completion of obtaining 12 measurements, subject data was entered onto a computer spreadsheet in preparation for statistical analysis.

## **Results**

For each eye, the means of the three vertical and horizontal power measurements and the axes were calculated for the B&L and Alcon keratometers. A paired t-test and simple regression were performed to determine the relationship of the measurements between the two instruments.

The accuracy of measurements taken on the known spheres are displayed in scattergram form as Figure 1. Simple regression analysis produced correlation coefficients (R) of 1.0 and standard errors of .013 mm and .014 mm for the vertical and horizontal powers respectively. A paired t-test analysis indicated no significant difference at  $p < .05$  between Alcon and B&L readings for both meridians on the known test spheres.

Using the same statistical analyses as used for the known spheres, data from the subjects produced correlation coefficients (R) of .987 and .987 and standard errors of .25 diopters and .245 diopters for the vertical and horizontal powers, respectively. See Figures 2 and

3. A paired t-test indicated significant differences between Alcon and B&L findings for both vertical and horizontal powers at the .05 level. The actual mean differences between the two instruments were .326 diopters in the vertical meridian and .151 diopters in the horizontal meridian. A frequency histogram for dioptric differences between instruments for both vertical and horizontal meridians is presented in Fig. 4. As can be seen for both vertical and horizontal meridians most differences were less than .5 diopters.

A problem arose with the method used to analyze the horizontal axis data, for axes between 1 and 45 degrees. Although there is only a 1 degree difference between cylinder axes of 1 and 180 degrees, there would appear to be a 179 degree difference when analyzed by standard techniques. A modified version of the technique first employed by Tate et al.<sup>8</sup> was used to account for this problem. The technique used is such that 180 is added to all horizontal axes from 1 to 44, inclusive. This adjustment allowed us to reference all horizontal axes to the 180th meridian, therefore, some of our axes appear to be greater than 180 degrees.

When the cylinder axes of all the subjects were analyzed, a poor correlation between Alcon and B&L axes was found for both vertical and horizontal meridians,  $R = .428$  for vertical and  $R = .425$  for horizontal. A re-analysis of axis data for only clinically significant amounts of cylinder (1.00 diopter or greater) was also performed. The regression analysis of this data proved quite favorable. Correlation coefficients ( $R$ ) of .874 and .871 and standard errors of 5.827 degrees and 5.899 degrees were found for the vertical and horizontal axes respectively. (See Figs. 5 & 6) Using a paired t-test, no statistically significant difference was found at  $p < .05$  between the two keratometers for both meridians. A frequency histogram for difference in axis (for cylinder  $\geq 1.0$  D) between instruments is illustrated in Fig. 7. As can be seen almost 88% of the axis differences are less than 10 degrees.

### **Discussion**

The results of this study suggest that the Alcon Renaissance Series Keratometer is an extremely accurate instrument and compares well to the B&L keratometer. The correlation coefficients ( $R$ ) of .987 and .984 for power measurements and .874 and .871 values for axes measurements for cylinder powers  $\geq 1.00$  diopter are higher than the .888 and .847 values for power and .741 and .821 for axes measurements found by Tate et al.,<sup>8</sup> in their comparison study between various autokeratometers..

A potential problem of this new keratometer, illustrated by the findings, was the poor correlation for axis between the instruments for cylinder powers less than 1.00 diopter. In examining data found by Sunderajj,<sup>1</sup> it was also shown that axes variabilities were a problem with other automated instruments. He found that 65% to 75% of cases fell within 11 degrees of the manually operated instrument. Using cylinder values of 1.00 diopter or greater, the Alcon handheld keratometer findings showed that 87.5% of cases were within 10 degrees of manually determined values. When using all cylinder values 69.5% fell within 10 degrees of each other (See Fig. 8) and 75% fell within 11 degrees of each other.

Possible causes for axis disparity would include the dynamic refinement required by the examiner while focusing and aligning the indicators of the manual instrument until the appropriate end point is reached. With the Alcon keratometer, readings are "instantaneous" and may be influenced by variations in instrument position and alignment as well as patient position and movement. The vertical alignment for this instrument is most crucial. Alcon may want to consider a mechanism that would provide feedback to the examiner as to the vertical position of the instrument upon operation. A possible mechanism suggested by one examiner involved in the study included a leveling bubble such as one utilized in a carpenter level. It could be placed somewhere within the field of the examiner as they look into the instrument while taking measurements. In this way, vertical alignment could be obtained before engaging the instrument. It must be pointed out that any handheld instrument will be more difficult for the examiner to maintain proper alignment. The examiners involved in this study do not feel this is a big enough problem to justify not using the instrument.

The price of the Alcon keratometer may be a deterrence for some practitioners. Retail purchase price of the Alcon keratometer is \$5995.00<sup>b</sup> (Alcon System, Inc., Aug 1993). The retail purchase price for a B&L keratometer varies due to the ability to purchase it through a number of different distributors. A new B&L can be purchased for approximately \$1800.00 and a previously owned keratometer can be purchased for substantially less. Whether or not keratometry measurements are important enough to justify this expense is left to the individual practitioner.

Other studies should be done with the Alcon keratometer before making an all inclusive statement regarding the instrument. Such studies would include an actual timed study to determine how much time is saved by using the Alcon keratometer as opposed to the

traditional manual keratometer. Although the examiners in this study feel that readings are obtained in significantly less time, a timed study is in order. Studies using specific populations, such as pediatrics, geriatrics, contact lens patients, and physically impaired individuals, are needed to conclusively determine the ease of use of the instrument with these groups.

It is the authors opinion that such studies will show that keratometry can be an easier to perform test than is presently done on these special populations. The use of a handheld device, such as the Alcon, will facilitate testing for the physically impaired, geriatric and pediatric patient who may have difficulty maintaining alignment in a standard keratometer.

In this preliminary study of the Alcon Renaissance Series Handheld Keratometer, the instrument proved to be extremely easy to use and very accurate in a "normal" population. All three examiners liked it because the patient does not have to be seated and adjusted in the examination chair, thus reducing the amount of time spent taking the readings. Other features that were liked included it's lightweight, cordless, ease of handling as well as being able to easily transfer it from one exam room to another. If a practitioner determines that the expense of an automated keratometer is justified, the Alcon Renaissance Series Handheld Keratometer would be a viable, reliable instrument.

## **Acknowledgements**

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## Footnotes

- a. Alcon Systems, Inc., 4221 Forest Park Blvd., St. Louis, MO 63108-2810, 800-289-1991. The Alcon Renaissance Series Handheld Keratometer used for this study was obtained in February 1993.
- b. Personal Communication, Alcon Systems, Inc. August 1993.

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8. Tate GW, Safir A, Mills CZ, et al. Accuracy and Reproducibility of Keratometer Readings. *CLAO Journal*. Jan. 1987. Vol 13, No. 1:50-58.



Fig.1 COMPARISON OF RADIUS OF CURVATURE OF KNOWN SPHERES BY ALCON AND B & L KERATOMETERS

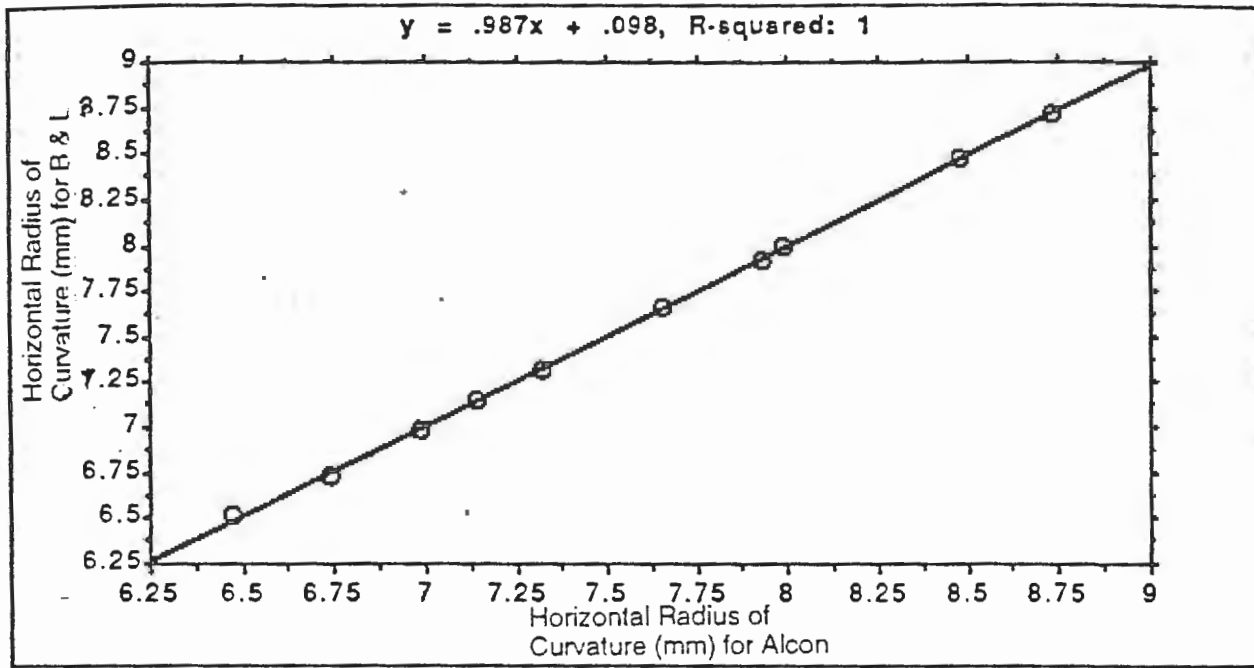


Fig. 2 COMPARISON OF SUBJECTS CORNEAL VERTICAL POWER FOR ALCON AND B & L KERATOMETERS. (n = 200)

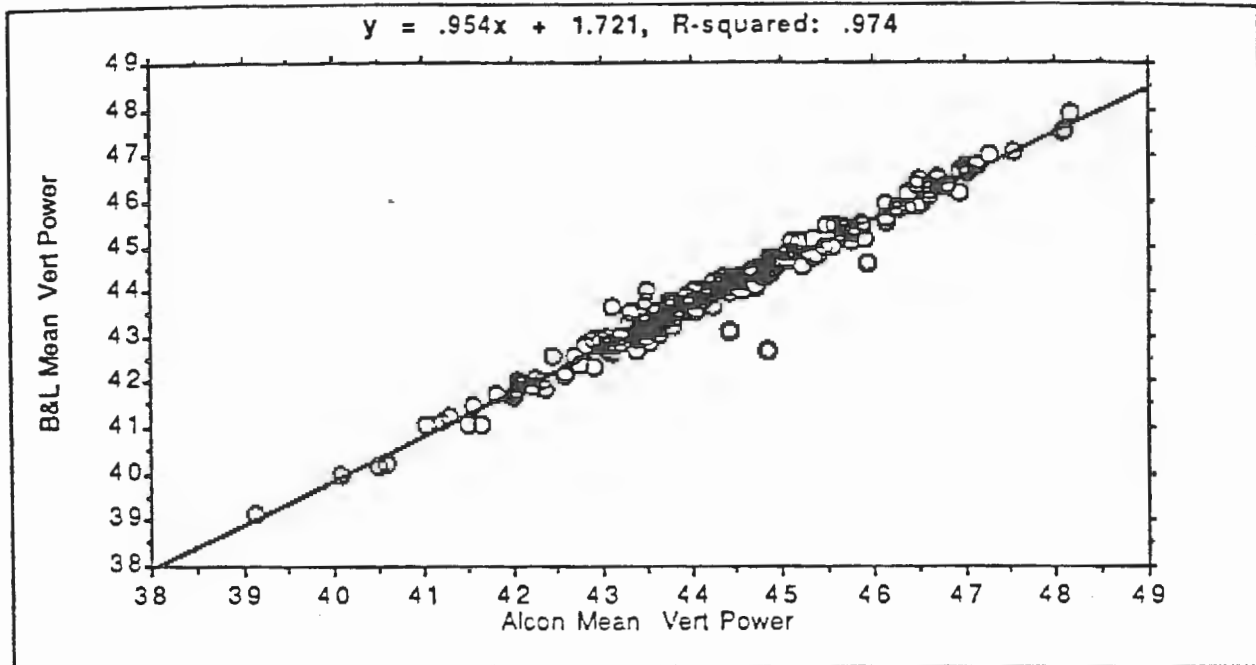


Fig. 3 COMPARISON OF SUBJECTS CORNEAL HORIZONTAL POWER FOR ALCON AND B & L KERATOMETERS. (n = 200)

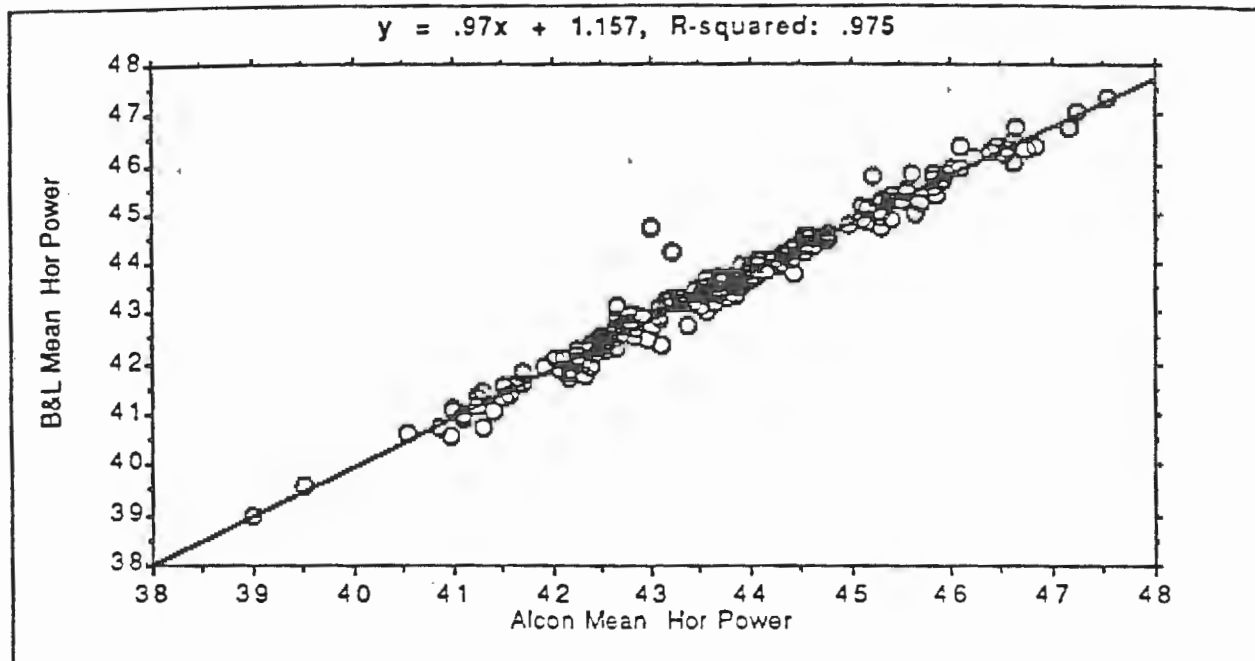


Fig. 4 POWER DIFFERENCES BETWEEN INSTRUMENTS  
(n = 200)

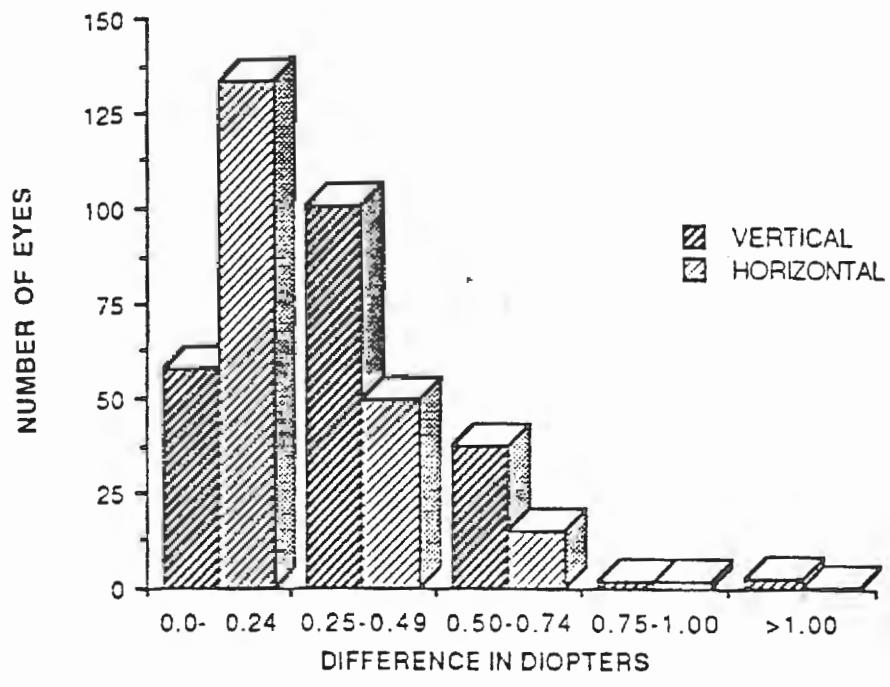


Fig. 5 COMPARISON OF SUBJECTS CORNEAL VERTICAL CYLINDER AXIS FOR ALCON AND B & L KERATOMETERS FOR CYLINDER POWERS  $\geq 1.00$  D. (n = 80)

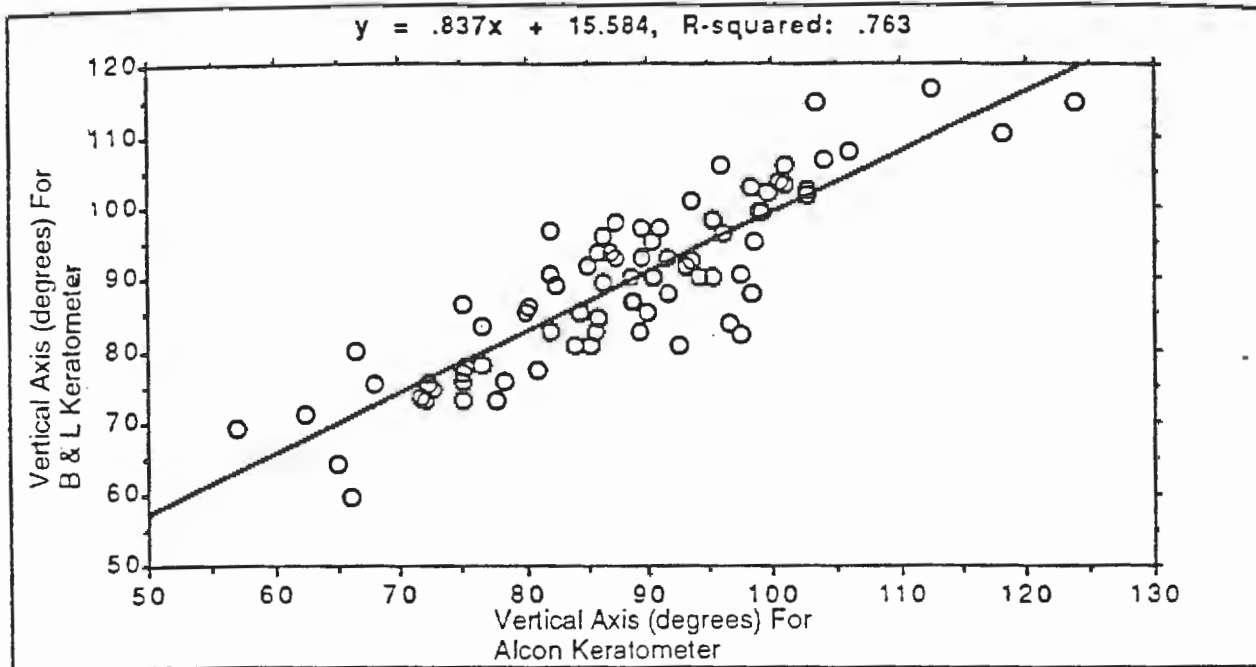


Fig. 6 COMPARISON OF SUBJECTS CORNEAL HORIZONTAL CYLINDER AXIS FOR ALCON AND B & L KERATOMETERS FOR CYLINDER POWERS  $\geq 1.00$  D. (n = 80)

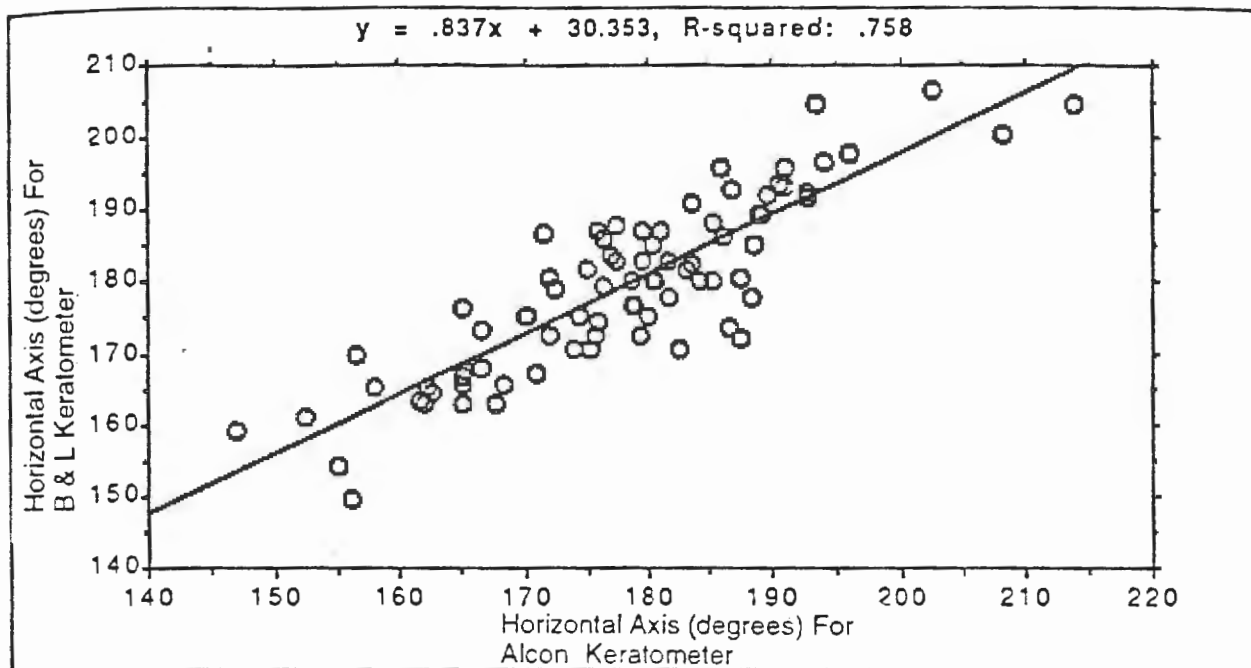


Fig. 7 DIFFERENCES IN AXES BETWEEN INSTRUMENTS FOR CYLINDER  
POWER  $\geq 1.0$  D. (n=80)

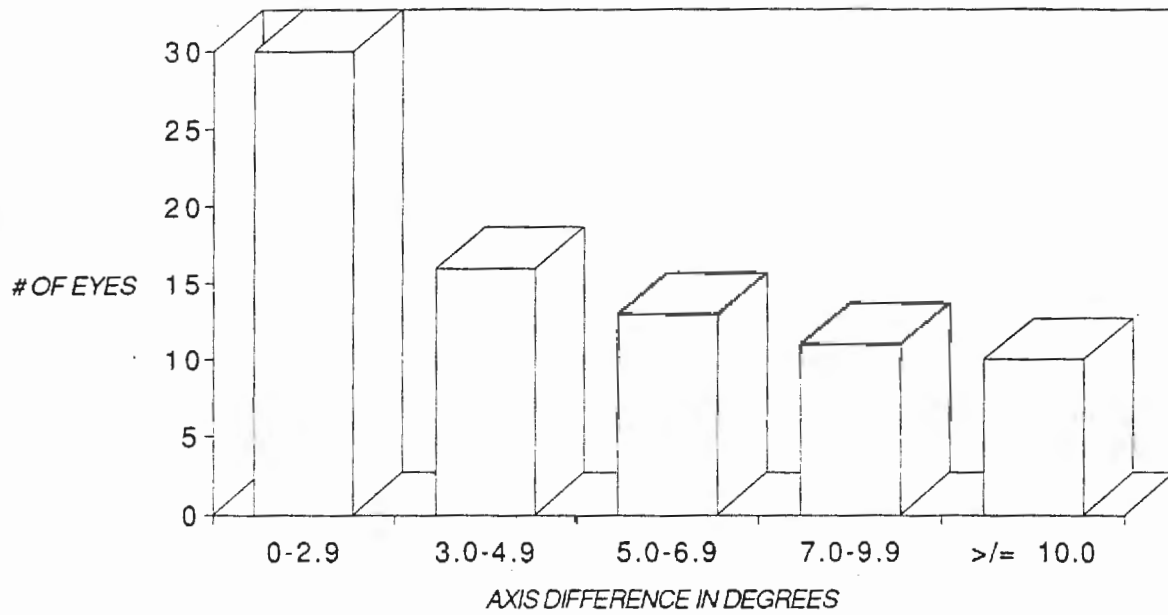


Fig. 8 DIFFERENCES IN AXES BETWEEN INSTRUMENTS FOR ALL CYLINDER POWERS. (n=200)

