An evaluation of the usefulness and reliability of the Alcon Renaissance handheld keratometer within a population of children under six years of age

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Thesis

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AN EVALUATION OF THE USEFULNESS AND RELIABILITY OF THE ALCON RENAISSANCE HANDHELD KERATOMETER WITHIN A POPULATION OF CHILDREN UNDER SIX YEARS OF AGE.

BY

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A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
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Advisor:
Paul Kohl, O.D.
Abstract
The Alcon Renaissance handheld keratometer was evaluated for percent testable and repeatability in children under six years of age. Sixty children participated in the study. Three readings per eye were attempted for each child. For those children over two years of age, a seventy-five percent testable level or better for three readings was found. The study also indicated consistent repeatability with excellent correlations between the first reading and the mean of three readings found for the horizontal meridian (90% <0.50D), vertical meridian (87% <0.50D), Delta K (96% <0.50D), and axis values (76% <ten degrees). The Alcon Renaissance keratometer is a useful instrument for measuring corneal toricity in children two years and older.

Key Words
Keratometry, keratometer, automated keratometry, Renaissance Series, astigmatism, toddlers, infants
Introduction
In the field of pediatric optometry there is a demand for accurate and reliable keratometer measurements of the anterior corneal surface. This is an essential component of every first time pediatric vision examination and yields information regarding the young patient's refractive error and/or the presence of corneal pathology.

Currently, the two most common methods used to take assess corneal curvature in children under six years of age are the Placido Disk keratoscope and the Baush & Lomb keratometer. When taking readings of the corneal curvature in young children, these two instruments each have their own disadvantages. The Placido Disk keratoscope only provides a qualitative assessment of the corneal curvature while B&L readings can suffer due to the smaller size of the patient's head and the potential lack of cooperation on the part of the young child.

With the introduction of the Renaissance Handheld keratometer, a possible, easy to use with infants keratometer, is now available. Alcon, its manufacturer claims that it's accuracy is comparable to traditional keratometers but with greater flexibility. In a recent study by Travis et al, the Alcon handheld keratometer's accuracy and precision was analyzed by comparing its readings with that of the B&L keratometer in 100 subjects. A high correlation between the two instruments was found on adult patients with clinically significant cylinder (>1.0D), with respect to both power and axis determination\(^1\). If similar results could be obtained with children under six years of age, then the Alcon handheld keratometer would be an invaluable instrument for the general practitioner to use during a pediatric vision analysis and provide a quick and easy assessment of corneal curvature in the infant/toddler population.
Past studies involving keratometry readings in children under five years of age have been performed using the B&L keratometer with the child under local anesthetic\(^3\). This method, while effective, is not a practical solution for the general practitioner in a pediatric environment. The purpose of this study is to assess the ease of use of the Alcon Keratometer when used in a toddler population. The percent of children testable, by age, and the test/retest reliability of results will be analyzed.

**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 release of the alignment button, 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.\(^2\)
Subjects and Methods

Subjects
Fifty-six subjects (112 eyes), ages birth to six years, were the children of Pacific University College of Optometry students, friends and family of the students, pediatric patients undergoing screenings or follow up care, and members of the Little Red Caboose Preschool. There were thirty-one boys and twenty-nine girls who were divided into six age categories at one year intervals. Of the sixty subjects that participated in the study, none had any corneal diseases. Prior to participation, a brief explanation of the study was presented to the parent of each subject and informed consent was obtained.

Methods
The examiners involved in the study consisted of two third year optometry interns and the chief of pediatric services at Pacific University. All examiners were trained and allowed adequate time to practice using the instrument, thus being able to obtain measurements accurately and efficiently throughout examination of subjects.

Three measurements per eye from each child were attempted using the safest and most accurate methods possible. Depending on the child's age, each subject was seated comfortably on either the exam chair, the floor or their parent's lap. The subject was then coaxed by various methods into looking at the red light of the keratometer. If the examiner was successful in maintaining
the fixation of the child for about to five seconds, then a keratometer reading
was usually obtainable. If the examiner was unable to record a reading within
two minutes, the trial was abandoned and the other eye was attempted in the
same manner, if possible. For each of the sixty subjects in the study, the right
eye was always the first to be measured.

Since the measurements obtained by the Alcon autokeratometer are not
dependent upon manual manipulations by the operator, bias was not a
concern. Upon completion of obtaining six measurements (three readings per
eye), when possible, subject data was entered onto a computer spreadsheet in
preparation for statistical analysis.

Results
After dividing the subjects into six age categories, the number of readings taken
from each right eye (the first eye tested) was then used to measure the percent
testable. For the maximum of three readings, there was a steady rise in the
percent testable as the age of the children increased (figure 1 and table 1). Of
the zero to one year olds (n=5), not one subject yielded three readings. Twenty
percent of these subjects were testable for two readings, twenty percent for one
reading and sixty percent had no readings. For the one to two year olds (n=4),
twenty-five percent were testable for three readings, while seventy-five percent
of the two to three years olds (n=12) could achieve the same number of
readings. All age categories older than this were at or above the eighty-four
percent level testable for three readings with a high of ninety-four percent
recorded for the four to five year olds. For all subjects tested, ninety percent
yielded at least one successful reading.
To gauge the test/retest reliability for the horizontal and vertical meridians, the difference between the first reading and the mean of the three readings was analyzed for all eyes in the study that yielded three measurements (n=91). For the horizontal meridian, the first reading was within a 0.25 D of the mean of the three readings seventy-nine percent of the time for those subjects over one year of age (see table 2 and figure 2). In the one subject under one year of age, the difference was between 0.25 D and 0.50 D. In one hundred percent of the one to two year old subjects (n=2), the horizontal difference was 0.0 to 0.25 D, and for subjects in higher age groups, the percentage within this same 0.0 to 0.25 D range was at least seventy-five with the high being one hundred percent in the five to six year olds (n=20). The three to four year olds (n=19) were the exception to this with fifty-seven percent in the 0.0 to 0.25 range and twenty-six percent in the 0.26 to 0.50 range. In total, ninety percent of all subjects were within 0.50D of the mean and ninety-three percent were within 0.75 D of the mean. The vertical meridian differences were calculated in the same manner and similar results were found (see table 3 and figure 3). The one subject under one year of age was in the 0.0 to 0.25 D range. As with the horizontal meridian, one hundred percent of the one to two year olds (n=2) were within 0.25 and 0.50D range and for this same range, all subjects in higher age groups were at or above the eighty-one percent level. The exception, as before, was the three to four year olds (n=19) who had sixty percent between 0.0 to 0.25 D and forty percent between 0.26 and 0.50 D. Of all of the subjects tested, eighty-seven percent had a difference of 0.50 D of less and ninety-six percent had a difference of 0.75 D or less.

To assess the keratometer's reliability when measuring the difference between the horizontal and vertical meridians, or Delta K, the same technique of analysis
was applied. For all eyes yielding three readings, the difference between the powers of the horizontal and vertical meridians of the first reading was compared to the mean of the three readings (see table 4 and figure 4). The one subject in the zero to one year category was different by only 0.0 to 0.25 D as were all of the two year old eyes (n=2). All other subjects in older age groups were at or above the seventy-nine percent level for the 0.0 to 0.25 D range with the high being ninety-three percent for the four to five year olds (n=33). In total, ninety-six percent of all subjects tested were within 0.0 to 0.50 D of the mean and ninety-eight percent were within 0.75 D. For those subjects whose average corneal cylinder (mean delta K) exceeded one and a half diopters (n=20), sixty percent were within 0.0 and 0.25 D of the mean while eighty percent were within 0.50 D of the mean.

A problem arose with the method used to analyze the 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. was used to account for this problem. The technique used is to add 180 to all axes from 1 to 44, inclusive. This adjustment allowed us to reference all horizontal axes to the 180th meridian.

To determine the reliability of the axes readings, the difference between the first axis reading and the mean of the other three axis readings was compared. Statistically, the axes readings were the most varied relative to the other parameters measured. The difference for the single one year old subject was less than five degrees as were both of the two year old readings. In the higher
age groups, only the three to four year olds (n=19) had seventy-five percent in the zero to five degree range (see table 5 and figure 5). The next highest belonged to the five to six year olds (n=20) at sixty-six percent with the lowest being the two to three year olds (n=16) at forty-four percent. The four to five year old age group (n=33) and the five to six year old age group (n=20) each had the highest percentages (ten percent) of differences greater than twenty-five degrees in axes. However, of all the subjects tested, seventy-six percent had a first axis value within ten degrees of the mean of the three readings and only four percent yielded a twenty degree difference or more.

Discussion
The results of this study suggest that the Alcon Renaissance Series Keratometer is an easy to use instrument for testing children between the ages of two and six years. After the age of two years, the percent testable for three readings increases dramatically (table 1 and figure 1) and finally levels off between eighty-four and ninety-four percent after three years of age. The best explanation for this is that as children age, they are better able to understand the procedure, are less anxious around strangers, and cooperate more when asked to look for prolonged periods of time at the red fixation light of the keratometer. The only subject under one year of age able to be tested was a child measured after falling asleep (before Bell's reflex set in). Also, the number of subjects under two years of age was limited (n=9), and therefore, the percent testable for this age group may be found to be different if a larger population was tested.
This study also supports the statement that the Alcon Renaissance Keratometer is a very repeatable instrument when recording horizontal power, vertical power, delta K and axis value in children under five years of age.

For all subjects tested, the horizontal difference for ninety percent of the subjects tested was between 0.0 and 0.50 D while the vertical difference was similar with eighty-seven percent of all subjects tested falling into the 0.0 to 0.50 D range. The delta K differences were also repeatable as ninety percent of all subjects tested and eighty percent of those subjects with over one diopter of corneal cylinder were within the 0.0 to 0.50 D range. The axis readings were not nearly as repeatable, but still, seventy-six percent of all subjects tested had a difference of only zero and ten degrees. A possible explanation for greater variability with the Alcon keratometer than with the standard keratometer may be the lack of steady fixation by some of the subjects tested combined with the ability of the instrument to occasionally take readings while slightly off axis. Therefore, it is recommended that great care and awareness of how the instrument is lined up with the child's eye be utilized for any readings taken.

It was found that keeping the child actively entertained and comfortably postured, either seated or standing, was the best way to reduce fixation losses and obtain keratometry readings. With younger subjects, under the age of three, the amount of stranger anxiety can be reduced by having the child seated in their parent's lap at all times. Fixation can best be maintained with these same children by coaxing the subjects to look at the red light while making animal noises such as chirping like a bird or meowing like a cat. Older children may be coaxed in the same manner by telling them to look for the animal which lives in the red light.
From these results, it can be concluded that the Alcon Renaissance Handheld Keratometer is a very easy to use and repeatable instrument for taking corneal curvature readings in children under the age of six years. In the future, it is recommended that similar studies be conducted for geriatric and handicapped populations. Due to the lack of subjects under two years of age in this study, we feel that another study with children under the age of two years would also be appropriate.
References


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Figure 1

Right Eye Percent Testable by Age (N=60)
Figure 2

Difference Between the First Horizontal Reading and the Mean of the Three Readings (D)
Figure 3

Difference Between the First Vertical Reading and the Mean of the Three Readings (D)

- 0 to 0.25 D
- 0.26 to 0.50 D
- 0.51 to 0.75 D
- 0.76 to 1.00 D
- 1.01 to 1.50 D
- >1.50 D

Percent Testable

Difference Between First Reading and Mean of Three Readings (D)

- 0 to 1 years
- 1 to 2 years
- 2 to 3 years
- 3 to 4 years
- 4 to 5 years
- 5 to 6 years
Figure 4

Difference Between the First Delta K Value and the Mean of the Three Delta K Values

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Legend:
- ■ 0 to 1 years
- □ 1 to 2 years
- ■ 2 to 3 years
- ■ 3 to 4 years
- ■ 4 to 5 years
- ■ 5 to 6 years
Figure 5

Difference Between the First Axis Reading and the Mean of the Three Readings (Degrees)

Difference Between First Horizontal Reading and Mean of Three Readings (Degrees)

- 0 to 1 years
- 1 to 2 years
- 2 to 3 years
- 3 to 4 years
- 4 to 5 years
- 5 to 6 years