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Bruce D. Babcock
Pacific University

Carolyn J. Baker
Pacific University

Shelly A. Cadman
Pacific University

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Abstract

The purpose of this study was to develop a keratometric device that would give a peripheral corneal measurement approximately 3.0mm from the center of the cornea and to compare the accuracy of the peripheral keratometry readings to an industry standard, a computerized corneal topographer. The EyeSys Corneal Analysis System by EyeSys laboratories in Houston, Texas, was chosen as a representative of available computerized corneal topographers. A fixation device, with peripheral fixation targets was created and attached to a standard Bausch & Lomb keratometer. Thirty-one subjects (five in the initial phase and twenty-six in the final phase) who were free from corneal disease and were not contact lens wearers, were subjects for this study. Each subject had four keratometric readings per eye taken 3.0mm from the center of the cornea and compared to the same location on their topographic map. Ninety-one percent of all readings fell within ±0.500. The device may prove to be a useful tool to aid in the base curve selection when fitting RGP lenses on both normal and pathologic eyes (i.e. keratoconus, post-keratoplasty and post-refractive surgery).

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COMPARISON OF THE EYESYS CORNEAL ANALYSIS SYSTEM AND PERIPHERAL KERATOMETRY USING A B&L KERATOMETER AND A LIGHTED FIXATION DEVICE

By

BRUCE D. BABCOCK
CAROLYN J. BAKER
SHELLY A. CADMAN

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Advisors:
Patrick J. Caroline, C.O.T., F.A.A.O.
James E. Peterson, O.D., F.A.A.O.

Authors' Signatures

Bruce D. Babcock

Carolyn J. Baker

Shelly A. Cadman

Advisors' Signatures

Patrick J. Caroline C.O.T., F.A.A.O.

James E. Peterson O.D., F.A.A.O.

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BIOGRAPHY

Bruce D. Babcock attended Concordia College in Moorhead, Minnesota where he graduated with a Bachelor of Arts in Biology with honors. He will graduate from Pacific University in May, 1995 with a Doctor of Optometry. He plans to return to the mid-west and enter private practice optometry with an emphasis on primary care and contact lenses.

Shelly A. Cadman attended Central Wyoming College before transferring to Pacific University where she obtained a Bachelor of Science in Visual Science. She will graduate with a Doctor of Optometry in May, 1995. Her future plans are to return to the Rocky Mountain region and enter private practice with an emphasis on primary care and contact lenses.

Carolyn J. Baker attended the University of California Davis where she graduated with a Bachelor of Science in Biological Sciences. She will graduate with a Doctor of Optometry in May, 1995 and her future plans are to enter private practice in Northern California.

ABSTRACT

The purpose of this study was to develop a keratometric device that would give a peripheral corneal measurement approximately 3.0mm from the center of the cornea and to compare the accuracy of the peripheral keratometry readings to an industry standard, a computerized corneal topographer. The EyeSys Corneal Analysis System by EyeSys laboratories in Houston, Texas, was chosen as a representative of available computerized corneal topographers. A fixation device, with peripheral fixation targets was created and attached to a standard Bausch & Lomb keratometer. Thirty-one subjects (five in the initial phase and twenty-six in the final phase) who were free from corneal disease and were not contact lens wearers, were subjects for this study. Each subject had four keratometric readings per eye taken 3.0mm from the center of the cornea and compared to the same location on their topographic map. Ninety-one percent of all readings fell within ±0.50D. The device may prove to be a useful tool to aid in the base curve selection when fitting RGP lenses on both normal and pathologic eyes (i.e. keratoconus, post-keratoplasty and post-refractive surgery).

KEY WORDS

Peripheral keratometry, EyeSys, corneal topographer, fixation device

INTRODUCTION

In the 1950s, practitioners began to establish the fundamental principles of fitting rigid corneal contact lens designs. The most important of these principles was that the fit of any corneal contact lens could be determined by the relationship between the posterior of the contact lens and the anterior mid-peripheral cornea. At that time, the only method available to determine this relationship was through the use of sodium fluorescein with cobalt blue light, a technique developed by Obring in 1949.

In 1957, May described a more quantitative technique of measuring the peripheral cornea through the use of auxiliary fixation points on the mire illumination plate of the keratometer.[1] The technique was soon referred to as peripheral keratometry. Peripheral keratometry consisted of central keratometric readings followed by the patient's fixation being directed to points off the line of sight of the keratometer, thus measuring the mid-peripheral cornea.

Peripheral keratometry gained significant clinical acceptance in the early 1960s with a number of authors reporting success with the technique.[1-7] However, by the mid-1960s the technique had fallen out of vogue due to significant criticisms of its accuracy.[8,9] The first was that in taking a central corneal measurement, the optic axis of the keratometer is directed at the corneal apex (assuming the apex is centered on the line of sight). The mires from the keratometer actually reflect from two small areas about 1.5mm on either side of the apex and, the resulting measurement is a mean between these two points. (Figure 1). Because a mean of such a relatively large area of the corneal surface is measured, data from these keratometric readings were considered too general of a measure of the peripheral cornea. The second criticism was that as the mire reflects off the mid-peripheral cornea, one side of the mire reflects off a steeper portion of the cornea while the other falls on a flatter portion of the cornea. (Figure 2). Again, the measured radius is the mean between two points. As the surface measured deviates from sphericity, the errors of measurement increase. Due to the increased asphericity of the peripheral cornea, the more peripheral the measurements, the greater the error.

The original peripheral keratometry devices directed patient gaze eccentrically approximately 20 to 25°. This gave a measurement of the peripheral cornea approximately 4.5 to 5.0mm from center or a cord of 9 to 10 mm. This distance is far beyond the mid-peripheral cornea, where the dynamics between contact lens and cornea typically occur.

In re-addressing the topic of peripheral keratometry, two questions needed to be answered: 1. Where on the mid-peripheral cornea does the actual fit of a contact lens take place? Much of the success of a rigid lens fit is predicated on the delicate balance which exists between the anterior corneal surface and the posterior contact lens design. This fitting relationship creates numerous bearing and clearance points which must be of appropriate pressure and positioning to maintain optimum lens dynamics and corneal health. These fitting relationships are most critical in the mid-peripheral cornea in an area approximately 3.0 to 4.0mm from geometric center, therefore the radius of the central cornea plays little or no role in the physical fit of a rigid lens.

2. How far does one move patient fixation to achieve this measurement? The answer to this question is difficult to determine mathematically due to a number of physical and optical factors which include: individual variation in the angle of rotation of the eye, differences in the area of the reflected mire projected peripherally, and individual differences in the degree of peripheral asphericity. These factors account for the inherent errors of the peripheral keratometry technique.

The purpose of this study is to determine a keratometric device that would give a peripheral corneal measurement approximately 3.0mm from the center of the cornea and to compare the accuracy of the peripheral keratometry readings to an industry standard, a computerized corneal topographer.

INSTRUMENTATION

The EyeSys Corneal Analysis System by EyeSys laboratories in Houston, Texas, was chosen as a representative of available computerized corneal topographers. It uses a large, flat set of eight broad rings that constitute sixteen edges that are projected onto the cornea. The computer digitizes the focused image of the rings and obtains 360 data points per ring. From these points, the radius of curvature, and subsequent dioptric value of the cornea is calculated. The computer translates these values into a color-coded topographic map.[10]

The Bausch & Lomb keratometer was chosen as a representative keratometer on the basis of its universal use and similarity to most available keratometers. For the purpose of this study, a lighted fixation device was fabricated since commercially available fixation devices did not meet out target placement requirement. Our lighted fixation device consists of a clear plastic disc 7.4cm in diameter. The disc fits against the target plate of the keratometer so that its' mires are not disturbed. Four 1mm diameter red LED lights, powered by a nine-volt battery, are attached to the disc. Each light is located 1.4 cm from the center of the ring at ninety degree intervals in the horizontal and vertical meridians. Lighted fixation points were used to give patients and easier target to fixate therefore yielding a steadier fixation.

METHODS

Subjects for this study were drawn from the Pacific University College of Optometry primary care clinic. This study consisted of thirty-one subjects (five in the initial phase and twenty-six in the final phase) eighteen to forty-five years of age who were not wearing contact lenses and were free from corneal disease. All subjects had not worn either rigid or soft lenses on a regular basis for at least one year. The anterior segment of each subject was examined to evaluate the presence of any corneal, tear film, or anterior segment abnormalities. These criteria were used to rule out any previous effect a contact lens or corneal disease may have had on a subject's cornea. Each subject was informed of the purpose of the study. Neither the researchers or the subjects had a financial incentive as to the outcome of the study. All supplies and materials were provided by Pacific University College of Optometry and Beta Sigma Kappa, the study sponsor.

The first phase of this study, conducted over a one-day period, involved empirically locating a peripheral fixation point with the keratometer that correlated to a specified area on an EyeSys corneal topographic map. The location of these areas, whether mathematically or empirically determined, would utilize assumptions or estimations. Therefore, an analysis of five subjects meeting the established criteria was done using the EyeSys and peripheral keratometry. Peripheral areas representing 3.0, 3.5 and 4.0mm from the corneal apex on the EyeSys topographic map were recorded. These distances approximate points of the cornea that interact with an area near the edge of the optic zone of a typically-fit rigid contact lens. The data points were then compared to points taken with the keratometer using a fixation device with varying target distances - 1.3, 1.4, and 1.5cm from the line of sight of the keratometer. For each subject's eye, four points (superior, inferior, nasal, and temporal) were recorded with each apparatus. The nine combinations of keratometric and EyeSys distance variables yielded correlations ranging from 0.84 to 0.96. The best correlation was between the 1.4cm target on the keratometer and the 3.0mm measurement taken from the EyeSys topographic map (Table 1).

The next phase of the study, conducted over a two-day period, involved twenty-six subjects who met the established criteria. All data for one subject was collected on the same day. Before any corneal topographic measurements were made, the corneal and anterior segment health of each subject was evaluated. Utilizing the empirically established standards, the corneal topography of the each subject's right eye was then measured utilizing the EyeSys and peripheral keratometry.

The keratometer was calibrated each day using a standard contactometer. Four peripheral points of the right eye were measured with the subject fixating each of the red LED lights on the fixation target. Each of the peripheral points measured by the keratometer was recorded to the nearest 0.12D.

The EyeSys Corneal Analysis System was calibrated at the beginning of each day of data collection utilizing the calibration apparatus and operations manual received with the instrument. A digitized photokeratograph of each subject's right eye was recorded for later computer analysis and editing. The computer locates the edges of each of the rings by contrast. Therefore, errors are made in ring location where contrast in the photokeratograph occurs, such as the limbus, prominent iris crypts and shadows from the nose or eyelashes. The edges of the rings may be missed by the computer when irides are light in color and therefore give too little contrast between the light rings and the iris. Editing of the computer-located rings was necessary in order to obtain reliable data. Editing involved removing excess computer-generated lines at the limbus and superior and inferior lid margins. Addition of lines in areas where the rings were missed by the computer was done only if the ring was clearly visible on the photokeratograph and the length of the gap was small. From these edited photokeratographs, a topographic map was generated. The dioptric power corresponding to a point 3.00mm superior, inferior, nasal and temporal from the line of sight was rounded to the nearest 0.12D and recorded.

Statistical analysis was performed on the measurements to determine their correlation level and statistical difference (Table III). A frequency histogram (Table IV) of the data was created showing the frequency with which the instruments differed in their measurement of the peripheral cornea for each meridian measured.

RESULTS

Four individual measurements were obtained from the right eye of each of the twenty-six subjects with each device (Table II). Measurements from the two devices showed a high correlation in each of the four quadrants measured (ranging from 0.961 to 0.985). The correlation was highest for the superior quadrant and lowest for the temporal quadrant (Table III).

Evaluation of the paired t-test shows that there is not a significant difference between the mean values for any of the four quadrants (using $p < 0.05$ as the significance level). However, each of the quadrants differ widely in the degree of significance. The t-test results range from 0.076 to 0.578. The quadrant with the largest difference between means statistically is the nasal with $p = 0.076$. The other quadrants measured showed a less significant difference between mean values (Table III).

In addition to the above analysis, a frequency histogram showing the dioptric difference of measurements from both devices in each meridian was prepared (Table IV). The histogram shows that ninety-one percent of the measurements taken yielded a difference of 0.50D or less.

The left eye of each subject was also evaluated in each of the four quadrants utilizing both devices. The data from these measurements showed similar results.

DISCUSSION

In this study, the authors undertook a re-evaluation of the keratometer as an instrument clinically useful in measuring peripheral corneal topography. This re-evaluation involved a comparison of keratometric data taken with an illuminated fixation device to that of the EyeSys computerized topographer. Such computerized devices are currently an accepted standard for the evaluation of corneal topography. We believe that our use of an empirically determined fixation target for the keratometer is a valid estimate. Any other estimates, either mathematical or otherwise determined, would use approximations for the various physiological aspects of the human eye (such as the line of sight and center of rotation).

The expected accuracy of the keratometer and the EyeSys corneal topographer is ± 0.25D. [11] This is sufficiently accurate for clinical applications, assuming that an accuracy between 0.25 and 0.50D is considered clinically relevant.

An understanding of errors inherent to each device is important in the evaluation of either device as an acceptable instrument for assessing corneal topography. The clinically important error inherent to both the keratometer and any current computerized topographer is that the visual axis (an imaginary line from the fovea through the nodal point to the object looked at) is not usually coincident with the pupillary axis (an imaginary line passing through the center of the pupil, normal to the cornea)[12-14]. The angle formed by these two axes is termed angle kappa (also known as angle alpha)[12-14]. An error, greater in the nasal peripheral corneal measurement occurs due to this angle. Even a symmetrical cornea will have its' nasal quadrant measure flatter because the typical corneal apex is rotated temporally when observed from the visual axis. Since both devices measure along the visual axis through the use of fixation lights, the error from each should not effect the results of this study. Measurements from one device were compared to measurements taken for a corresponding corneal area with the other device and therefore, mutual errors should cancel. Although angle kappa varies between patients, future fixation devices for either peripheral keratometry or computer-assisted corneal topography that compensate for angle kappa may be an option in the attempt to achieve more accurate and useful topographical measures of the cornea.

Mandell in his chapter on corneal topography argues that even "the most elaborate [fixation target attached to the keratometer] cannot compensate for errors inherent in peripheral keratometry."[8] The major error inherent to the keratometer alone is that its' design allows for only truly accurate measures of spherical corneas.[8,15,16] Typically, the human cornea is not spherical throughout the entire area of the cornea, but is aspherical and becomes more aspherical away from the corneal apex. The degree of error will therefore be directly related to the rate of flattening (or asphericity) of the cornea measured.[8] This error is not as great with the EyeSys or other computerized topographers since they measure smaller zones of the cornea.

The data from this study show that the keratometer and the EyeSys correlate highly in their measurement of peripheral corneal topography (Table III). These results are similar to the results found by other investigators in analysis of the EyeSys and the keratometer when measuring the central cornea.[17, 18] This indicates a fairly close correlation between all keratometric and EyeSys measurements.

When the differences between mean values for each of the four quadrants measured are analyzed, the largest difference occurs in the nasal quadrant (Table III). A proposed reason for the difference is the presence of angle kappa. Therefore, most fitting philosophies utilizing peripheral keratometry do not use the nasal reading. As discussed earlier, the typical corneal apex is decentered temporally from the visual axis. This causes a distortion in the readings taken with either instrument. This distortion may occur more readily with the keratometer due to its' measurement of approximately a three millimeter zone of the cornea.[8] Whereas the EyeSys measures much smaller areas of the cornea, the resulting average would not be as susceptible to as much distortion.

Since neither the EyeSys nor the keratometer is free from measurement errors, either inherent or due to the observers, it is difficult to know which device is at fault.

CONCLUSION

It appears from this study that a newly calculated peripheral keratometry disc has a clinically acceptable correlation to the readings obtained through corneal mapping. The technique may serve as a guide to aid in appropriate RGP base curve selection and help to explain unanticipated fluorescein pattern appearances.

The disc may also prove to be a useful tool to aid in the RGP base curve selection for the pathologic cornea (i.e. keratoconus, post-keratoplasty, and post refractive surgery). For those practitioners not fortunate enough to have a corneal mapping unit, the disc provides some further insight into the status of the mid-peripheral corneal topography where the RGP fitting relationship takes place. The price of computer assisted topographic analysis systems varies widely depending on the hardware and software packages chosen (Table V).[15] The usefulness of such instruments regarding the wealth of information attainable for research and for the clinician is not disputed. Each clinician must decide, based on their practice requirements, whether such a purchase is necessary or whether reliance on keratometry or peripheral keratometry will suffice.

As has already been stated, there is no dispute as to the usefulness of computer-assisted corneal topographic analysis systems - especially in the area of refractive surgery. It has been the intention of the authors to investigate an alternative method in the acquisition of corneal topographic data as it relates to rigid contact lens fitting. The fitting of rigid contact lenses on a keratoconic, post-RK, or otherwise irregular cornea usually requires more than just a measure of the central cornea. Peripheral keratometry may allow clinicians to obtain data accurate enough to successfully fit such patients. This realization alone warrants further research as to the usefulness of corneal topographic measurements taken with a fixation attachment to the keratometer.

The authors of this study believe that peripheral keratometry represents an alternative method in obtaining additional information regarding the curvature of the peripheral cornea. This study demonstrates that peripheral keratometry may be clinically useful as well as less cost-prohibitive when compared to computer-assisted corneal topographic analysis systems. The authors also encourage further research exploring the accuracy of peripheral keratometry on irregular corneas and subsequent rigid contact lens fitting success or failure and comparing this to results from computer-assisted corneal topographic analysis systems.

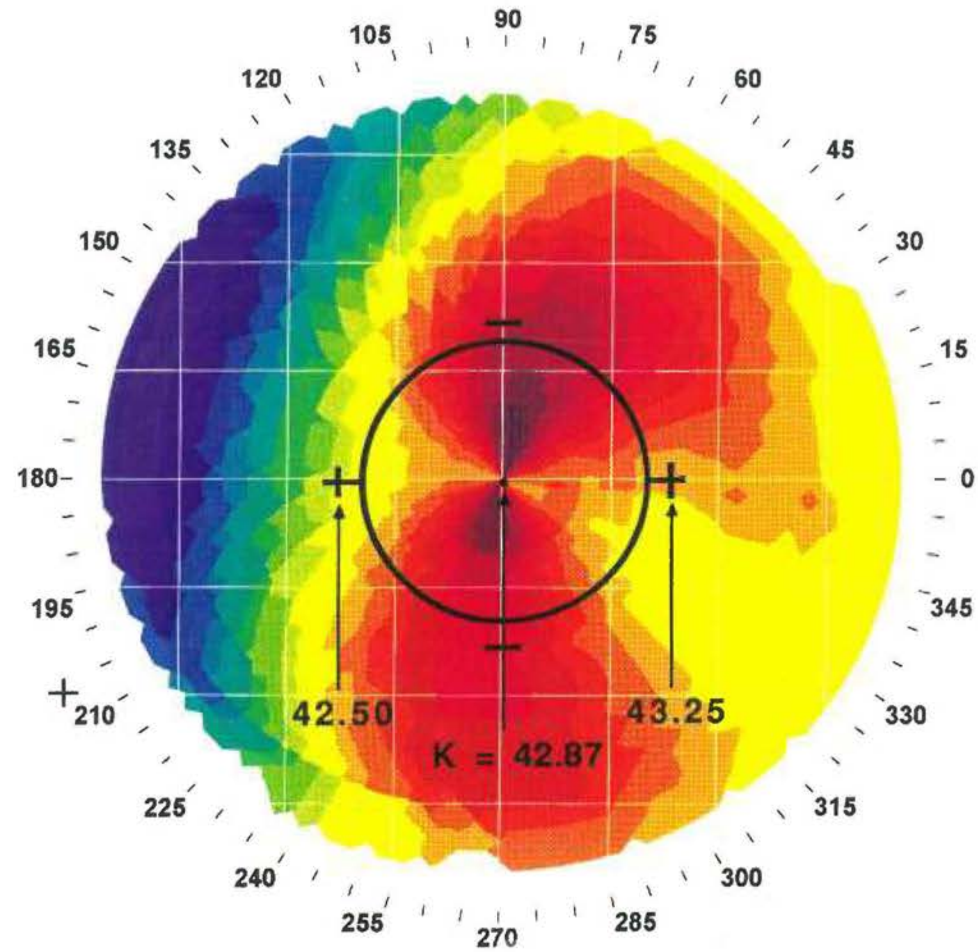

Figure 1. Diagram showing the approximate location of keratometer mires superimposed on a computer-generated topographical map of a cornea and a mean value given by the keratometer.

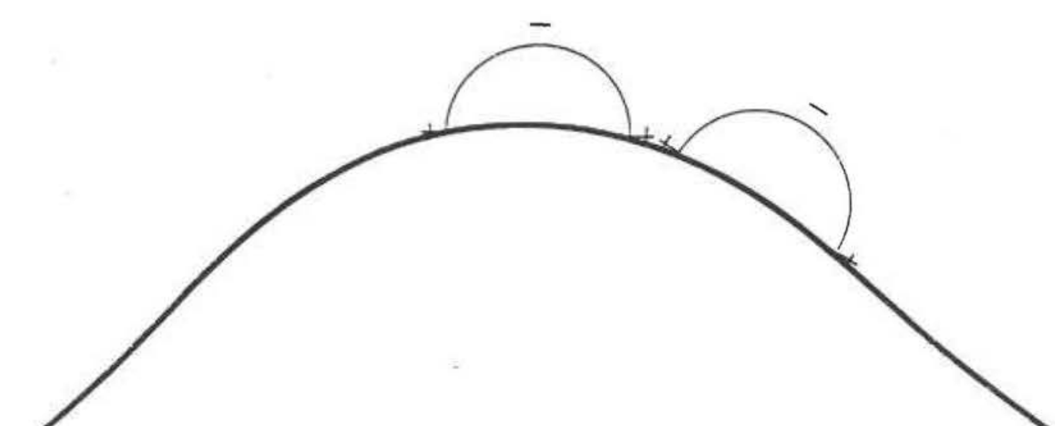

Figure 2. Schematic diagram of the cornea showing the position of the keratometer's mires on both central and peripheral portions of the cornea.

Table I. **Preliminary correlation data of the EyeSys and keratometric measurements of the peripheral cornea**

		EyeSys		
		3.0mm	3.5mm	4.0mm
Keratometer	1.3cm	0.93	0.92	0.84
	1.4cm	0.96	0.94	0.90
	1.5cm	0.94	0.94	0.88

Source: Experimental Data

Table II. **Raw Data: Keratometric and EyeSys readings of the peripheral cornea in four quadrants**

Subject	Superior K'meter	Superior EyeSys	Inferior K'meter	Inferior EyeSys	Nasal K'meter	Nasal EyeSys	Temporal K'meter	Temporal EyeSys
A	45.25	45.50	45.75	45.37	43.75	44.12	44.00	44.75
B	44.37	44.12	44.50	44.12	43.25	43.37	43.37	44.37
C	46.12	46.00	45.25	45.87	46.00	45.62	46.00	46.00
D	43.50	43.50	43.75	43.87	42.50	42.62	43.87	43.75
E	44.25	43.87	45.75	45.62	44.25	43.87	44.00	44.50
F	43.75	43.87	44.25	44.25	44.00	43.37	43.75	43.87
G	44.00	44.00	43.87	44.25	42.87	42.87	43.87	44.00
H	45.50	45.25	45.25	45.25	46.00	45.87	45.25	45.12
I	44.62	45.50	45.25	45.12	44.87	44.37	44.12	44.62
J	46.37	46.00	45.75	45.75	43.75	43.75	45.00	44.75
K	41.50	41.50	42.50	42.37	41.50	41.37	42.00	41.87
L	41.50	41.87	42.75	42.62	41.75	41.62	41.75	41.62
M	45.75	45.75	45.75	46.00	45.00	44.87	45.25	45.25
N	43.75	43.12	43.00	43.50	43.25	42.87	43.25	43.25
O	41.25	41.75	42.50	43.00	41.25	41.50	41.50	41.87
P	42.75	42.25	42.50	42.75	40.87	41.50	42.75	42.50
Q	42.00	42.37	42.25	42.50	42.25	42.12	42.75	42.00
R	42.00	42.12	43.00	43.25	41.75	41.87	42.50	42.50
S	44.37	44.25	44.87	45.37	44.50	44.00	43.75	43.75
T	42.75	42.87	43.75	43.62	43.62	43.37	44.62	44.25
U	42.50	43.00	43.37	43.75	42.75	42.50	44.00	43.12
V	46.75	46.12	46.50	46.37	43.75	43.75	44.50	44.75
W	41.62	41.62	42.00	41.75	41.50	41.37	41.75	41.50
X	42.62	42.62	43.12	43.75	42.12	42.00	42.87	42.75
Y	42.87	42.75	44.37	43.37	43.25	43.00	42.87	42.75
Z	41.50	41.75	43.37	44.00	42.12	42.25	42.87	42.75

Source: Experimental Data

Table III. **Statistical Data of peripheral corneal measurments using the EyeSys and peripheral keratometry**

Quadrant	Correlation	Paired t - Test	Difference between Means
Superior	0.985	0.397	0.053 D
Inferior	0.972	0.134	0.095 D
Nasal	0.982	0.076	0.103 D
Temporal	0.961	0.578	0.038 D

Source: Experimental Data

Table IV. **Frequency Histogram showing the prevalence of differences between keratometry and EyeSys readings**

Difference (Diopters)	Superior	Inferior	Nasal	Temporal	Total	Percent	Cumulative Percent
0	6	4	3	6	19	18	18
0.12	6	7	10	9	32	31	49
0.25	4	5	2	4	18	17	66
0.37	5	5	5	2	16	15	82
0.50	3	3	2	2	10	10	91
0.62	2	2	3	0	6	6	97
0.75	0	0	1	2	2	2	99
0.87	0	0	0	1	1	1	100
1.00	0	0	0	0	0	0	100
>1.00	0	0	0	0	0	0	100
Total	26	26	26	26	104	100	

Source: Experimental Data

Table V.

Computer-Assisted Corneal Topographic Analysis Systems[15]

Company	Device	Cost
Computed Anatomy	Topographic Modeling System	$24, 950
EyeSys Laboratories	Corneal Analysis System	approx. $20, 000
Visioptic	Computerized Corneal Topographer	$29, 950

Source: Reference 14.

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