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Abstract

The purpose of this study was to observe the corneal and refractive changes that occur when a PMMA wearer is refit with a highly gas permeable contact lens. Pachometry data indicated that the corneal thickness of most subjects increased after having worn the lenses for two weeks. The corneal curvatures of nearly all subjects steepened and showed an increase in cylinder. Increases in myopia, which correlated with the steepened corneal curvatures, occurred after two weeks of Paraperm wear. These results could differ if the subjects were followed for a longer period of time.

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A CLINICAL EVALUATION OF CORNEAL AND REFRACTIVE CHANGES OBSERVED WHEN SWITCHING FROM PMMA TO PARAPERM O_2 CONTACT LENS WEAR

By

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and

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Submitted as Partial Fulfillment of the Requirements
for the Doctor of Optometry Degree to
Dr. Don C. West

Don C. West

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ABSTRACT

The purpose of this study was to observe the corneal and refractive changes that occur when a PMMA wearer is refit with a highly gas permeable contact lens.

Pachometry data indicated that the corneal thickness of most subjects increased after having worn the lenses for two weeks. The corneal curvatures of nearly all subjects steepened and showed an increase in cylinder. Increases in myopia, which correlated with the steepened corneal curvatures, occurred after two weeks of Paraperm wear. These results could differ if the subjects were followed for a longer period of time.

PREFACE

The main purpose of this study was to observe the corneal and refractive changes that occurred when a patient wearing PMMA contact lenses was refit with a highly gas permeable rigid lens. The characteristics of Paraperm O_2 lens material produced by Paragon Optical were also evaluated. Experience was gained by working with one of the new PMMA-silicone polymer materials available on the market today.

Current knowledge of corneal physiology indicates that the oxygen needs of the cornea are currently best supplied by gas permeable lenses, because of this the study of their characteristics become important. There are considerable differences that exist between the fitting characteristics of a PMMA lens and the new gas permeable lenses.

INTRODUCTION

With increasing numbers of gas permeable materials available the clinician needs information with which to select materials. The aim of this study was to monitor and quantify some of the corneal and refractive changes that occurred when a compromised corneal physiology was refit with a gas permeable material. The information obtained would allow the clinician data by which to evaluate one of the new materials, Paraperm O_2. An easily incorporated system to assess the fitting characteristics of a lens was used. A description of the system and comments on its use are also made available to the clinician.

The first hypothesis set forth was that the refractive error would become less astigmatic and more spherical.[4] This implies that the corneal cylinder would decrease more than the spherical component would increase. The manifestation would be a more spherical refraction after wearing the lenses. A second hypothesis was that the corneal thickness would decrease. It was felt that the corneal compromise attributed to PMMA lens wear causes clinical or sub-clinical levels of edema. With increased oxygen permeability the edematous situation would be relieved. The literature reports a general thinning trend in corneal thickness with decreased edema.[7,13,16]

This aspect can be monitored and quantified by pachometry. The last hypothesis was the amount of corneal cylinder would decrease. The venting required under a PMMA contact lens could be responsible for inducing corneal cylinder. While the Paraperm material must also vent, the anoxic environment created by the PMMA lens would be relieved. Cylinder change can be quantified by keratometry measurements and qualified by use of corneascope photographs.

SUBJECTS

The initial subject population consisted of eleven people, seven females and four males. Demographic data follows in Appendix I. One male subject could wear his PMMA lenses no longer than six hours per day due to corneal exhaustion and one female subject had discontinued wear on the weekends because the PMMA lenses "hurt her eyes". Four female subjects could not complete the study for the following reasons: moving out of the area, poor compliance with the arranged schedule, lack of interest, and difficulties in achieving a proper fit. The study ended with a population consisting of three females and four males. All were in good physical condition and had no ocular pathologies.

Corneal cylinders (ΔK) ranged from 0.54 D to 1.54 D in the females with an average of 1.14 D. ΔK in the male subjects ranged from 0.45 D to 2.79 D with a mean of 1.45 D. Keratometry readings ranged from 41.37 D to 45.00 D among the female subjects while the range among male

subjects was 43.00 D to 46.75 D. With-the-rule corneal cylinder was exhibited by 13 of the 14 eyes with the remaining eye exhibiting against-the-rule corneal cylinder.

MATERIALS

The Paraperm O_2 lens is a silicone-PMMA mixture manufactured by Paragon Laboratories. Paraperm O_2 had a reported wetting angle of 23.1° and a Dk value of 12.2 x 10^{-11} ml O_2/cm^2. The lenses were available in any parameters requested. The Dyer Chart was used to determine center thickness with 0.12 mm being a suggested minimum (see Appendix III). The Paraperm lens could be ordered as a clear lens or in several tints including blue, gray, and green. At the time of the study the material was under FDA Phase III investigation.

FITTING

The Paraperm lenses for each subject were designed from several considerations. A diagnostic lens fitting session using the American Optical Master Control Method (AO MCM) fitting set provided PMMA lenses of known parameters. Fitting characteristics of different base curves, overall diameters, and optic zone diameters on each subject were evaluated. The overall fluorescein pattern was considered as was the lacrimal line/reference line ratio (LL/RL ratio).

With the contact lens on the eye, the LL/RL ratio was obtained using a cobalt blue optic section and

fluorescein dye. Using the joystick, an optic section was focused on the anterior surface of the contact lens. The subject was instructed to look straight ahead. The oculars were rotated to a position 35 to 45 degrees temporal to the subject to observe the optic section. Both magnification and illumination were increased to facilitate observation. Judgements were made in determining the width of the LL with respect to the RL. The RL is considered to be a unimolecular layer of tears that wet the anterior surface of the contact lens and appear as a bright green line. The LL is the tear pool that is seen behind the contact lens profile. The cross-section of the contact lens itself is seen as a black band sandwiched between the RL anteriorly and the LL posteriorly. The width of the LL will vary depending upon the fitting characteristics of the lens being evaluated. The LL/RL ratio will be less than one if the relationship between the cornea and the lens is one of apical touch, equal to one if an alignment fit is produced, and greater than one for apical clearance. Our goal was to fit diagnostically using a ratio between 1.2 and 1.5. This allowed slight apical clearance in the design of the lens so that modification would produce an alignment fit.

The lens of best fit was also evaluated on movement, centering, and lens to cornea characteristics. Generally, if the diagnostic lens had an alignment fit it would drop to the inferior limbus. To correct this the base curve was decreased by 0.1 mm (0.50 D) and the lens would center

much better. Using the optic section setup discussed previously, the inferior portion of the lens was evaluated. A small tear triangle formed between the peripheral curves of the lens and the anterior surface of the cornea can be observed at the inferior portion of the contact. If this triangle had a pointed appearance at the apex it indicated bearing restriction which correlated with the overall fluorescein pattern. Preferably the tear triangle was truncated at the apex indicating good tear flow under the lens and no bearing restriction. At the base of the tear triangle the tear meniscus was also evaluated. The tear meniscus provides an evaluation of the relationship of the peripheral curves to the cornea. For a given region of the cornea, if the meniscus was drawn up under the edge of the lens the peripheral curves were flatter than the cornea, if the meniscus was pushed out from under the edge of the lens the peripheral curves were steeper than the cornea, and an alignment fit of the peripheral curves produces a meniscus which is flush with the edge of the lens. The evaluation of the tear meniscus was not quantified, but was recorded as "at", "under", or "out" from under the lens edge. Evaluation of the tear triangle was recorded as either "truncated" or "pointed". The preferred method of fit was to have the tear meniscus out from under the edge of the lens to allow good centration.

If the PMMA lenses that subjects were currently wearing were judged to meet all the requirements of a good

fit, then Paraperm lenses were ordered in the same parameters. Most of the Paraperm lenses ordered were 8.2 mm overall diameter. Final dioptric power for the lenses were determined by a combination of the diagnostic lens power and the over-refraction in the usual manner.

APPARATUS

Besides using familiar equipment such as a phoropter and keratometer, an electric digital pachometer, Reynolds corneascope and comparator were also used.

The Dicon Digital Computerized Pachometer Model II RK was used to quantify the corneal thickness changes that occurred. Each experimenter practiced with the instrument until consistency in measuring the thickness of a contact lens of known parameters was within a deviation of 0.007 mm or less on five consecutive measurements. It was decided that the accuracy of these measurements be within 0.002 mm of the actual center thickness of the contact lens used for calibration. Less than five measurements would not give a valid average while greater than five could produce a misleading deviation. Before each measurement was taken the pachometer was calibrated as outlined by the manufacturer's instructions. The deviation was considered to be critical in determining corneal thickness. An assumption was that if the deviation were low the corneal thickness measurement would be more accurate since the measurement was repeatable. When measuring the corneal thickness of a subject, their cooperation and

concentration became a factor in determining how large a deviation was accepted.

When taking the central thickness measurement the slit of the biomicroscope was positioned so that it was very near, but not on, the specular reflex. This allowed the best slit definition and consistent relocation of the same area to be measured at each session. After setting up for the central reading, the joystick was not moved during succeeding measurements except to refocus the beam. Measurements were taken in the same order each session with the right eye followed by the left. Following calibration five positions were measured. A central reading was taken first, followed by four peripheral readings, one in each major meridian at the same distance from the central reading. Following the central measurement was the inferior cornea; then temporal cornea on the right eye or nasal on the left; superior cornea; ending with the nasal cornea on the right eye or temporal cornea on the left eye. Once the sequence was completed a printout provided the mean, deviation, and range of measurements at each of the five positions for each eye.

A Reynold's corneascope and comparator were used to qualify any corneal topographical changes that occurred. The pictures were placed in the comparator to determine a base curve which was compared to the keratometer measurements. The manufacturer's instructions were followed in operating both the corneascope and the comparator. Best photographic results were obtained with the corneascope

when the subject kept his cheek pressed against the cheek-rest with head tilted so the chin was closer to the instrument than the forehead. This positioning brought the cornea out from under the upper lid. After the subject had been aligned in the instrument, instructions were given to blink several times then widely open the eyes before the picture was taken.

Attempts were made to use the same phoropter and keratometer, but in a clinical setting such as Pacific University College of Optometry's, this was impossible. Significant variations in keratometry readings could have been introduced into the data since each keratometer was focused but not calibrated before use.

BASELINE

Prior to dispensing the Paraperm lenses, three sets of baseline data measurements were taken on each subject over the course of one week (see Appendix IV). The data was taken at the same time each day to minimize diurnal variations in corneal thickness, refraction, and corneal curvature. Following baseline data collection the Paraperm lenses were dispensed. At the time of dispensing modifications were made to ensure a good mechanical relationship of the lens to the cornea. Subjects were given instructions to continue wear on the same schedule as they had been using with their PMMA lenses. This was done so that changes observed were not due to differences in wearing time. In most cases the appointments for data

collection were after eight hours of lens wear.

Approximately 24 hours after the initial dispensing of the Paraperm lenses the subjects were seen again. The measurements taken during baseline data week were repeated. Subjects were seen four times during the two weeks following dispensing for further data collection. Tests were administered in the same order during baseline and follow-up data collection. The order of testing was: visual acuities through the contact lenses, over-refraction, and slit lamp evaluation of the lens fit; following removal of the lenses: pachometry, keratometry, visual acuities without the lenses, and a refraction. Corneascope pictures were taken of each subject while they were still wearing their PMMA lenses, and again two weeks after dispensing of the Paraperm lenses.

RESULTS AND DISCUSSION

Materials

During the course of the study four lenses were broken or damaged. One lens chipped and broke during modification, another shattered during initial cleaning, a third lens was broken by one of the subjects, and the fourth lens was chipped, but not broken during modification. The damage which occurred during modification and cleaning of the lenses is believed to be associated with the thin center thickness of the lenses combined with the flexibility of the material. Out of 24 lenses ordered for the study one was rejected for failure to meet specifications.

The initial diagnostic lenses used in the study were bicurve lenses from the AO MCM fitting set which incorporated relatively flat peripheral curves in comparison to the base curve (approximately 3 mm flatter). It is interesting to note that the lenses which were broken during modification were of the MCM design. PMMA lenses designed from the MCM set can apparently withstand the stress put on them better than the Paraperm polymer. A solution to this problem would be to increase the center thickness of the lenses, trading modifiability for other considerations.

After dispensing a number of the Paraperm lenses a majority of them were observed to fall to the limbus and could not be made to center well. The subjects were refit using the same base curve, but incorporating steeper

peripheral curves (ozr + 0.5 mm for the intermediate curve and ozr + 1.0 mm for the peripheral curve). The lab encountered difficulties in producing these specifications and substituted ozr + 1.0 mm for the intermediate curve and ozr + 1.5 mm for the peripheral curve. The steeper peripheral curves provided a better centering lens than the flat peripheral curves of the MCM design and changed the tear meniscus to a more favorable configuration.

Approximately 80 percent of the lenses were modified before they were dispensed. Most of the modifications were done because of poor edge design. Using the steeper peripheral curves produced a lens with thin edges and the lab recommended care in modification. If the lens was inserted concave side down into a 60 degree cone tool the edge would thicken and provide stability during modification so that edge chipping did not occur.

Inspection of the lenses with a shadowgraph revealed that regardless of the power, the lab used a standard 90 degree anterior bevel on every lens. In most cases this was not a problem, but the high minus lenses required modification of the anterior bevel with a cone tool. Appendix II has suggested tools for minus powers. The lens was inserted convex side down into the cone tool lined with mole skin or velveteen to round the junction of the bevel with the anterior surface of the lens.

Paraperm's modifiability was deemed fair, considering the parameter changes necessary to alleviate the problems with lens breakage.

Another problem encountered with the Paraperm lenses was their poor initial wettability. Some success in alleviating this problem was achieved by rubbing the lenses with a light solvent to remove a wax believed used in the final lens polish at the lab. This did not solve the problem completely and may have been detrimental to the lens. Another approach was to have the subject vigorously scrub both surfaces of the lens twice a day for two weeks. This seemed to help, but was tedious for the subjects.

LL/RL Ratio

When evaluating the fit of a contact lens using the LL/RL ratio, care must be taken to know which section of the lens (superior, central, or inferior) is being evaluated. During the study LL/RL ratio determinations were made observing the central part of the lens. Unless the lens has an alignment fit the ratio will vary between superior and inferior locations on the lens. If the lens has a steep fit the LL will be widest in the central part of the lens and if the lens has a flat fit the LL will be widest superiorly and inferiorly. These variations in the width of the LL are helpful in the evaluation of a contact lens fit, but the LL/RL ratio should be used along with fluorescein patterns and other observations before a final decision is made on the fit of a lens.

The LL/RL ratio was difficult to estimate with the Paraperm lenses since the polymer does not wet as well as PMMA. If the subject had a very aqueous tear composition the break up time on the front surface of the lens was

further shortened, making it harder to estimate the true width of the RL. The most accurate LL/RL ratio determinations were felt to be made immediately after the subject blinked as tear evaporation from the front surface of the lens had not yet begun.

The final point to be made concerning the LL/RL ratio is the need to specify a standard angle between the illumination system and the oculars. Although the ratio should remain the same no matter what this angle is, consistent interexperimenter determinations would be made if the angle was standardized.

Refractive Changes

The spherical component in ten of the fourteen post-refractions increased in myopia while the cylindrical component decreased in nine of the fourteen. Spherical equivalent data shows that the magnitude of increase in myopia was greater than the decrease in minus cylinder power.

As an increased amount of oxygen is available to the cornea when wearing a Paraperm material lens less corneal edema was expected. Assuming that long term PMMA wear would cause clinical or sub-clinical levels of edema this would manifest as a decrease in the amount of myopia in the post-refractions of the subjects. Appendix XI reveals that the majority of subjects actually showed an increase in myopia after two weeks of lens wear.

One explanation for the overall increase in myopia comes from the keratometry data. The steepening trend in

corneal curvatures outweighed the effects of any corneal thinning, producing an overall increase in the power of the eye. Most of the eyes which exhibited an increase in myopia had keratometry readings at least 0.50 D steeper at the end of two weeks of Paraperm wear than they did during baseline findings. Of the nine eyes whose spherical equivalents increased in myopia, four had an overall power increase of 0.50 D and five exhibited increases of up to 1.50 D over their baseline refractions.

A second explanation for the increased myopia is that the corneas were still fluctuating and had not stabilized after two weeks of Paraperm wear. One study indicated that corneal fluctuations continue for four to six weeks before stabilization occurs.[8,9]

Pachometry Changes

The graph in Appendix V illustrates the intrasubject and intersubject variability of the pachometry data. The mean corneal thickness for each subject's right eye in the central position is plotted against time. The dark line is the average reading of the seven subjects for each session and depicts a gradual trend of increasing corneal thickness at the end of the two week follow-up period.

Appendices VI and VII are the average readings of the seven subjects at each of the five measurement locations. Appendix VI is the right eye data and Appendix VII is the data from the left eye. The central cornea is the thinnest with the temporal cornea next, with the other locations being thicker. Each of the five locations show a thickening

trend from baseline to the end of the study.

The original hypothesis of corneal thickness decrease was not substantiated by the data. Results indicate that by the end of the second week of follow-up visits the corneas of nearly all subjects had thickened. These results proved to be somewhat misleading. Statistical analysis using analysis of variance of repeated measures showed corneal thickness changes to be insignificant due to high intrasubject variability (see Appendix IX). Calculations for each measurement position used the mean thickness values and did not include the deviation or range in considering the significance of the data. Measurements that had a small range and deviation were treated the same as data with a large deviation and range. Most measurements were taken toward the end of the day to minimize diurnal fluctuations, but this took away the randomization that statistics depend upon. Considering these facts it is difficult to determine whether the applied statistical tests were valid in concluding that the data was not statistically significant.

The left eye data of Appendix VII shows the most variability, especially at the temporal position. An explanation for this observation is the order that data was gathered. The right eye readings were taken first, followed by the left eye. The left temporal measurement was always taken last. Pachometry measurements took eight to ten minutes per session to gather data. Towards the end of this time the subjects were growing tired of

the restricted head movement required to take the readings and the constant concentration required. Experimenters also became fatigued. These factors could be the reason for the high variability in the left eye measurements.

A contributing factor in the variability of the reading from both eyes is tear evaporation. In the pachometer design both tear layer and corneal thickness are measured. Thus, the measurements will fluctuate depending on the length of time that the eye is held open, the individuals tear viscosity, and blink rate. A possible solution to this problem is to use fluorescein dye to differentiate the tear layer from the cornea during pachometry measurements.

A final observation on the pachometry readings had to do with the differences in corneal diameter between each subject. Those with smaller diameter corneas had the peripheral readings taken at a more limbal location than those with larger corneas. Since the cornea is thicker towards the limbus, higher readings were found at the peripheral locations on smaller diameter corneas. There is no compensating for this complication since it is inherent to the instrument design.

The thickening trends at the end of two weeks of wear were surprising. Statistical analysis concluded the changes in corneal thickness observed were not statistically significant, yet graphical analysis showed a thickening trend. We can neither conclude that the corneal thickness increased or decreased. A similar corneal thickening

pattern has been reported.[8] The cornea initially thickened for two weeks after being fit with gas permeable lenses then showed a decrease in thickness after four to six weeks. This is in agreement with our findings.

Keratometric Changes

Total changes in corneal cylinder ranging from 1.8 percent to 66 percent occurred between the baseline data and the conclusion of the study. Appendix IX illustrates the amount of baseline corneal cylinder in each eye, arranged from the largest amount to the smallest. The dioptric change in corneal cylinder after two weeks is shown in the right hand column. There seems to be no direct correlation between the original amount of corneal cylinder and the amount of change observed, but there are some trends. Those subjects having corneal cylinder greater than 1.25 D generally showed a decrease in the amount of cylinder; subjects with cylinder between 0.62 D and 1.25 D showed an increase in delta K; those with corneal cylinders less than 0.62 D showed a decrease in delta K. Males tended to show both a greater decrease in the magnitude of corneal cylinder and had a larger percentage of the eyes which showed decreases than the females.

Appendix X lists the average baseline keratometry readings and the amount of corneal cylinder present in each of the fourteen eyes at the time of baseline data. It also shows the average keratometry readings and corneal cylinder after two weeks of Paraperm wear. The columns labelled "delta K" and "percent change in corneal

cylinder" indicate the changes that took place between baseline and the follow-up period. The arrows indicate whether there was an increase or decrease in corneal cylinder.

Corneascope pictures give an average of .12 D flatter reading than the keratometer. This small amount is within the amount of error of both the keratometer and the comparator. This agrees favorably with the report that the comparator will give a base curve reading that is .25 D flatter than the keratometer will read. The qualification of the before and after pictures was difficult and therefore will not be discussed.

The hypothesis concerning keratometric changes was that when a PMMA wearer is refit with a gas permeable lens both corneal meridians tend to steepen, with the flattest meridian showing the most increase in curvature.[4] The greater increase in curvature in the flatter meridian tends to make the keratometric readings more spherical.

All but two of the fourteen eyes showed steepening keratometry readings in both meridians as expected, however, six of the fourteen exhibited an increase in corneal cylinder which was not expected. The six eyes which showed an increase in corneal cylinder also had corneal steepening in both meridians. Four of these six were fit with lenses which were 0.16 mm to 0.19 mm steeper than the flattest corneal meridian. Whether this was a factor in causing an increase in the amount of corneal cylinder is unknown.

Two eyes showed flattening in both meridians. The corneal cylinder in these two also decreased considerably. These were the only cases of alignment fit in the study, suggesting a possible correlation between fit and corneal change.

CONCLUSIONS

1. The best fitting characteristics were achieved when the Paraperm lenses had steep peripheral curves in relation to the base curve.

2. The wettability of the Paraperm material was not what we had expected given the reported wetting angle. Wetting seems to improve with cleaning and wearing.

3. The modifiability of the Paraperm polymer was deemed to be fair due to the lens breakage during modification procedures.

4. Pachometry data indicated that the cornea of most subjects thickened after two weeks of Paraperm wear. Analysis of the data using statistics found changes to be insignificant. The applicability of the analysis is questioned. We can neither conclude that the corneas increased or decreased in thickness.

5. The keratometry readings of nearly all subjects steepened after two weeks of Paraperm wear, but nearly half of the eyes exhibited an increase in corneal cylinder which was not expected.

6. At the end of two weeks of wear most subjects showed an increase in myopia in their post-refraction. The results may have been different if data had been gathered for a longer period of time.

7. The LL/RL ratio is a valuable tool in evaluating the fit of a contact lens. It should be combined with other observations such as the overall fluorescein pattern,

tear meniscus, and tear triangle when doing a complete contact lens workup.

SUGGESTIONS FOR FURTHER RESEARCH

1. Develop a method to alleviate the fatigue of both examiner and subject during pachometry measurements.

2. Do not take pachometry measurements in the same order at each session because of the statistical and increased variability introduced.

3. Use the same instruments each time for each subject to eliminate instrument variability.

4. Use fluorescein to differentiate the tear layer from the cornea when taking pachometry measurements.

5. Use a randomized clinical control type of format when doing a study of this nature.

6. Carry out follow up data for longer than two weeks to be sure that corneal stability has been reached.

APPENDIX I

Subject Demographic Data

	Total	Males	Females
average age	26.5 years	27.7 years	23.7 years
age range	22-43	22-43	22-28
average PMMA wearing time	7.07 years	2.62 years	6.3 years
PMMA wear range	2.5-20	4-20	2.5-10

APPENDIX II

Power to Cone Tool Modification Table*

Power	Cone
pl - 2.00	90°
2.25 - 4.00	100°
4.25 - 6.00	110°
greater than 6.00 D	120°

*As suggested by Dr. Don West.

APPENDIX III

DYER OC® NOMOGRAM THICKNESS CHART

Diameter (All Single Cut)

PLUS POWER

	6.5	7.0	7.5	8.0	8.5	9.0	9.5
	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch
+20.00 to +20.87	.40/.016	.45/.018	.51/.020	.58/.023	.65/.026	.72/.028	.84/.033
+19.00 to +19.87	.38/.015	.43/.017	.50/.020	.56/.022	.63/.025	.70/.028	.81/.032
+18.00 to +18.87	.37/.015	.42/.017	.48/.019	.54/.021	.60/.024	.68/.027	.78/.031
+17.00 to +17.87	.36/.014	.41/.016	.46/.018	.52/.020	.58/.023	.65/.026	.75/.029
+16.00 to +16.87	.35/.014	.40/.016	.45/.018	.50/.020	.56/.022	.63/.025	.72/.029
+15.00 to +15.87	.34/.013	.38/.015	.43/.017	.48/.019	.53/.021	.60/.024	.68/.027
+14.00 to +14.87	.32/.013	.36/.014	.41/.017	.46/.018	.51/.020	.57/.022	.64/.025
+13.00 to +13.87	.31/.012	.35/.014	.39/.015	.44/.017	.49/.019	.55/.022	.61/.024
+12.00 to +12.87	.30/.012	.34/.013	.38/.015	.42/.017	.47/.019	.52/.020	.58/.023
+11.00 to +11.87	.28/.011	.32/.013	.36/.014	.40/.016	.44/.017	.49/.019	.55/.022
+10.00 to +10.87	.27/.011	.31/.012	.35/.014	.38/.015	.42/.017	.47/.019	.52/.020
+9.00 to +9.87	.26/.010	.29/.011	.33/.013	.36/.014	.39/.015	.44/.017	.49/.019
+8.00 to +8.87	.25/.010	.28/.011	.31/.012	.34/.013	.37/.015	.41/.016	.46/.018
+7.00 to +7.87	.24/.009	.27/.011	.30/.012	.32/.013	.35/.014	.39/.015	.43/.017
+6.00 to +6.87	.23/.009	.25/.010	.28/.011	.30/.012	.33/.013	.36/.014	.39/.015
+5.00 to +5.87	.21/.008	.24/.009	.26/.010	.28/.011	.30/.012	.33/.013	.37/.015
+4.00 to +4.87	.20/.008	.22/.009	.24/.009	.26/.010	.28/.011	.31/.012	.34/.013
+3.00 to +3.87	.18/.007	.20/.008	.22/.009	.24/.009	.26/.010	.28/.011	.31/.012
+2.00 to +2.87	.17/.007	.19/.007	.21/.008	.22/.009	.24/.009	.26/.010	.28/.011
+1.00 to +1.87	.16/.006	.17/.007	.19/.007	.20/.008	.22/.009	.23/.009	.25/.010
0 to + .87	.16/.006	.16/.006	.17/.007	.18/.007	.19/.007	.21/.008	.22/.009

Diameter

MINUS POWER

	6.5	7.0	7.5	8.0	8.5	9.0	9.5
	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch	mm-inch
0 to — .87	.16/.006	.16/.006	.16/.006	.16/.006	.16/.006	.16/.006	.16/.006
—1.00 to —1.87	.15/.006	.15/.006	.15/.006	.15/.006	.15/.006	.15/.006	.15/.006
—2.00 to —2.87	.14/.006	.14/.006	.14/.006	.14/.006	.14/.006	.14/.006	.14/.006
—3.00 to —3.87	.13/.005	.13/.005	.13/.005	.13/.005	.13/.005	.13/.005	.13/.005
—4.00 to —4.87	.12/.005	.12/.005	.12/.005	.12/.005	.12/.005	.12/.005	.12/.005
—5.00 and up				.10/.004			

FOR OC LENSES A THICKNESS BELOW .10 mm. OR .004" IS NOT RECOMMENDED.

LABORATORY TOLERANCE PLUS OR MINUS .02 mm

NT_____ APPENDIX IV NUMBER_____

BASELINE DATA

TIME_____

	Habitual Rx Distance	Habitual Rx Near
OD	/	/
OS	/	/
OU	/	/

20/		
20/	4	
	5	
20/		
20/		
20/	7	
20/		
20/		
20/	7A	

METRY TIME_____

tach printout)

TOMETRY OD

_____@_____ _____@_____

_____@_____ _____@_____

_____@_____ _____@_____

OS

_____@_____ _____@_____

_____@_____ _____@_____

_____@_____ _____@_____

CTION

	Unaided Acuity Distance	Unaided Acuity Near
OD	/	/
OS	/	/
OU	/	/

20/		
20/	4	
	5	
20/		
20/		
20/	7	
20/		
20/		
20/	7A	

DATE_____ TIME_____

WTT_____

	Habitual Rx Distance	Habitual Rx Near
OD	/	/
OS	/	/
OU	/	/

OD		20/
OS	4	20/
OD		
OS	5	
OD		20/
OS		20/
OD	7	20/
OS		20/
OD		20/
OS	7A	20/

PACHOMETRY TIME_____

(attach printout)

KERATOMETRY OD

1._____@_____ _____@_____

2._____@_____ _____@_____

3._____@_____ _____@_____

OS

1._____@_____ _____@_____

2._____@_____ _____@_____

3._____@_____ _____@_____

REFRACTION

	Unaided Acuity Distance	Unaided Acuity Near
OD	/	/
OS	/	/
OU	/	/

OD		20/
OS	4	20/
OD		
OS	5	
OD		20/
OS		20/
OD	7	20/
OS		20/
OD		20/
OS	7A	20/

DATE_____ TIME_____

WTT_____

	Habitual Rx Distance	Habitual Rx Near
OD	/	/
OS	/	/
OU	/	/

OD		20/
OS	4	20/
OD		
OS	5	
OD		20/
OS		20/
OD	7	20/
OS		20/
OD		20/
OS	7A	20/

PACHOMETRY TIME_____

(attach printout)

KERATOMETRY OD

1._____@_____ _____@_____

2._____@_____ _____@_____

3._____@_____ _____@_____

OS

1._____@_____ _____@_____

2._____@_____ _____@_____

3._____@_____ _____@_____

CORNEASCOPE PICTURES

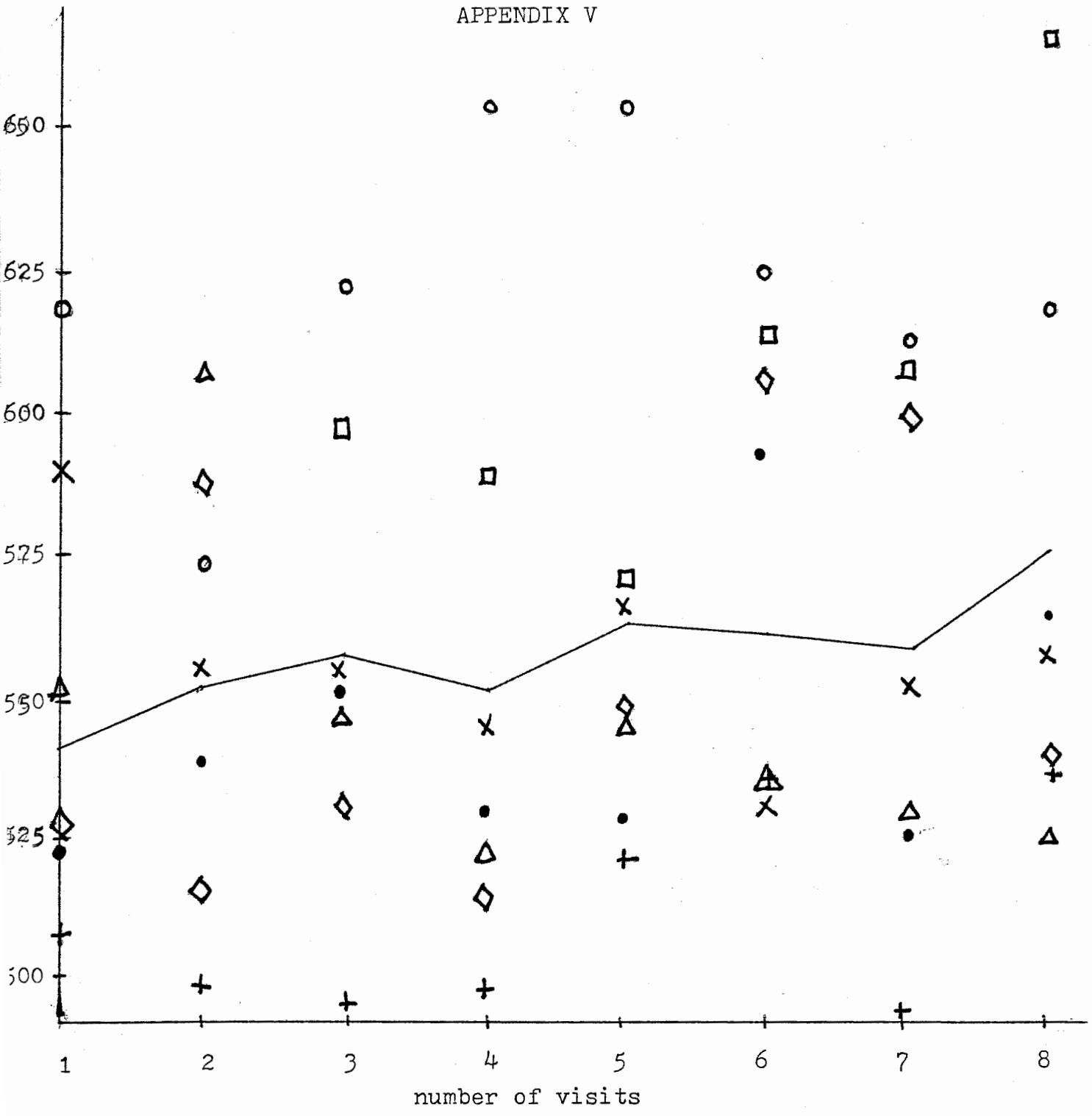
(attach pictures)

REFRACTION

	Unaided Acuity Distance	Unaided Acuity Near
OD	/	/
OS	/	/
OU	/	/

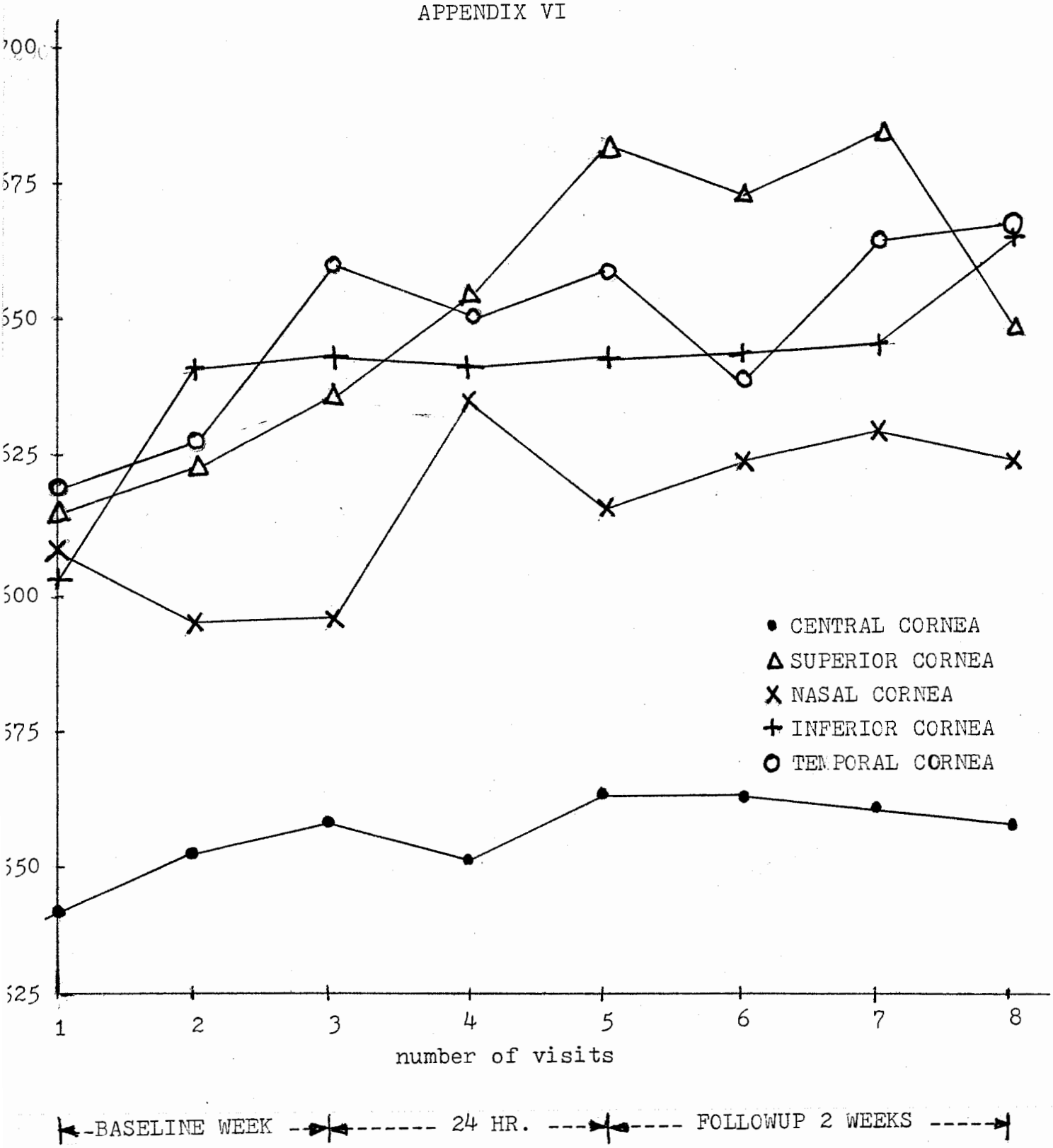
OD		20/
OS	4	20/
OD		
OS	5	
OD		20/
OS		20/
OD	7	20/
OS		20/
OD		20/

APPENDIX V



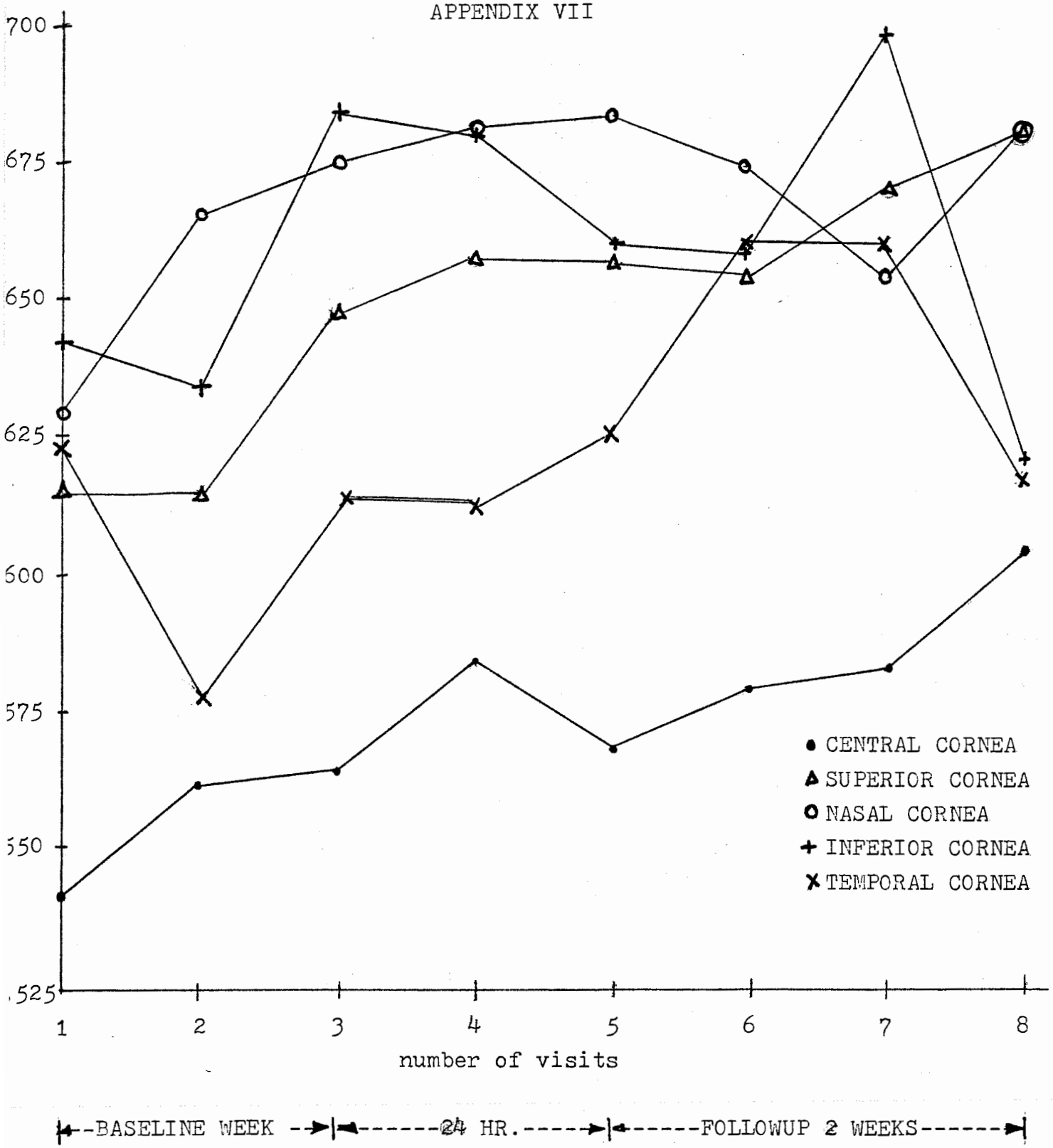
INDIVIDUAL CENTRAL CORNEAL THICKNESS VARIATIONS
RIGHT EYE

APPENDIX VI



THICKNESS AVERAGE FOR ALL SUBJECTS
RIGHT EYE

APPENDIX VII



THICKNESS AVERAGE FOR ALL SUBJECTS
LEFT EYE

APPENDIX VIII

Statistical Analysis Results

	sum of squares	degrees of freedom	mean square	F value
OD L-1				
category means	.0636	7	.00109	1.02
within means	.0527	48	.00107	
total	.1163	55		
OD L-2				
category means	.0764	7	.00734	1.49
within means	.258	48	.00492	
total	.334	55		
OD L-4				
category means	.248	7	.00445	0.866
within means	.247	48	.00515	
total	.495	55		
OD L-6				
category means	.126	7	.00216	1.17
within means	.0924	48	.00184	
total	.218	55		
OD L-8				
category means	.144	7	.00307	1.51
within means	.106	48	.00203	
total	.251	55		
OS L-1				
category means	.071	7	.00693	1.57
within means	.233	48	.00441	
total	.304	55		

	sum of squares	degrees of freedom	mean square	F value
OS L-2				
category means	.0277	7	.00363	0.382
within means	.423	48	.00948	
total	.451	55		
OS L-4				
category means	.352	7	.00476	0.624
within means	.354	48	.00763	
total	.707	55		
OS L-6				
category means	.0751	7	.00509	0.997
within means	.250	48	.00511	
total	.325	55		
OS L-8				
category means	.194	7	.00462	0.803
within means	.274	48	.00575	
total	.468	55		

For the data to be statistically significant the F value must be greater than $F_{.95}(7,48) = 2.20$

The L = location

The numbers stand for the area of the cornea:

1 = central cornea

2 = superior cornea

4 = nasal cornea of OD and temporal cornea for OS

6 = inferior cornea

8 = temporal cornea of OD and nasal cornea for OS

APPENDIX IX

Changes in Corneal Cylinder

amount of baseline corneal cylinder	direction of change	amount of change in the corneal cylinder
2.79 D	decrease	0.26 D (9.3%)
2.54 D	decrease	0.36 D (14.0%)
1.71 D	increase	0.04 D (2.3%)
1.54 D	decrease	0.44 D (27.2%)
1.54 D	decrease	0.27 D (17.5%)
1.45 D	decrease	0.13 D (9.0%)
1.29 D	decrease	0.29 D (22.5%)
1.21 D	increase	0.54 D (44.6%)
1.08 D	increase	0.02 D (1.8%)
1.00 D	increase	0.25 D (25.0%)
0.70 D	increase	0.22 D (31.0%)
0.54 D	increase	0.07 D (13.0%)
0.54 D	increase	0.16 D (30.0%)
0.45 D	decrease	0.30 D (66.0%)

APPENDIX X

	OD		OS	
	Horiz./Vert.	ΔK	Horiz./Vert.	ΔK
411				
Pre-wear:				
K_f	42.62/42.87		43.00/42.37	
K_s	42.62/43.50		43.25/42.87	
K_a	42.62/43.12	.45	43.08/42.54	.54
Post-wear:				
K_f	42.37/42.25		42.87/42.37	
K_s	42.62/42.75		43.25/42.75	
K_a	42.47/42.55	.15 (66%)	43.10/42.62	.47 (13%)
412				
Pre-wear:				
K_f	43.25/44.50		43.00/44.87	
K_s	43.75/44.50		43.50/45.12	
K_a	43.50/44.50	1.00	43.29/45.00	1.71
Post-wear:				
K_f	43.50/44.37		43.25/45.12	
K_s	44.00/45.50		44.00/45.87	
K_a	43.70/44.95	1.25 (25%)	43.70/45.45	1.75 (2.3%)
413				
Pre-wear:				
K_f	43.37/46.00		43.00/45.25	
K_s	43.75/46.75		43.12/46.00	
K_a	43.54/46.33	2.79	43.04/45.58	2.54
Post-wear:				
K_f	43.50/45.62		43.87/46.00	
K_s	44.12/46.50		44.50/46.75	
K_a	43.77/46.30	2.53 (9.3%)	44.07/46.25	2.18 (14%)

	OD		OS	
	Horiz./Vert.	ΔK	Horiz./Vert.	ΔK
414				
Pre-wear:				
K_f	43.50/44.37		43.50/44.50	
K_s	44.00/45.87		44.00/45.00	
K_a	43.87/45.25	1.45	43.75/44.87	1.08
Post-wear:				
K_f	44.25/45.87		44.00/45.25	
K_s	45.50/46.37		44.50/45.50	
K_a	44.85/46.17	1.32 (9%)	44.20/45.30	1.10 (1.8%)
421				
Pre-wear:				
K_f	41.62/43.75		42.00/43.62	
K_s	42.50/43.87		42.50/43.87	
K_a	41.95/43.83	1.21	42.25/43.87	1.54
Post-wear:				
K_f	42.25/44.00		42.62/43.75	
K_s	42.50/44.37		42.87/44.87	
K_a	42.45/44.20	1.75 (44.6%)	42.75/43.87	1.12 (27.2%)
424				
Pre-wear:				
K_f	41.37/42.12		41.37/42.12	
K_s	42.00/43.00		42.00/43.00	
K_a	41.72/42.54	.92	41.77/42.47	.70
Post-wear:				
K_f	41.37/42.00		41.37/41.87	
K_s	41.37/42.12		41.50/42.12	
K_a	41.37/42.12	.70 (31%)	41.45/42.00	.54 (30%)

	OD			OS		
	Horiz./Vert.	ΔK		Horiz./Vert.	ΔK	
426						
Pre-wear:						
K_f	42.62/44.25			43.00/44.12		
K_s	42.87/44.62			43.25/45.00		
K_a	42.78/44.08	1.29		43.12/43.74	1.54	
Post-wear:						
K_f	42.12/43.12			43.00/44.12		
K_s	42.62/43.75			43.12/44.75		
K_a	42.45/43.42	1.00	(22.5%)	43.02/44.30	1.27	(17.5%)

K_f = flattest corneal meridian

K_s = steepest corneal meridian

K_a = average between the corneal meridians

% refers to the amount of change in corneal cylinder between the pre-wear and the post-wear data

numbers refer to the subjects

APPENDIX XI

Figure 6: Refractive Changes

Subject no.		Baseline	24 Hr. Af. Disp.	Second Week
411	OD	-9.50-1.00x30	-9.00-1.00x44	-9.25-.50x75
	OS	-4.25-1.00x90	-4.00-.75x93	-4.75-.75x89
Eq. Sph.	OD	-10.00	-9.50	-9.50
	OS	-4.75	-4.37	-5.12
412	OD	-2.00-.75x15	-.50-1.25x180	-.50-1.50x10
	OS	-1.50-1.25x155	-.75-2.00x165	-1.00-1.00x170
Eq. Sph.	OD	-2.37	-1.25	-1.25
	OS	-2.12	-1.75	-1.50
413	OD	-1.75-2.00x175	-2.00-2.50x180	-2.50-2.25x180
	OS	-1.50-1.75x10	-2.25-2.00x5	-2.50-1.50x180
Eq. Sph.	OD	-2.75	-3.25	-3.75
	OS	-2.37	-3.25	-3.25
414	OD	-1.50-1.50x165	-1.75-1.75x180	-2.75-1.00x165
	OS	-2.00-.75x155	-2.25-.50x180	-2.75-.50x155
Eq. Sph.	OD	-2.25	-2.62	-3.75
	OS	-2.37	-2.50	-3.00
421	OD	-3.50-1.50x180	-4.25-1.75x138	-4.75-1.25x175
	OS	-3.75-.75x2	-4.00-1.25x32	-4.75-.50x25
Eq. Sph.	OD	-4.25	-5.12	-5.37
	OS	-4.12	-4.62	-5.00
424	OD	-1.25	-1.75	-1.75
	OS	-1.00	-1.75	-1.50
Eq. Sph.	OD OS	Same	Same	Same
426	OD	-4.75-1.50x180	-4.25-1.00x15	-2.50-.75x15
	OS	-4.00-1.00x180	-4.25-1.25x15	-4.25-1.25x50
Eq. Sph.	OD	-5.50	-4.75	-4.87
	OS	-5.00	-4.87	-4.87

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