4-2-1983

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2 April 1983

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Acknowledgements

The authors would like to thank Dr. Lynn Coon for his guidance throughout this project.

We would also like to thank Dr. John Roggenkamp and Dr. Don West for their clinical advice and technical knowledge.

We are deeply grateful to Syntex Ophthalmics, Inc., for their continued support of this project; particularly for the provision of Polycon II diagnostic lenses and complimentary lenses to our patients. Especially important in our interaction with Syntex Ophthalmics, Inc., were Dr. Michael Simons and Debbie Ryan.

Another thank you goes out to Beta Sigma Kappa (BSK) honor fraternity and the Oregon Optometric Association (OOA) for providing financial assistance to defray research costs.

Finally, we thank Pacific University for making available clinic facilities during the research.

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I. Statement of Problem

The hard contact lens, specifically that made of PMMA, has long been the standard by which corneal astigmatism has been neutralized in contact lens wearers. However, due to problems occurring from long-term wear or the anoxic conditions which may be created by PMMA lenses, other lens materials must be found to replace PMMA as a contact lens correction for astigmatism. So far it seems that toric hydrophilic soft lenses have not had the success that had been anticipated by their manufacturers. The relatively new gas permeable lenses are enjoying a rapid growth in the contact lens market and their usefulness in neutralizing corneal cylinder still needs to be investigated.

In our research, we attempted to determine the effectiveness of masking corneal cylinder using the 8.5, 9.0, and 9.5 mm diameter Polycon II (Silafocon A) lenses. Also, we intended to develop a correlation between peripheral corneal topography and the amount of corneal cylinder that can be masked using Polycon II lenses. In the past, the ability of Polycon II lenses to mask corneal cylinder has been debated due to its flexible nature as compared to other rigid contact lenses.

II. Literature Survey

The usage of contact lenses has been increasing ever since their development. This can probably be attributed to the number of improvements made in lens materials, lens parameters, and a better understanding of corneal physiology. Most of the advances today involve new gas permeable materials and thinner lens designs to prevent anoxic conditions from occurring at the corneal surface. With these improvements arise questions about lens flexure and its effect on residual astigmatism. According to Wechsler,[1] ". . . little has been written about the clinical effect of lens flexure in the case of these oxygen permeable lenses."

Much of the research concerning contact lens flexure and residual astigmatism has been done by Michael G. Harris, an O.D. at the University of California, School of Optometry. In a preliminary study done back in 1970,[2] Harris looked at the effects of contact lens thickness and diameter on residual astigmatism. In his study, residual astigmatism was defined as the astigmatic refractive error present when a contact lens is used to correct existing ametropia. This residual astigmatism can be altered by the bending or flexing of a contact lens on an eye. He used two subjects with normal corneas, one with no significant corneal toricity and one with over 3.00 D. of corneal cylinder. Twelve PMMA lenses were ordered for each cornea and the lenses were identical except for thickness and diameter. Overall diameters used were 8.0, 8.5, and 9.4 mm. Thickness of the lenses was varied between .08 mm and .20 mm. Both base curve and front surfaces were measured prior to insertion to insure sphericity. After the lens settled, a sphero-cylindrical refraction was done and keratometry (K) readings of the front surface of the contact lens were taken. The same phoropter and keratometer were used throughout. From 10 cylindrical refractions, a standard deviation of ± .12 D. was found while for 10 K readings there was a standard deviation of ± .12 D. in both meridians. The results showed that for spherical corneas, an average flexure of +.12 DC. x 180 ± .12 DC. and residual astigmatism of -.25 DC. x ± .15 DC. were found. Neither finding was deemed significant, nor was any different in lens flexure or residual astigmatism found for different lens thickness or diameter. For the toric corneas, no difference was found for various lens diameters, but differences were found for various lens thicknesses. No significant flexure or change in residual astigmatism was found for lenses of center thicknesses greater than 0.12 mm. For lenses less than 0.12 mm thick, Harris found average flexure of +.52 DC. x 180 ± .20 DC. and associated residual astigmatism of -.35 DC. x 180 ± .15 DC. He concluded that factors affecting lenses on corneas, such as lid pressure, adhesion, and surface tension, have more influence on thin lenses. Bailey[3] believed the flexure to be about one-half the corneal toricity and also that large lenses flex more than small lenses. On the other hand, Harris found flexure to be about one-fifth the corneal toricity.

In several articles,[2,4,5] Harris proposed how induced cylinder due to lens flexure could be used to counter the predicted or measured residual astigmatism in some cases. For example, if the predicted or measured residual astigmatism with thick lenses (i.e. greater than .12 mm thick) is against-the-rule, a thin lens will reduce the residual astigmatism by the amount of lens flexure (K). If the residual astigmatism is with-the-rule, a thin lens will increase the residual astigmatism by K. The opposite would be true for an against-the-rule cornea.

Further study concerning the effect of lens thickness and corneal toricity on flexure and residual astigmatism was done by Harris and Chu.[5] They used five college students, age 17 to 24 years with corneal toricities varying from spherical to 6.12 DK with-the-rule. The PMMA lenses used were identical except for center thickness. The thickness varied from .08 mm to .12 mm in .01 mm steps and from .12 mm to .20 mm in .02 mm steps. After each lens settled, K readings were taken to determine lens flexure. Results showed that on spherical or nearly spherical corneas (K less than .50 DK) none of the lenses flexed significantly. However, significant lens flexure was found on toric corneas. Thick lenses (ct greater than .13 mm) did not flex significantly on toric corneas, while thin lenses (ct less than .13 mm) did. In general, on a toric cornea lens flexure and residual astigmatism increased as center thickness decreased. For a given thickness the amount of flexure and associated residual astigmatism increased as the corneal toricity increased in a predictable manner.

Harris and Appelquist[6] studied the effects of lens diameter and power on flexure and residual astigmatism. They used five college students, age 21 to 26 years, as subjects. They had corneal toricities ranging from spherical to 3.00 DK with-the-rule. The study was done in two parts, the first part involving diameter and the second part involving lens power. For the first part the lenses were PMMA with diameters varying from 8.00 mm to 10.0 mm in

.5 mm steps. All other parameters were kept constant except the optic zone diameter which was proportionally increased with the overall diameter. For the second part, the lenses varied in power from -2.00 DS to -10.00 DS in 2.00 DS increments. All other parameters were kept constant. A center thickness of .10 mm was used to allow for lens flexure. The lenses were alternated between right and left eyes and K readings were taken over the lenses once they had settled, to determine flexure. Their results showed that varying the lens diameter did not cause a significant change in lens flexure or residual astigmatism on spherical or toric corneas. This would indicate that factors other than eyelid pressure are involved in causing flexure. As for varying the lens power, no significant difference in lens flexure or residual astigmatism was seen on spherical corneas, but flexure and residual astigmatism were seen to decrease as minus power increased, on toric corneas. Again, the changes found increased as the toricity increased. Since all parameters except front surface curvature and edge thickness (which varies with power) were identical, it would appear that increased edge thickness was the cause of the decreased flexure.

A study published in 1974, was performed by Kimball and Mandell[7] using so called "ultrathin" lenses. They used right eyes of ten subjects. The toricities varied from spherical to -2.12 DS with-the-rule. The lenses were fit between .50 D steeper and .50 D flatter than K. The powers used were -2.62 D to -3.25 D and center thickness varied from .07 mm to .10 mm. Approximately eight lenses were tried on each patients. Five to ten minutes were allowed to let the lens settle, after which K readings and a sphero-cylindrical over-refraction was done. Their conclusion was that the base curve of ultrathin contact lenses had little effect on residual astigmatism and lens flexure.

Since the introduction of the gas permeable Polycon lens in the late 1970's, very little literature has been published regarding Polycon lens flexure and residual astigmatism. The Polycon lens is a copolymer of approximately 70 percent methyl methacrylate and 30 percent silicone derivative.[8] It is optically stable, wettable, capable to be manufactured to a minimal lens thickness and according to Williams, has flexure characteristics similar to PMMA.[9]

C.E. Williams published a study in 1979 involving 73 patients.[10] Overall diameter, edge thickness, power and optic zone diameter were all held constant with only center thickness varied. Data included: corneal keratometry readings, keratometry readings over the lens being tested for flexure and a sphero-cylindrical over refraction. Williams found flexure with the Polycon lens to be "regular" and "irregular" flexure only occurred with an extremely thin lenses coupled with a moderately toric cornea (especially an against-the-rule toric cornea). As center thickness was decreased, lens flexure increased although a minimal thickness desired for good oxygen transmission could be used without flexure problems. For with-the-rule corneas with up to 2.00 D of corneal toricity, Williams found lens flexure to be approximately 20 to 30 percent of the total corneal toricity. For corneas with corneal with-the-rule toricity greater than 2.00 D, flexure was usually less than or equal to 20 percent with occasional cases of more severe flexure. Williams therefore concluded, as stated previously, that Polycon lenses have flexure characteristics similar to PMMA lenses.

This Polycon-PMMA flexure similarity has been disputed in the very latest study published by Michael G. Harris et. al.[11] Harris took eight subjects (sixteen eyes) with corneal toricities ranging from 1.25 D to 4.25 D and fitted each subject with four pairs of PMMA and Polycon lenses with identical parameters. They were all 9.5 mm in overall diameter with a -3.00 D power. Only lens center thickness was varied, from 0.07 to 0.16 mm in 0.03 mm steps. Three investigators were utilized, one to verify the base curve before insertion and after removal to insure lens sphericity, another to take keratometry readings over the lens and another to perform a spherocylindrical over refraction. Results showed that Polycon lenses flexed significantly more than PMMA lenses of similar center thickness. The mean difference between PMMA and Polycon lenses was reported to be 0.37 D for both flexure and residual astigmatism. Generally, a 0.13 mm thick Polycon lens flexed the same amount as a 0.10 mm thick PMMA lens and a 0.10 thick Polycon lens flexed the same amount as a 0.07 mm thick PMMA lens. Harris finished by stating that previous studies show overall diameter and base curve have no effect on PMMA lens flexure but, "further studies with Polycon lenses of different dimensions are needed before making similar conclusions for Polycon lenses."[12]

III. Experimental Design

A. Subject Selection

A sample population of 26 eyes was chosen. A minimum criterion of 1.00 diopters of corneal cylinder per eye, as measured by the Bausch and Lomb keratometer, was used in patient selection. Fourteen out of the 26 eyes had no recent history of contact lens wear (i.e. 6 months). Of the 12 contact lens wearing eyes, 4 wore soft contact lenses, 4 wore gas permeable lenses, and 4 wore PMMA lenses.

Relative to the corneal cylinder measured, 24 of the eyes had with-the-rule corneal cylinder and 2 of the eyes had oblique principal meridians. The amount of corneal cylinder ranged from 1.125 diopters to 4.00 diopters. (See Appendix A.)

All of the subjects selected were of good health and free from ocular pathology.

B. Methodology

Data collection was done at Pacific University College of Optometry, Forest Grove Clinic. Standard optometric equipment such as phoropter and biomicroscope were used, as well as a Canon Autorefractor (AUTOREF R-1, T.V. monitor and AUTOREF PRINTER R-P)* and an IDI Corneascope.* Polycon II trial lenses were provided by Syntex Ophthalmics, Inc.

With the selected patient population, baseline data of corneal topography was taken with the corneascope and baseline refractive status was taken with the Canon AUTOREF.

Each eye was then successively fit with 8.5, 9.0 and 9.5 mm overall diameter lenses. In pre-experimental trials, a fitting procedure was established to standardize the contact lens fits. 9.5 overall diameter lenses were fit to align with the flattest keratometry reading ("on flat K"), 9.0 overall diameter lenses were fit steeper than the flattest keratometry meridian by a factor of one-fifth the corneal cylinder $(K_f + \frac{K}{5})$ and the 8.5 overall diameter lenses were fit steeper than the flattest keratometry meridian by a factor of one-half the corneal cylinder $(K_f + \frac{K}{2})$.

Corneascope photographs were then taken over the contact lenses to determine the amount of lens flexure and thereby to indirectly determine the amount of corneal cylinder masked. The residual refractive status was determined through use of the Canon AUTOREF R-1, through the contact lenses. This made available another indirect objective means of determining the amount of corneal

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*More information on these instruments included in Appendices B and C.

cylinder masked.

Through statistical means, an attempt was then made to show a correlation between lens overall diameter and the amount of corneal cylinder masked. Flexure was determined in two ways with the corneascope data. First, corneascope pictures over the contact lens allowed determination of an "A-factor" or difference in radii of curvature in the horizontal and vertical meridians. This A-factor with the lens treatment was compared to the A-factor as derived from the subject's bare cornea. The difference in the A-factors gave us a quantitative idea of the lens flexure. The second means of flexure magnitude determination involved measurement of the Polycon II lens anterior radius of curvature prior to its use as the diagnostic lens. Comparison of these so-called "resting" radii of curvatures with the anterior radii of curvature of the lens on the cornea (as determined by the corneascope readings) gave us another measure of lens flexure.

All lenses used in this study were taken from a standard inventory set of Polycon II lenses. The center thickness of all 9.5 mm and 9.0 mm overall diameter lenses was .11 mm. For the 8.5 mm diameter lenses, all base curves less than or equal to 8.00 mm had center thicknesses of .10 mm, while the 8.10 and 8.20 base curves were .08 mm thick. All lenses were −3.00 diopters in power.

IV. Results

The data was first approached by separating it according to a particular ring number on each corneascope picture. The innermost ring was called Ring 1 and each of the successive rings were sequentially numbered on out to the outermost ring, Ring 9. As a matter of practicality, only the four innermost rings were considered since these are the ones most involved with vision. The diameter along the cornea corresponding to the width of the fourth ring was approximately 3.75 mm.

Since measurements were made in both the horizontal and vertical meridians, the difference between them was calculated to come up with a so-called A-factor. In all cases, the radius of curvature in the vertical meridian was subtracted from the radius of curvature in the horizontal meridian, at each particular ring.*

A Single Factor Analysis of Variance (SANVAR) was run to look for any significant differences between the A-factor on a bare cornea and the A-factors calculated from the 8.5, 9.0, and 9.5 mm overall diameter lenses, respectively, at a particular ring. All 26 eyes were treated together. (See Table 1 for results.)

The F values calculated by SANVAR show an increasing amount of significance between Ring 1 and Ring 4. Except for Ring 1, the other three rings show significance at the 0.5 percent (.005) criterion level, and even down to the 0.1 percent (.001) criterion level.

The student's t-value was then computed between the following sets of data:

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*In two eyes with definite oblique corneal cylinder, the 135° meridian was subtracted from the 45°.

1. X = A-factor from Ring 1 of bare cornea.
   Y = A-factor from Ring 1 of 8.5 mm lens.
2. X = A-factor from Ring 1 of bare cornea.
   Y = A-factor from Ring 1 of 9.0 mm lens.
3. X = A-factor from Ring 1 of bare cornea.
   Y = A-factor from Ring 1 of 9.5 mm lens.
4. X = A-factor from Ring 2 of bare cornea.
   Y = A-factor from Ring 2 of 8.5 mm lens.
5. X = A-factor from Ring 2 of bare cornea.
   Y = A-factor from Ring 2 of 9.0 mm lens.
6. X = A-factor from Ring 2 of bare cornea.
   Y = A-factor from Ring 2 of 9.5 mm lens.
7. X = A-factor from Ring 3 of bare cornea.
   Y = A-factor from Ring 3 of 8.5 mm lens.
8. X = A-factor from Ring 3 of bare cornea.
   Y = A-factor from Ring 3 of 9.0 mm lens.
9. X = A-factor from Ring 3 of bare cornea.
   Y = A-factor from Ring 3 of 9.5 mm lens.
10. X = A-factor from Ring 4 of bare cornea.
    Y = A-factor from Ring 4 of 8.5 mm lens.
11. X = A-factor from Ring 4 of bare cornea.
    Y = A-factor from Ring 4 of 9.0 mm lens.
12. X = A-factor from Ring 4 of bare cornea.
    Y = A-factor from Ring 4 of 9.5 mm lens.

Table 2 shows a summary of the above t-values.

From Table 2 it can be seen that all lenses showed a greater amount of significant corneal cylinder masking, at the .01 (1%)

level, on the outer rings, i.e. Rings 3 and 4. Looking at Ring 1, only the 9.0 mm lens showed significant corneal cylinder masking, while on Ring 2, both the 9.0 mm and 9.5 mm lenses showed significance at the .01 (1%) level.

Although there were differences between the rings, it was decided to separately average the horizontal and vertical measurements of Rings 1 through 4 for the bare cornea and each diameter of lens. From those averages a single A-factor was calculated for each treatment. For example, each eye had an A-factor for the bare cornea, one for the 8.5 mm lens, one for the 9.0 mm lens, and finally, one for the 9.5 mm lens. The averaged A-factors are shown in Table 3.

SANVAR was then run on the averaged A-factor to determine if there was still significance between lens treatments. As found before with the individual rings, the F-value was definitely significant at both the .5 percent (.005) and .1 percent (.001) criterion levels.

Next, the student's t-values were calculated to determine the differences between the lens treatments. A-factors from the bare corneas were successively compared to A-factors from the 8.5 mm, the 9.0 mm, and the 9.5 mm lenses. The results of the comparisons are shown in Table 4. All three comparisons showed a significant masking of corneal cylinder at the .01 (1%) criterion level. The 9.0 mm lens displayed the highest t-value and highest corneal cylinder masking as shown by the mean difference. The 8.5 mm lens had the next highest t-value, followed by the 9.5 mm lens. However, the mean difference between A-factors was greater for the 9.5 mm lens than the 8.5 mm lens. This meant that the 9.5

mm lens was able to mask a greater amount of corneal cylinder than the 8.5 mm lens, but did so in a less consistent manner.

The 26 eyes were then separated into two groups. The first group was categorized as "high astigmats" and were made up of eyes which had corneal A-factors greater than or equal to .20 mm. This group had a sample size of 12. The second category was called "low to moderate astigmats" and had corneal A-factors less than or equal to .20 mm. (See Table 5.) There were 14 eyes in this second group. As before, the student's t-values were calculated within each group by comparing the base cornea with each diameter of lens separately. Table 6 is a summary of those calculations.

Looking at the high astigmat group, all lenses showed significant corneal cylinder masking at the .01 (1%) criterion level. The 8.5 mm lens had the highest t-value, followed by the 9.0 mm lens, and then the 9.5 mm lens. The largest amount of corneal cylinder masked, however, was shown by the 9.0 mm lens, which had the largest mean difference. This was closely followed by the 9.5 mm lens, while the 8.5 mm lens masked the least. By also taking into account the standard deviation of the mean differences, the 9.0 mm lens appears to be the lens which can most consistently mask the greatest amount of corneal cylinder. Behind it somewhat would follow both the 9.5 mm and 8.5 mm lenses. Though the 9.5 mm lens masks a greater amount of cylinder, its standard deviation is twice as large as that of the 8.5 mm lens, making them nearly equal in masking ability.

When the low to moderate astigmats are considered, only the 9.0 mm and 8.5 mm lenses are significant at the .01 (1%) criterion level. The 9.0 mm lens has the largest t-value and the largest mean difference by far, masking more than twice the amount of corneal cylinder as the 8.5 mm lens, while still having nearly the same standard deviations. The 9.5 mm lens did have a larger mean difference than the 8.5 mm lens, but the 9.5 mm lens also had a larger standard deviation and its masking effects were more apt to occur by chance than either that of the 9.0 mm or 8.5 mm lenses.

Tables 7 through 9 illustrate another method used to measure lens flexure on toric corneas. The radii of curvature were measured on the anterior surface of all lenses at rest and these values were compared to the average horizontal and average vertical radii of curvature of the lenses while on the eye. Again, the bare cornea was compared to the 8.5 mm, 9.0 mm, and 9.5 mm lenses separately.

Table 10 shows the results of t-value calculations. For all three diameters of lenses, the horizontal meridian showed very low and insignificant t-values, meaning that any changes in curvature in that meridian were very small and probably occurred by chance. On the other hand, t-values for the verticial meridian showed significance at the .01 (1%) criterion level for all diameters of lenses. Of the three lens diameters, the 9.0 mm lens had the lowest t-value and smallest mean difference. This supported the results found previously, in which the 9.0 mm lens was found to mask the most corneal cylinder and flex the least. The 9.5 mm lens had the largest t-value, but the mean difference and standard deviation of the 8.5 mm lens were larger, making them about equally poor in their ability to resist flexure and mask corneal cylinder. In all cases the lenses flexed in the same direction as steepest corneal meridian.

V. Conclusions

The statistical analyses of our data suggests that significant amounts of corneal cylinder can be masked using Polycon II lenses. The 9.0 mm diameter lens demonstrated to be the most effective and consistent lens at masking corneal cylinder. This result was borne out by both of our methods of determining lens flexure.

The 9.5 mm diameter lens showed nearly comparable ability in masking corneal cylinder as the 9.0 mm lens. However, the 9.5 mm lens lacked the consistency of masking that the 9.0 mm lens demonstrated. Clinically speaking, this would suggest that the 9.5 mm lens is a possible lens of choice on significantly toric corneas, although the probability of successful cylinder masking would be less than with a 9.0 mm diameter lens.

The 8.5 mm diameter lens displayed good consistency in masking corneal cylinder, but to a lower extent than either the 9.0 mm or 9.5 mm lenses. This would make the 8.5 mm lens the poorest choice to fit on corneas with higher amounts of cylinder.

Though our study indicates that significant amounts of corneal cylinder can be masked with Polycon II lenses, it must be noted that our data was recorded at a particular moment in time. Some patients mentioned that the clarity of vision fluctuated over time with blinking and lens movements. This would suggest that variable amounts of lens flexure is occurring in these patients. The autorefractor readings also illustrated the wide variations in residual refractive error through the contact lens in certain patients. The instability of clear vision may make the lens intolerable.

It can be seen that a good deal of corneal cylinder can be masked using standard inventory Polycon II lenses, but there will always be some degree of flexure. In general, the higher the corneal toricity, the greater the flexure, especially in the direction of the steepest meridian.

All of our subjects showed some amount of residual astigmatism through the lenses. Most of them could maintain clear vision (i.e. 20/20 visual acuity or better) with a "spheres-only" correction. We would have liked to use the autorefractor readings of residual cylinder to indirectly measure corneal cylinder masking, however, the variety of the axes of the residual cylinder measurements made them too cumbersome to equate. Subjective findings would also not have given an adequate measure of flexure due to subject differences of correcting cylinder acceptance and differences in tolerance of uncorrected cylinder in different meridians (i.e. uncorrected with-the-rule cylinder is generally more tolerable than oblique or against-the-rule cylinder).

It was our intention when we began this study to also try to relate peripheral corneal topography to the amount of corneal cylinder that could be masked. Unfortunately, artifacts in our corneascope photographs, such as eyelids, eyelashes, and displaced lenses, prevented us from gaining adequate data on peripheral curvatures. So, no judgements could be made regarding peripheral corneal areas.

Table 1

SANVAR (Single Factor Analysis of Variance)

	Ring 1	Ring 2	Ring 3	Ring 4
F-Value	2.559	16.721	41.694	52.361

df (degrees of freedom) = 3 x 75

0.1% criterion level = 6.075

*0.5% criterion level = 4.672

*F-values larger than 4.672 are significant at the 0.5% criterion level.

Table 2

Comparison of Bare Cornea Versus Different Lens Treatments

By Individual Ring

			Mean Difference	Standard Deviation	T-Value
Ring 1	1)	8.50 OAD	0.047	0.135	1.776
	2)	9.00 OAD	0.063	0.105	3.068*
	3)	9.50 OAD	0.044	0.139	1.609
Ring 2	4)	8.50 OAD	0.048	0.123	1.987
	5)	9.00 OAD	0.126	0.147	4.368*
	6)	9.50 OAD	0.098	0.153	3.285*
Ring 3	7)	8.50 OAD	0.079	0.132	3.056*
	8)	9.00 OAD	0.141	0.153	4.685*
	9)	9.50 OAD	0.115	0.167	3.525*
Ring 4	10)	8.50 OAD	0.099	0.090	5.645*
	11)	9.00 OAD	0.157	0.116	6.875*
	12)	9.50 OAD	0.129	0.124	5.304*

*T-value is significant to .01 (1%) level.

Table 3

Average A-Factor (Over 4 Rings) Versus OAD

	naked	8.50	9.00	9.50
1	.13	.11	-.05	.12
2	.19	.12	.02	.07
3	.16	.07	.13	.04
4	.24	.08	-.10	.07
5	.15	.06	.03	.05
6	.18	.04	.10	.10
7	.16	.13	.05	.07
8	.35	.22	.19	.13
9	.44	.14	.05	0
10	.16	.12	-.03	.06
11	.18	.11	.06	.14
12	.18	.09	.10	.11
13	.27	.19	.20	.13
	naked	8.50	9.00	9.50
14	.23	.08	.03	.14
15	.17	.23	.04	.27
16	.19	.11	.08	.06
17	.27	.16	.09	.20
18	.33	.21	.11	.15
19	.10	.06	.02	-.01
20	.48	.29	.25	.13
21	.24	.11	.15	.09
22	.27	.12	.12	.18
23	.16	.18	.10	.06
24	.30	.19	.08	.16
25	.09	.08	.12	.23
*26	.24	.09	.01	-.04

Table 4

Comparison of Bare Cornea Versus Different Lens Treatments

A-Factors of Four Rings Averaged Together

	Mean Difference	Standard Deviation	Variance	T-Value
8.50	0.095	0.073	0.005	6.665
9.00	0.150	0.091	0.008	8.413
9.50	0.121	0.117	0.014	5.267

SANVAR (Single Factor Analysis of Variance) of four rings averaged together, within treatments = 29.178

df (degrees of freedom) = 3 x 75

0.1% criterion level = 6.075

*0.5% criterion level = 4.672

Table 5

Average A-Factor (Over 4 Rings) Versus

Overall Diameter (OAD)

I. High Astigmats (A-factor .20)

	naked	8.50	9.00	9.50
4	.24	.08	-.10	.07
8	.35	.22	.19	.13
9	.44	.14	.05	0
13	.27	.19	.20	.13
14	.23	.08	.03	.14
17	.27	.16	.09	.20
18	.33	.21	.11	.15
20	.48	.29	.25	.13
21	.24	.11	.15	.09
22	.27	.12	.12	.18
24	.30	.19	.08	.16
26	.24	.09	.01	-.04

II. Low to Moderate Astigmats (A-factor .20)

	naked	8.50	9.00	9.50
1	.13	.11	-.05	.12
2	.19	.12	.02	.07
3	.16	.07	.13	.04
5	.15	.06	.03	.03
6	.18	.04	.10	.10
7	.16	.13	.05	.07
10	.16	.12	-.03	.06
11	.18	.11	.06	.14
12	.18	.09	.10	.11
15	.17	.23	.04	.27
16	.19	.11	.08	.06
19	.10	.06	.02	-.01
23	.16	.18	.10	.06
25	.09	.08	.12	.23

Table 6

T-Values of High Astigmat/Low Astigmat Sub-Groupings

High Astigmats (A-Factor   .20)   n = 12

Comparison of Bare Cornea with:	Mean Difference	Standard Deviation	T-Value
8.50 mm OAD	0.148	0.055	9.247
9.00 mm OAD	0.207	0.091	7.860
9.50 mm OAD	0.193	0.112	5.970

*for n-1 = 11, t-value is significant at the .01 (1%) level if it is   3.106

Low to Moderate Astigmats (n = 14)

Comparison of Bare Cornea with:	Mean Difference	Standard Deviation	T-Value
8.50 mm OAD	0.049	0.052	3.570
9.00 mm OAD	0.102	0.059	6.436
9.50 mm OAD	0.061	0.084	2.711

*for n-1 = 13, t-value is significant at the .01 (1%) level if it is   3.012

Table 7

8.5 mm Diameter Lens Flexure Data

	Base Curve	Anterior Radius	(X) Average Horiz. Value*	(Y) Average Vert. Value *
1	8.00	8.50	8.57	8.46
2	8.00	8.50	8.50	8.37
3	7.50	7.90	7.86	7.79
4	7.50	7.90	7.96	7.88
5	7.40	7.83	7.90	7.81
6	7.70	8.13	7.93	7.89
7	7.60	8.03	8.04	7.92
8	8.00	8.50	8.26	8.04
9	8.00	8.50	8.26	8.12
10	8.10	8.59	8.60	8.48
11	8.10	8.59	8.58	8.46
12	7.50	7.90	7.88	7.79
13	7.40	7.83	7.86	7.66
14	7.80	8.30	8.33	8.21
15	7.40	7.83	7.93	7.70
16	8.00	8.50	8.56	8.46
17	7.70	8.13	8.18	8.10
18	7.40	7.83	7.97	7.76
19	8.00	8.50	8.48**	8.41**
20	7.30	7.69	7.75	7.48
21	7.70	8.13	8.12	8.02
22	7.50	7.90	8.01	7.82
23	8.00	8.50	8.48	8.29
24	7.70	8.13	8.16	7.97
25	7.40	7.83	7.83	7.75
26	7.90	8.39	8.30**	8.37**

*averages are taken from the first 4 rings

**averages were taken from the 45° and 135° meridians respectively

Table 8

9.0 mm Diameter Lens Flexure Data

	Base Curve	Anterior Radius	(X) Average Horiz. Value *	(Y) Average Vert. Value *
1	8.10	8.53	8.51	8.56
2	8.10	8.53	8.63	8.62
3	7.60	8.08	8.06	7.94
4	7.50	7.91	7.78	7.87
5	7.50	7.91	7.90	7.87
6	7.70	8.10	8.05	7.95
7	7.70	8.10	8.12	8.07
8	8.00	8.50	8.51	8.32
9	8.10	8.53	8.69	8.64
10	8.20	8.71	8.66	8.68
11	8.20	8.71	8.73	8.68
12	7.60	8.08	7.93	7.82
13	7.50	7.91	7.96	7.75
14	7.90	8.40	8.28	8.27
15	7.50	7.91	8.05	8.02
16	8.00	8.50	8.67	8.59
17	7.80	8.30	8.26	8.17
18	7.50	7.91	7.96	7.86
19	8.10	8.53	8.58**	8.57**
20	7.50	7.91	7.92	7.67
21	7.80	8.30	8.35	8.24
22	7.60	8.08	7.93	7.80
23	8.00	8.50	8.48	8.39
24	7.80	8.30	8.18	8.10
25	7.50	7.91	7.96	7.84
26	8.00	8.50	8.46**	8.51**

*averages are taken from the first 4 rings

**averages were taken from the 45° and 135° meridians respectively

Table 9

9.5 mm Diameter Lens Flexure Data

	Base Curve	Anterior Radius	(X) Average Horiz. Value*	(Y) Average Vert. Value*
1	8.10	8.57	8.62	8.50
2	8.20	8.72	8.78	8.71
3	7.70	8.14	8.11	8.07
4	7.60	8.04	8.04	7.96
5	7.60	8.04	7.98	7.97
6	7.80	8.23	8.26	8.17
7	7.80	8.23	8.26	8.19
8	8.10	8.57	8.41	8.28
9	8.20	8.72	8.71	8.71
10	8.20	8.72	8.62	8.56
11	8.20	8.72	8.71	8.57
12	7.60	7.92	7.92	7.81
13	7.60	8.04	8.11	7.98
14	8.00	8.50	8.53	8.22
15	7.50	7.94	8.03	7.76
16	8.10	8.57	8.46	8.41
17	7.90	8.34	8.40	8.29
18	7.60	8.04	8.12	7.97
19	8.20	8.72	8.65**	8.66**
20	7.60	8.04	7.95	7.78
21	7.90	8.34	8.23	8.14
22	7.60	8.04	8.04	7.86
23	8.10	8.57	8.48	8.42
24	7.80	8.23	8.24	8.08
25	7.60	8.04	8.18	7.95
26	8.10	8.57	8.47**	8.51**

*averages are taken from the first 4 rings

**averages were taken from the 45^{o} and 135^{o} meridians respectively

Table 10

Analysis of Lens Flexure Using Anterior

Radius of Curvature Deviations

Anterior Radius of Curvature Versus:	Mean	Standard Deviation	T-Value
1) Average 8.50 Horiz. Value	0.002	0.097	0.122
2) Average 8.50 Vert. Value	0.129	0.105	6.263
3) Average 9.00 Horiz. Value	0.002	0.089	0.088
4) Average 9.00 Vert. Value	0.071	0.113	3.218
5) Average 9.50 Horiz. Value	0.016	0.079	1.021
6) Average 9.50 Vert. Value	0.127	0.081	7.991

Appendix A

Summarized Data - Refractions Without Contact Lens and Over-Refractions From the Autorefractor

	Naked	8.50 mm OAD	9.0 mm OAD	9.50 mm OAD
1 PA OD				
O	-4.17-.72x158	-3.77-.11x81*	-3.46-.29x100*	-3.50-.44x161
K	41.50/42.87@90			
2 PA OS				
O	-4.14-.67x159	-3.76-.58x139	-3.36-.10x51	-2.96-.85x137
K	41.37/42.62@100			
3 KM OS				
O	+.57-1.80x176	-2.34-.94x158	-1.61-1.04x167	-1.78-.97x154
K	44.12/46.12@95			
4 KM OD				
O	+1.03-2.17x166	-1.55-1.27x174	-2.02-.98x173	-1.75-1.36x164
K	44.37/46.12@82			
5 JH OS				
O	-1.77-.78x24	-2.24-.42x33*	-2.18-.70x105	-2.04-.56x80*
K	44.62/46.25@95			
6 GY OD				
O	-6.30-.31x16	-5.15-.83x72	-4.97-.63x87	-4.21-.82x94
K	43.50/44.62@77			
7 GY OS				
O	-5.07-.61x169	-4.32-.80x151	-3.70-.52x129	-4.21-.54x137
K	43.50/45.25@105			
8 SS OD				
O	-6.42-2.33x6	-6.67-1.50x13.5	-5.82-1.02x13	-5.46-.82x27
K	41.62/44.25@90			
9 SS OS				
O	-6.59-2.36x4	-6.39-1.14x13	-5.67-.64x81*	-5.21-.62x4
K	41.25/44.00@90			
10 DD OD				
O	-6.26-1.47x174	-6.02-.97x167	-5.58-.77x121	-5.65-.70x107*
K	41.00/42.12@83			
11 DD OS				
O	-6.40-1.02x177	-5.70-1.10x143	-5.25-1.23x143	-5.22-1.17x143
K	40.87/42.00@98			
12 ML OD				
O	-6.01-1.33x167	-6.02-.76x154	-5.22-1.21x159	-5.11-1.15x161
K	44.25/46.25@90			
13 ML OS				
O	-6.86-1.75x5	-7.29-.84x170	-6.66-.91x164	-5.70-1.25x163
K	44.50/46.62@90			

* means that the standard deviation of axis measurements was greater than 20^{o}

	Naked	8.50 mm OAD	9.0 mm OAD	9.50 mm OAD
14 BL OD				
O	-3.17-1.81x004	-3.94-1.05x038	-3.51-0.57x027	+0.33-0.94x111*
K	42.00/44.12@091			
15 RG OD				
O	-5.65-1.68x010	-5.14-1.03x165	-4.63-0.99x132*	-5.22-0.69x161
K	44.62/46.00@100			
16 GK OD				
O	-6.51-0.75x180	-5.34-0.45x057*	-5.34-0.56x078*	-4.89-0.50x052
K	41.50/43.12@70			
17 RN OD				
O	-2.17-1.71x004	-3.03-0.59x136*	-3.83-0.36x105*	-3.49-0.30x085*
K	42.75/44.50@088			
18 PP OD				
O	-2.04-1.33x176	-2.27-0.67x174	-2.06-0.47x009	-1.55-0.28x134*
K	44.50/46.87@086			
19 LR OD				
O	-8.41-1.97x044	-7.86-1.20x045	-7.20-1.25x047	-7.26-0.90x050
K	41.37/43.00@116			
20 RT OD				
O	+0.19-3.19x046*	-0.82-1.14x019	+0.37-1.10x043*	+0.51-1.43x179
K	44.00/48.50@093			
21 BL OS				
O	-3.98-2.02x173	-4.19-0.98x163	-3.64-0.64x170	-3.56-0.22x163
K	43.00/45.00@086			
22 RG OS				
O	-4.43-1.98x164	-4.05-0.91x176	-3.44-1.09x092*	-3.80-0.39x175
K	44.25/46.00@071			
23 GK OS				
O	-5.97-1.08x023	-4.82-0.82x069	-5.18-0.34x083*	-4.71-0.49x107
K	41.50/43.00@110			
24 RN OS				
O	-1.78-1.67x013	-3.45-1.42x164	-3.54-0.89x157	-3.30-0.53x165
K	42.75/44.25@094			
25 PP OS				
O	-2.00-1.53x175	-3.71-0.92x175	-4.37-0.77x164	-4.66-0.50x174
K	44.50/46.25@090			
26 LR OS				
O	-9.48-2.05x132	-9.28-1.14x129	-8.65-1.08x131	-7.90-1.22x124
K	41.87/43.75@070			

* means that the standard deviation of axis measurements was greater than 20°

O = objective refraction K = keratometry readings

Over-refractions have -3.00 D diagnostic lens power into consideration.

Appendix B

The IDI Corneascope is a modern, light weight photokeratoscope. It utilizes Polaroid Type 108 Color Film, which serves as a record of the vascularity of the eye and the condition of the cornea, iris, and scleral area. Abnormalities of the cornea are more easily detected when the reflected rings are viewed against a colored background.

The theory behind photokeratoscopy is based on the science of photogrammetry. The main purpose of photogrammetry is for the construction of contour maps of terrain with steep slopes, where it is difficult to run a ground survey or obtain satisfactory aerial photographs. An example would be a mountain with many cliffs and steep slopes. If a small circle is made at the very apex of the mountain and then at 50 foot depth intervals thereafter, a 5000 foot mountain will have 100 lines between the base and apex. An airplane flying directly over the mountain could take a photograph of the lines around the mountain. By looking at the photograph, one can tell about the topography of the mountain. The surface is steeper where the contour lines are closer together and flatter as the lines get further apart. The use of contour lines makes it possible to compare different mountains and determine which is steeper. Photogrammetry is accurate to .001 inch per foot.

On the cornea, instead of drawing lines, a placido disc is reflected off of its surface and photographed. The larger the diameter of the disc, the greater the area of the cornea which will be covered by the lines. The IDI Corneascope uses a set of nine concentric rings, spaced so that the first ring is at a depth of approximately 0.1 mm down from the apex of the cornea and each successive ring is approximately an additional 0.1 mm down. These nine rings cover an area which is very near 43 percent of the corneal surface.

The keratographs can then be read on the IDI Comparator. The Comparator can be considered to be a trial set of 64,000 hard and soft lenses. It allows the practitioner to determine the radius of curvature anywhere along the corneal diameters marked off by the nine placido rings. The photograph is placed in the Comparator and is projected onto its screen where it can be compared to the ring pattern set on the Comparator view chart. The operator is able to see the relationship of the lens patterns, on the Comparator, to the corneal pattern, by comparing corresponding rings to each other. When the ring from the corneal pattern is superimposed on the corresponding lens ring, the cornea and lens have the same curvature at that point. When the corneal ring is outside the lens ring, the cornea is flatter than the lens at that point. Conversely, if the corneal ring is inside the lens ring, the cornea is steeper than the lens at that point.

To insure proper measurements, the photograph must be as sharply focused as possible, especially the cross seen at the four o'clock position between the two innermost rings. If the rings are out of focus, an error of up to .37 D can be made. With a clear picture and proper technique, the IDI Comparator is accurate to within .02 mm radius of curvature.

(The above information was taken from the manual on the IDI Corneagraph System and from conversations with Dr. John Roggenkamp. See the manual for more details.)

Appendix C

Canon AUTOREF R-1

The Canon AUTOREF R-1 is a binocular, infrared automatic refractor. The following is a list of some of its specifications:

Measureable range: Sphere: -15 to +15 D (in .12 D increments)

Cylinder: -7 to +7 D (in .12 D increments)

Axis: 1^{o} to 180^{o}

Minimum pupil diameter: 2.9 mm

Vertex distance of refraction: 12.0 mm

Measurement time: 0.2 sec.

To perform the testing, the patient views an external fixation target, preferable at 5 m away, but at least 2.5 m away from the instrument. The room can be any normally illuminated room and the occluder is not used unless the patient demonstrates a high heterophoria or tropia, making it necessary to help control fixation. The operator moves the instrument in front of the eye to be tested and aligns it by observing the image on the television monitor. The pupil, the alignment ring, and the two bright spots need to be aligned vertically and horizontally. (See diagrams for proper and improper alignment.) Also, the two bright spots must be focused as clearly as possible. When this is done, the iris should also be clearly visible. (See manual for illustrations of proper and improper focusing.) Reliable measurements cannot be obtained if alignment and focusing are improper.

After proper alignment is obtained, the measurement button can be pressed and within a second or so, the sphere, cylinder, and axis values will be digitally displayed on the television monitor. All of the readings can be recorded if a AUTOREF PRINTER R-P is available.

Measurements may be unreliable or impossible to obtain if one or more of the following occur:

1. The patient blinks or moves the eye during measurement.

2. The pupil of the eye to be measured is smaller than the alignment ring. When the room illumination is too bright, the pupil becomes too small. Optimum brightness is achieved when the pupil is slightly larger than the alignment ring.

3. Eyelid or eyelashes cover the pupil.

4. Pathology of the eye.

5. The refractive error of the eye to be measured exceeds the measureable range of the instrument.

Should any of the above occur and make measurement impossible, ERR will be displayed on the television monitor and the reading needs to be repeated.

Measurement can be performed over contact lenses or spectacles. With spectacles, there must be an angle of inclination of 15^{o} or more to obtain a measurement. However, in both cases aberration of the lens may induce errors in the cylinder values. So, refraction over lenses should be considered mainly as a reference.

(The above information was taken from the Canon AUTOREF R-A Operation Manual. See the manual for more information.)

Appendix D

Human Subject Release Form

1. THE EFFECTIVENESS OF CORNEAL CYLINDER MASKING USING POLYCON LENSES.

   PRINCIPAL INVESTIGATORS
   1) Riley F. Nakatsu
   2) Greg Y.G. Young

   ADVISOR
   Lynn Coon, O.D.

   PACIFIC UNIVERSITY COLLEGE OF OPTOMETRY
   FOREST GROVE, OREGON
   1982-1983

2. DESCRIPTION OF PROJECT

   The purpose of this project is to determine the amount of corneal cylinder that may be masked using various sizes of Polycon (Silafocon A) semi-rigid lenses. Overall lens diameters of 8.5, 9.0 and 9.5 mm will be used. Residual astigmatism will be measured with a corneascope and Canon autorefractor and an attempt will be made to correlate lens overall diameter with the amount of corneal cylinder masked. Additionally, an attempt will be made to correlate peripheral corneal topography, as measured by the corneascope, and the amount of maskable corneal cylinder. Approximately 20 to 30 eyes will be required to fulfill data requirements.

3. DESCRIPTION OF RISKS

   Typical contact lens fitting hazards, to include possible corneal abrasion and possible lid discomfort during time of fitting. As trial lenses will only be on long enough to photograph with the corneascope and to obtain an autorefraction, chances of contact lens induced ocular damage are minimal. The corneascope and Canon autorefractor are both proved to be safe, non-contact and non-invasive procedures.

4. DESCRIPTION OF BENEFITS

   To provide eye care practitioners with knowledge as to the limits of corneal cylinder that may be masked with semi-rigid, gas permeable Polycon lenses. To therefore increase the chances of a successful first time fit on a toric cornea with Polycon lenses.

5. COMPENSATION AND MEDICAL CARE

   Injuries sustained while enrolled in this experiment may not receive compensation or medical care from Pacific University, the experimenters or any organization associated with this experiment. However, all reasonable attempts at maintaining patient's safety and comfort will be made.

6. ALTERNATIVES APPLICABLE TO SUBJECTS

   Not applicable.

7. INQUIRIES AND SOURCES OF ADDITIONAL INFORMATION

   The experimenters will be happy to answer any questions that you may have during the course of this study.

8. FREEDOM TO WITHDRAW

   You are free to withdraw your consent and to discontinue your participation in this project or activity at any time without prejudices to you.

I have read and understand the above. I am 18 years of age or older.

NAME (Please Print) ______________________________

SIGNATURE ______________________ DATE __________

ADDRESS ______________________

____

____

PHONE NUMBER ____________________

NAME AND ADDRESS OF PERSON TO CONTACT IN CASE OF EMERGENCY

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PHONE NUMBER ____________________

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This thesis has been submitted in partial fulfillment of the Doctor of Optometry degree.

Riley F. Nakatsu

Riley F. Nakatsu

Gregory Y.G. Young

Gregory Y.G. Young

This thesis has been approved towards fulfilling the senior thesis requirement.

Lynn J. Coon Grade A

Lynn J. Coon, O.D.

April 11, 1983

Date