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An analysis of the unexplained changes in refractive error resulting from orthokeratology

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An analysis of the unexplained changes in refractive error resulting from orthokeratology

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Clifton M. Schor

Clifton Schor, advisor

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I. Introduction

The rise to prominence of orthokeratology has been accompanied by a scattering of papers describing methods and documenting results. This literature, for the most part, has been generated by a half dozen practicing optometrists in the United States. The orthokeratology procedure grew out of what these practitioners believed to be an arrest of "developmental myopia" in contact lens wearers[1-6].

As the procedure developed, practitioners noticed that the correlation between changes induced in anterior corneal curvature and concommittant changes in refractive error was not unity. In most cases, changes in refraction were greater than could have been expected by the amounts of corneal change. The belief developed, however, that the relation between these changes was an orderly one. This relation was generally described in the form of a ratio of change in refractive error per change in Keratometer reading. Nielson, Grant, and May[7] initially determined this ratio to be 1.5. Nolan[8] found it to vary between 1.5 and 2. In a more comprehensive study, Grant and May[9] established the ratio at 2, and it is this value which now seems to be the accepted one in the orthokeratology literature. This ratio and the unexplained refractive changes implied by it are the subjects of this study.

Due to the tedious nature of the mathematics involved in the project, the vast majority of calculations were performed on the Pacific University College of Optometry central computer. All programs were written in the Basic language. Several of the statistics programs were already available on disc file and are documented elsewhere[10]. The program to perform calculations relating to refractive changes in the eye was written as part of this thesis and is documented in Appendix A. The program is a mathematical schematic eye based on Gullstrand's constants[11](see Appendix B). Any physical variable (length, curvature, refractive index) along the optic axis can be changed and the effects on optical component power, and refractive error at the anterior cornea or measured at the phoroptor can be directly determined.

The problem has been approached in two steps. The first considers "extraocular" sources of the "unexplained" changes in refraction. This section deals with factors influenced by measurement methods and instruments, data treatment and so on. The second step considers "intraocular" sources of "unexplained" changes. This section deals with changes occuring in the eye posterior to the anterior corneal surface.

II. Extraocular Sources of Discrepancy

A. Keratometer Calibration

The instruments in most common use today for measurement of anterior corneal curvature are the Keratometer (Bausch and Lomb) and the Ophthalmometer (American Optical). Although the instrument measures a variable based upon the convex mirror property of the anterior cornea, most instruments are calibrated in dioptors of refracting power. This power is determined using an arbitrarily low refractive index designed to take into account the diverging effect of the posterior cornea, thus yielding an estimate of the entire cornea's contribution to total ocular astigmatism[12]. It is valid as a gauge of absolute refractive change in the cornea, however, only if the anterior curvature change is accompanied by a precise combination of posterior curvature and corneal thickness changes. It seems unlikely that with the anterior flattening induced by contact lenses, the relationship would hold. The clinician generally measures only the anterior curvature change and by using Keratometer change as a gauge of corneal refractive change introduces an error of unknown amount.

Considering the limiting case where only the anterior curvature changes, that error can be quantified. The following proof indicates this relationship:

1. Let n2 and n1 be refractive indeces on either side of an optical boundary whose radius of curvature was r1. Let r2 be the new radius of curvature for this surface. Let n2' be an arbitrary index of refraction.

2. Then $P1 = \frac{n2-n1}{r1}$, $P2 = \frac{n2-n1}{r2}$, $P1' = \frac{n2'-n1}{r1}$, $P2' = \frac{n2'-n1}{r2}$

3. $$P1-P2 = \Delta P = \frac{n2-n1}{r1} - \frac{n2-n1}{r2}$$

$$= \frac{r2(n2-n1) - r1(n2-n1)}{r1r2} \qquad \text{rearrange}$$

$$= \frac{(n2-n1)(r2-r1)}{r1r2} \qquad \text{factor}$$

4. Similarly $$\Delta P' = \frac{(n2'-n1)(r2-r1)}{r1r2}$$

5. $$\frac{\Delta P}{\Delta P'} = \frac{(n2-n1)(r2-r1)}{r1r2} \cdot \frac{r1r2}{(n2'-n1)(r2-r1)}$$

$$= \frac{(n2-n1)}{(n2'-n1)} \qquad \text{simplify}$$

6. $$\Delta P = \Delta P' \frac{(n2-n1)}{(n2'-n1)}$$

This ratio describes the error factor introduced in describing the curvature using the arbitrary index. For the Keratometer this factor is: (1.376-1)/(1.3375-1) = 1.114. For the Ophthalmometer the factor is: (1.376-1)/1.336-1) = 1.119. Thus the actual power change (ΔP) is equal to the product of ΔP' (change in Keratometer reading) and the error factor. By using Keratometer change, the actual corneal power change is underestimated by more than ten percent. (Note: 1.376 is Gullstrand's refractive index for the cornea[11].)

B. Lens Effectivity

A measurement artifact is introduced by the distance of the phoroptor from the in subjective determination of refractive error. The effectivity of a lens is determined by the formula $P' = P(1-dP)$, where P is the effective power at the cornea, P' is the effective power at the lens plane, and d is the distance between the lens plane and the cornea. Because of this effect any change in refraction at the anterior cornea is magnified when measured at the spectacle plane. This magnification effect increases faster than the magnitude of change and is also enhanced by higher refractive errors. The proof of this is not straightforward and has been omitted, but the following hypothetical examples illustrate the effect. A 20 mm phoroptor-eye distance is assumed. The first finding in each example represents the original refractive error. The second finding represents the refractive following the hypothetical orthokeratology.

Correcting Lens		Change in Correction	
at Phoroptor	at Cornea	at Phoroptor	at Cornea
- 3	-2.83		
0	0	+3	+2.83
- 5	-4.55		
0	0	+5	+4.55
-10	-8.33		
- 5	-4.55	+5	+3.78

Table I

For changes of refractive error greater than 2 D or for smaller changes with high myopia, failure to consider effectivity can lead to significant inflation of the ΔRE/ΔK ratio (change in refractive error per change in keratometer reading). This effect will not add significantly to error for magnitudes of change accomplished in the majority of orthokeratology patients.

C. Calculations Involving "Flattest K"

The method for deriving the accepted ΔRE/ΔK ratio of 2 was described by Grant[14] who utilized data submitted by orthokeratologists to a central computer facility. In calculating the ratio, Grant used the flattest corneal meridian as the measure of corneal curvature. As the cornea changes curvature, changes in the flattest meridian accurately describe overall changes only if corneal cylinder remains constant in power and axis. However, when contact lenses are applied to the eye, the relationship between flattest and steepest corneal meridians can develop along any of several lines.

Due to the many ocular factors influencing refraction, it is difficult to assign a given corneal parameter as being representative of the corneas overall contribution to refractive error. Javal's rule and the Keratometer index itself represent attempts to do so. Changes in the flattest meridian of the cornea should be compared to changes in refractive error only in that same meridian. Grant[14] does not state what parameter (such as change in the least myopic meridian) has been used as the gauge of refractive change in his study. It is unlikely that Keratometer and refractive error measurements were matched meridian for meridian however. In the majority of reported orthokeratology cases, where refractive astigmatism is low, a simple and reasonable method would seem to be the use of spherical equivalents in comparing Keratometer and refractive error measurements.

The use of "flattest K" can serve to enhance or diminish $\Delta RE/\Delta K$ relative to the same ratio calculated using "average K" (spherical equivalent). In cases where myopia is being reduced the relative effects of the two calculations can be summarized qualitatively by table II. In column a, "S" is the steepest corneal meridian, "F" the flattest. Column b shows the relative effects of using flattest K rather than average K as the gauge of cornea change. When change in flattest K is greater the ratio is diminished ("D"). When change in flattest K is less than change in average K the ratio is inflated ("I"). The actual effect on corneal cylinder is listed in column c.

	a. Relationship of change	b. Effect on RE/ K	c. Effect on corneal cylinder
1.	S,F do not change or change equally	equal	no change
2.	F flattens more than S	D	increased
3.	S flattens more than F	I	decreased
4.	F flattens, S steepens	D	increased
5.	F steepens, S flattens	I	decreased
6.	F steepens more than S	I	decreased
7.	S steepens more than F	D	increased

Table II

Table II shows that if changes in corneal cylinder are normally distributed, the cases where Grant's method[14] overestimates the average K change should equal the cases where it underestimates the same.

Note that in the cases where corneal cylinder is increased, the flattening effect is overstated by Grant's method. In those where corneal cylinder is decreased, the flattening effect is understated. To the extent that orthokeratology tends to decrease corneal astigmatism, that method will understate the total amount of corneal flattening and enhance the ratio of change in refractive error to change in Keratometer reading. The effect of this artifact on Grant's calculations is not stated and should be investigated.

D. Data from children

Many orthokeratology patients reported in the literature are young adolescents who had begun to show progression into myopia. As the human child progresses from hyperopia toward emmetropia, Sorsby et al[15] found that the population trend is is for a continuing increase in axial length through 13, at which point this parameter is at adult levels. The elongation was found to be partially compensated by a flattening of the crystalline lens. Corneal curvature changes were described over the same age span as "trivial". Several studies have implicated axial length as the primary source of "environmental myopia" in humans[16,17] and other primates[18-21]. Sorsby and Fraser[22] found that of all ocular optical parameters, axial length shows the largest tendency to depart from distributions expected by a solely hereditary theory of quantitative development of ocular parameters. Corneal power is a less significant source of anisometropia than axial length[23]. Thus axial length seems to be the primary factor associated with ametropia, especially that which appears to be non-hereditary.

In view of this, corneal curvature changes measured during early adolescence would not be expected to correlate well with changes in refractive error, since the major process affecting refractive status (axial length)is ignored.

E. Reliability of data

Available literature containing orthokeratology case information reveals large variability in the ratio of refractive change to Keratometer reading change. This problem was recognized by Grant and May[9] and attributed to the use of "diverse techniques" utilized by orthokeratologists. If this hypothesis is correct, refractive change and keratometer reading change should correlate well when the data points being correlated come from the same doctor. The best matched sample conditions would be a data set made up of findings taken from the same eye by the same doctor during the orthokeratology procedure. To examine this, 6 cases (12 eyes) were selected from published case histories on the basis of having the most data points (examination visits) and thus most meaningful analysis. They represent findings reported by 4 different optometrists; Shed[24], Ziff[25], Harris[26], and Nolan[27]. The correlations were performed by computer using Pearson's product moment correlation coefficient. The results are summarized in table III. Each patient is identified by his patient number from the original article. "n" represents the number of measurements taken. "$\bar{x}$" is the mean value and "s" the standard deviation for the change identified. "r" is the correlation coefficient between corresponding Keratometer and refractive changes from one visit to another.

				ΔRE		ΔK		
Doctor	Patient	Eye	n	$\bar{x}$	s	$\bar{x}$	s	r
Shed	1	OD	5	.40	.50	.12	.62	.12
Shed	1	OS	6	.33	.52	.16	.53	.56
Ziff	2	OD	8	.20	.87	.19	.54	.57
Ziff	2	OS	8	.31	1.06	.26	.71	.65
Ziff	3	OD	7	.39	.69	.16	.72	.70
Ziff	3	OS	7	.43	.54	.19	.81	.64
Harris	1	OD	6	.83	.79	.37	.50	.77
Harris	1	OS	6	.42	.38	.42	.57	.65
Harris	2	OD	11	.18	.53	.08	.47	.15
Harris	2	OS	11	.16	.34	.08	.47	.33
Nolan	2	OD	5	.25	.18	.22	.60	-.07
Nolan	2	OS	5	.20	.21	.12	.23	-.16

Table III

None of the correlations were significant for $r_{.025}$. Four of the eyes showed essentially no correlation between refractive change and change in Keratometer reading. It should be noted that the correlation is not based on a specific relation between ΔRE and ΔK, but on the possible presence of any linear relation. Table III might be interpreted to mean that ΔRE and ΔK are in fact not correlated at all, defying any meaningful description of their relationship. An alternate interpretation is that their relationship is simply not linear. In either case, measures of central tendency such as the mean are not appropriate descriptive statistics. To determine the character of unexplained sources of ΔRE, a third variable (UK) was derived for each data set by the following formula: ΔUK = ΔRE - ΔK. Since for any given data point, ΔUK is inversely related to ΔK, a correlation between the two parameters was performed to check for systemic relationships for each eye. The results of that analysis are listed in Table IV.

				ΔUK		ΔK		
Doctor	Patient	Eye	n	$\bar{x}$	s	$\bar{x}$	s	r
Shed	1	OD	5	.27	.74	.12	.62	-.75
Shed	1	OS	6	.16	.49	.16	.53	-.49
Ziff	2	OD	8	.01	.72	.19	.54	-.01
Ziff	2	OS	8	.04	.80	.26	.71	-.02
Ziff	3	OD	7	.23	.54	.16	.72	-.44
Ziff	3	OS	7	.26	.59	.19	.81	-.81^{a}
Harris	1	OD	6	.46	.64	.37	.50	-.06
Harris	1	OS	6	0	.74	.42	.57	-.87^{a}
Harris	2	OD	11	.12	.63	.08	.47	-.55
Harris	2	OS	11	.08	.48	.08	.47	-.74^{c}
Nolan	2	OD	5	.07	.60	.22	.60	-.94^{b}
Nolan	2	OS	5	.07	.34	.12	.23	-.80

Table IV

As expected from an inverse relationship, all correlations were negative. Those with "a" superscripts are significant correlations for $r_{.025}$, "b" denotes significance for $r_{.01}$, and "c" for $r_{.005}$. The pattern shown indicates that the smaller the change in Keratometer reading, the greater will be the relative refractive change from unexplained sources.

To test this effect, initial and final visit Keratometer and refractive error measurements were used to determine $\Delta RE/\Delta K$ for each patient reported in the previously discussed studies[24-27]. Values used are contained in appendix C. Each ratio is plotted against its corresponding ΔK in figure 1.

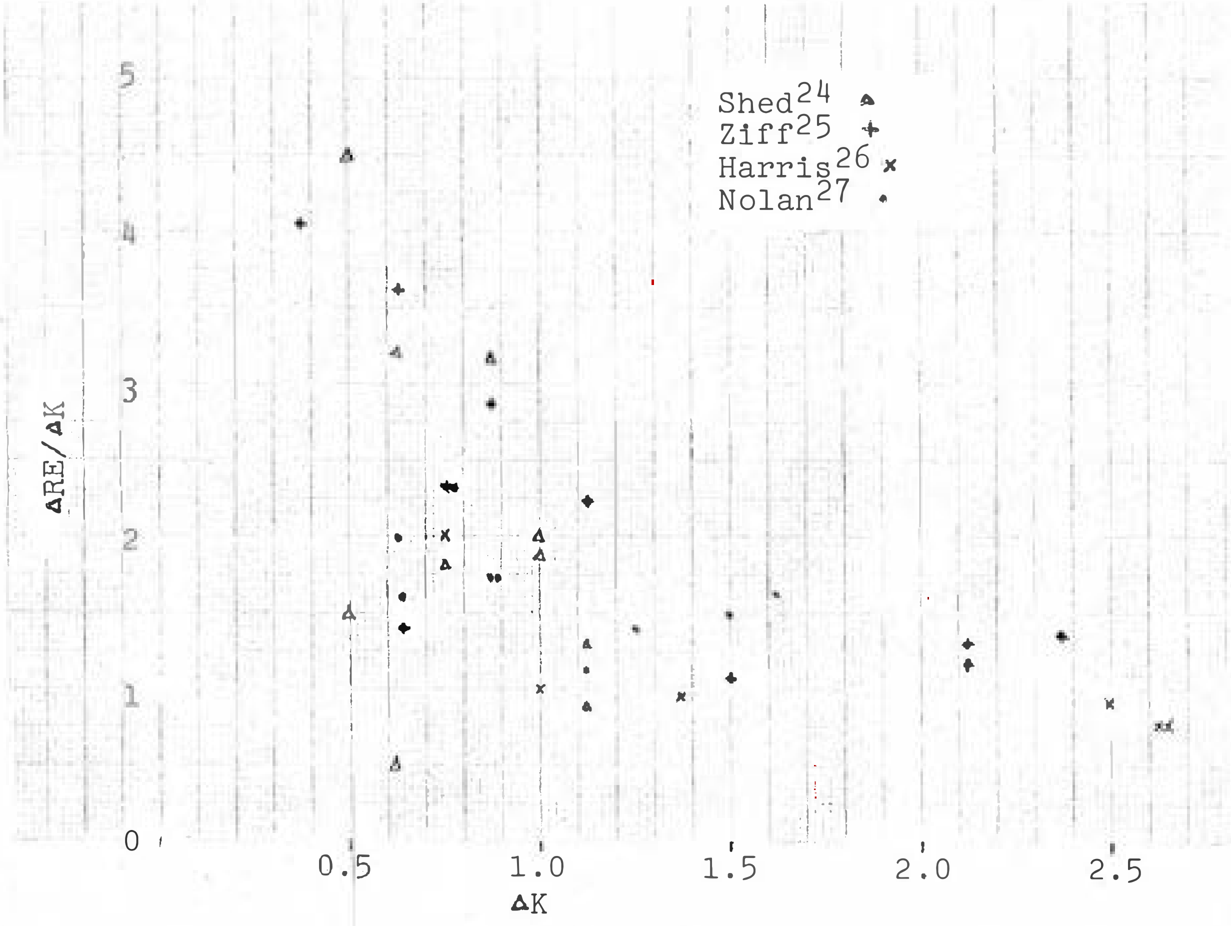


Figure 1

To examine further the trend exhibited in figure 1, a larger sample was considered. Published results obtained by Ziff[28], Nolan[29], and Fontana[30] were plotted in the same manner. This data represents total changes in K and RE for each patient. The Ziff[28] study encompassed 14 eyes and the Nolan[29] study 88 eyes. In both these, all refractive and Keratometric findings were converted to spherical equivalents to avoid the problem previously discussed in using only flattest meridians. Patterson[30] used Fontana's findings from 54 eyes and presented only ΔK and ΔRE for each eye without stating the method of determination. The findings from these 3 studies are represented in figures 2 and 3.

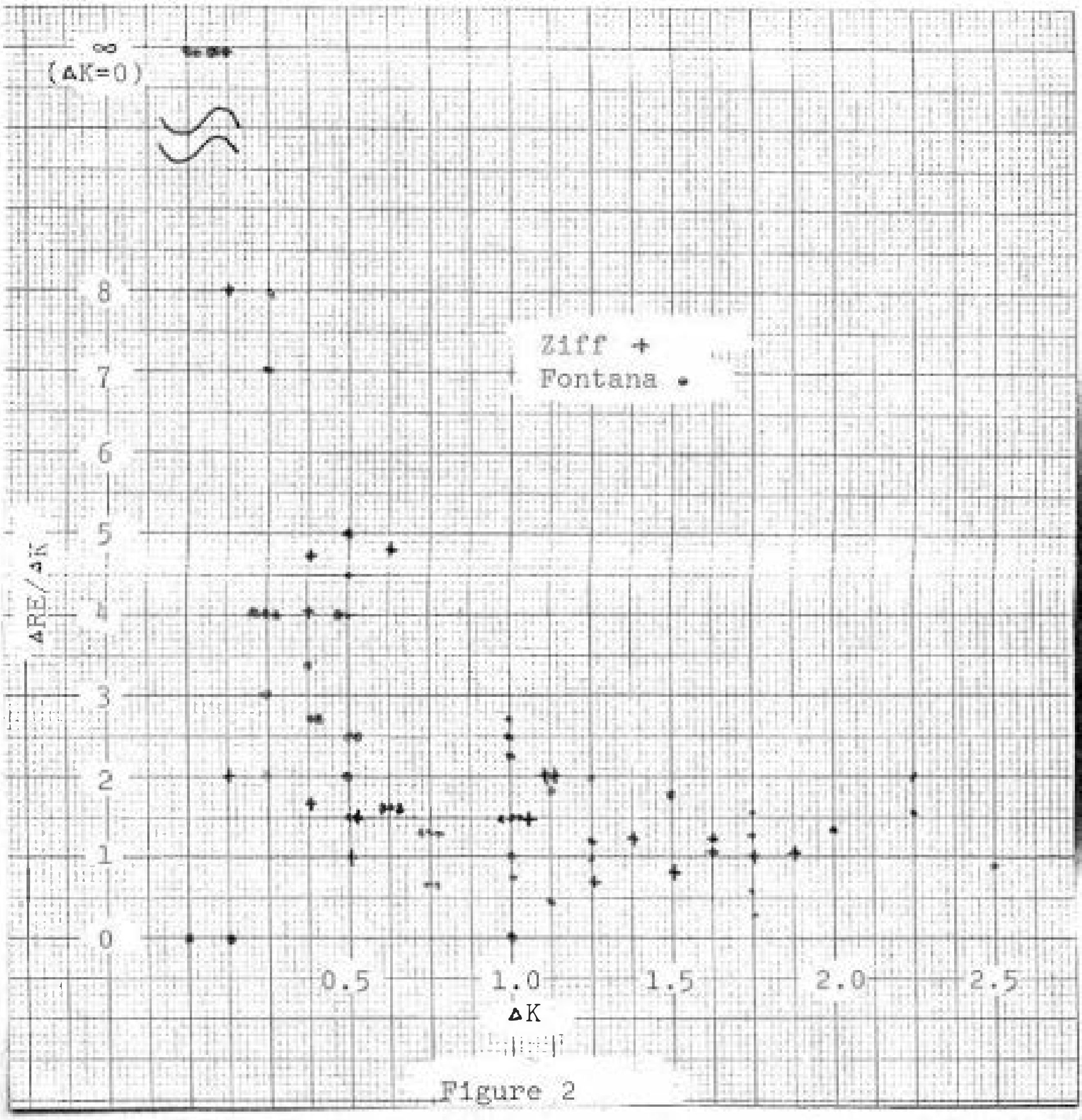


Figure 2

Figure 3

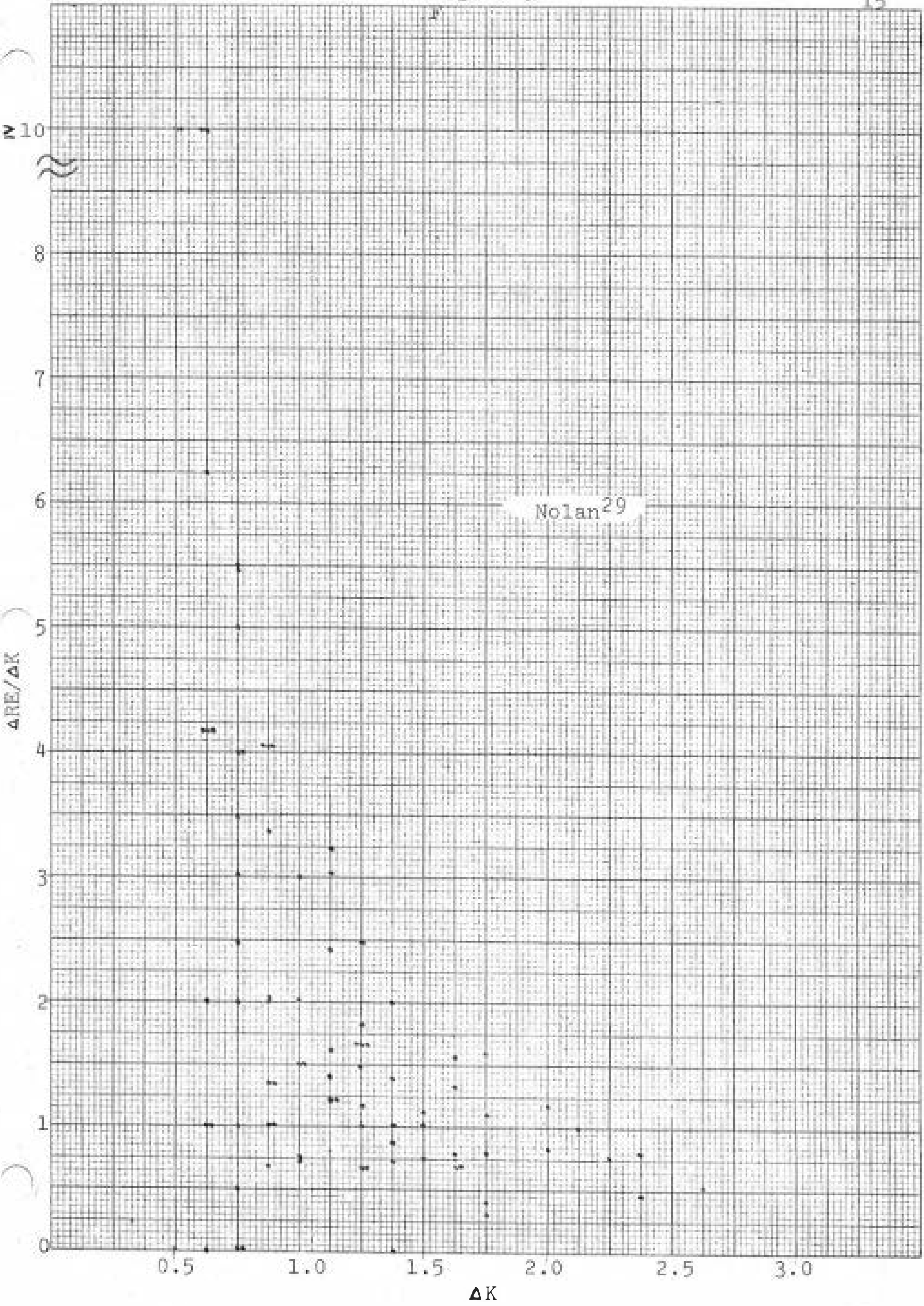
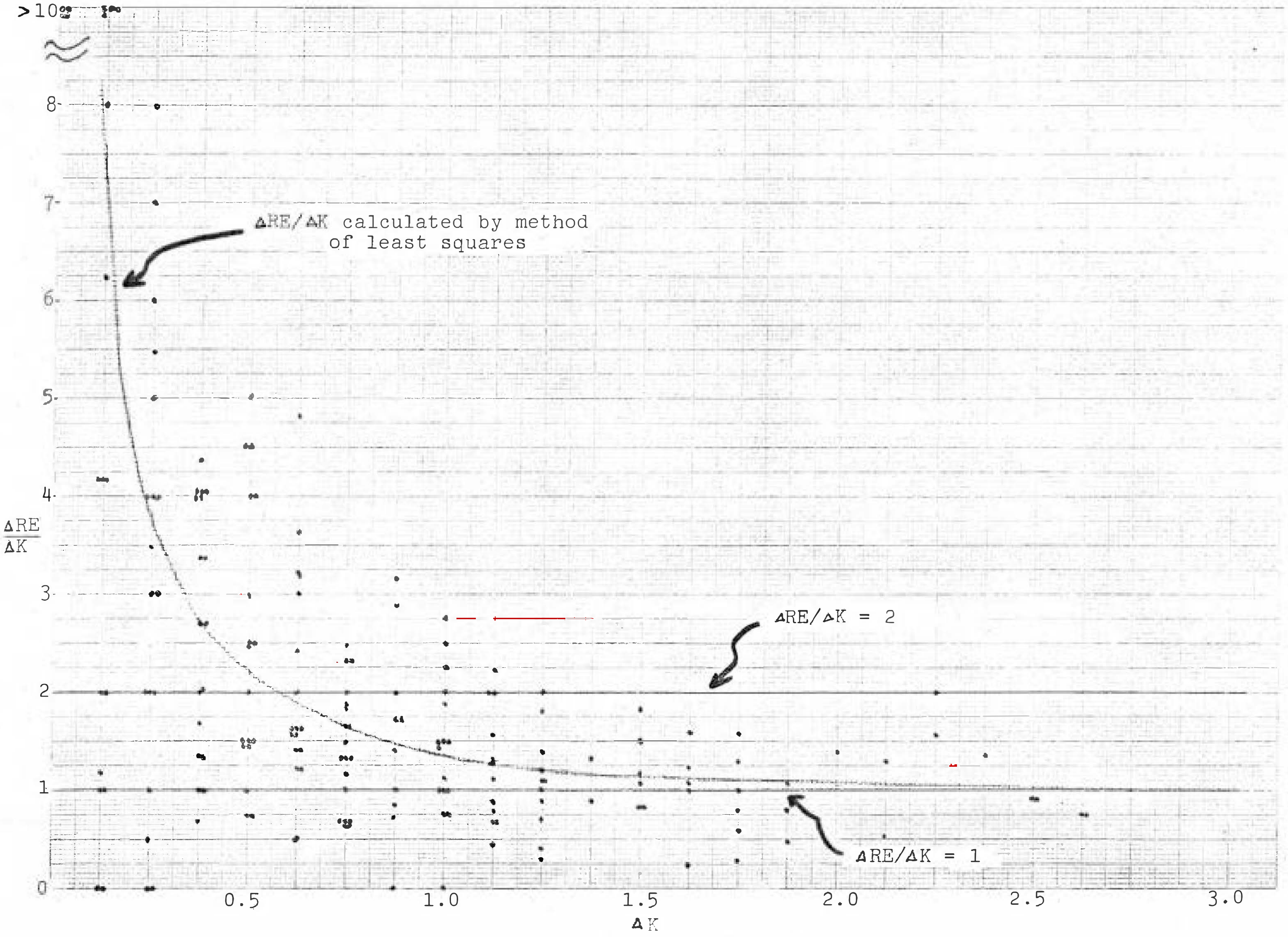


Figure 4 (Combined data)



The combined data from all seven papers[24-30], representing 192 eyes, is plotted in figure 4. It can be readily seen from the preceding figures that the trend showing ratios decreasing with increasing ΔK is present in all these studies. The large variability in $\Delta RE/\Delta K$ is seen not to be dependent upon any particular fitting method or practioner, but rather upon the high variability in $\Delta RE/\Delta K$ for low amounts of ΔK.

In examining figure 4, it is obvious that the $\Delta RE/\Delta K = 2$ line provides a very poor fit for the data. In fact no line parallel to the abcissa fits well. This points out a weakness in the method generally used to derive the ratio. The practice has been to determine the ratio by dividing the mean change in refractive error by the mean change in K[9,17,26,30]. If this were a valid method of describing the relationship, the data points in figure 4 should follow some line parallel to the abcissa. They do not. To determine a better impression of the existing relationship, a least squares calculation of linear regression was performed. The data was then separated into one group containing data in which ΔK was 1 D or less and another group in which ΔK was greater than 1 D. Separate regression calculations were performed on each group. These are shown in appendix D. The following formulas were obtained:

1. All data: $\Delta RE = 0.74 + 0.66(\Delta K)$
2. $K \leq 1.0$ D: $\Delta RE = 0.80 + 0.58(\Delta K)$
3. $K > 1.0$ D: $\Delta RE = 0.35 + 0.89(\Delta K)$

These relationships are plotted in figure 5. The least squares curbe plotted in figure was determined using formula 2 for ΔK of 1 D or less and formula for ΔK greater than 1 D.

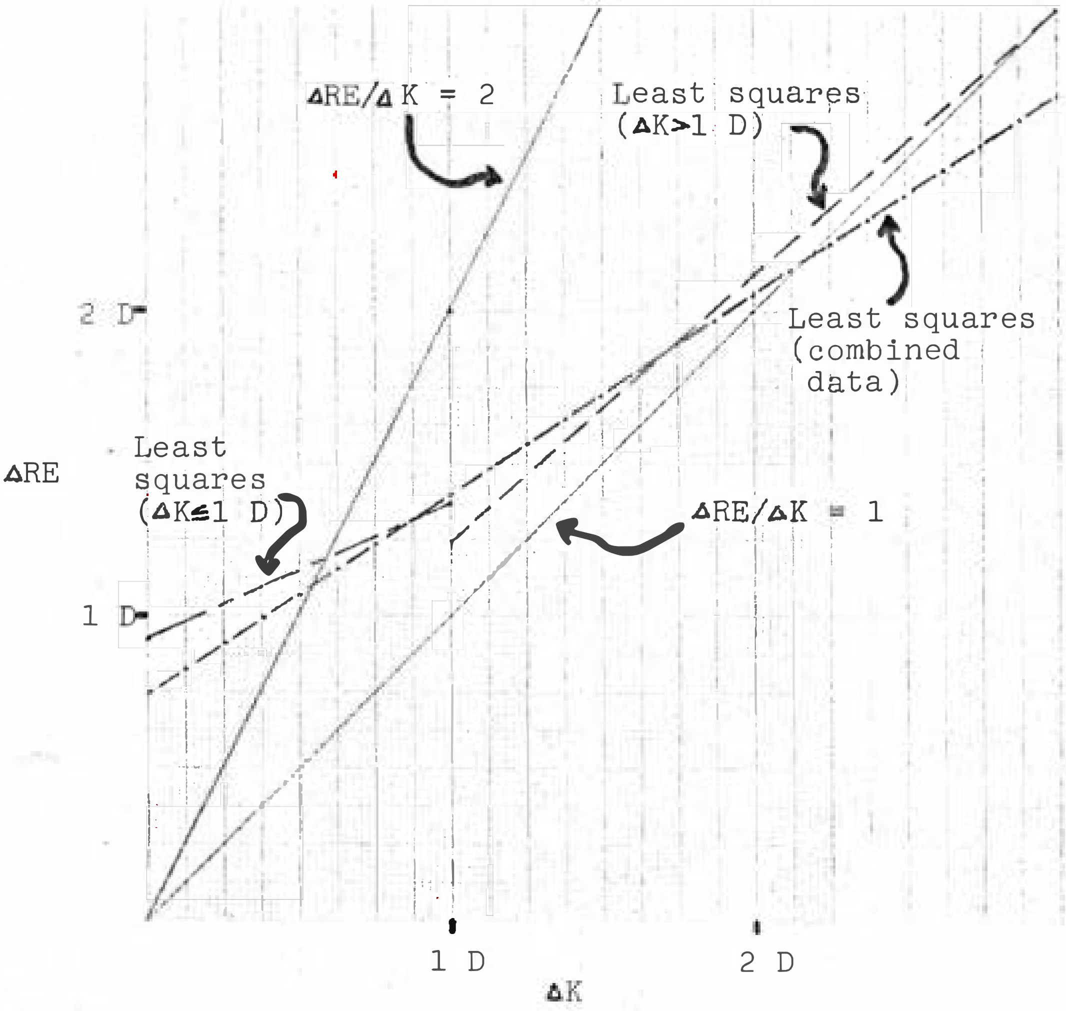


Figure 5

The least squares calculation shows that an initial 0.75D reduction in myopia may be expected before any changes in K reading are manifested. From that point, RE is seen to change more slowly than K. The implications of this phenomena will be discussed later. Furthermore, before making claims or postulating mechanisms concerning any ΔRE/ΔK relationship, it is important to consider the high variability for Keratometer changes of 1 D and less.

In dealing with a ratio, the addition of any given quantity to the numerator or denominator has a greater effect when those values are small relative to the quantity added. For example, a 0.12 D error in RE measurement can change a ratio of 0.25/0.12 (=2) to 0.37/0.12 (=3). The same error for a ratio of 3.00/1.50 (=2) yields 3.12/1.50 (=2.08). The mean ratio for these examples varies from 2 to 2.54. This factor alone could account for a great deal of variability, especially when changes are not large.

If a measurement bias were present, such errors could also inflate the ratio significantly. There exists a comprehensive body of literature concerning the reliability of the Keratometer as a measurement tool. The design of the instrument is such that several patient and examiner variables will contribute to variability in readings. These factors were outlined by Wittenberg[13] from a treatment of the subject by Littman. This variability can be quite large. Kennedy[31] estimated that errors of up to 1 D could occur on any given reading. Two studies[32,33] indicate that readings can be reliable to 0.12 D. Brungardt[34], using steel ball targets, found a normal measurement variation range of 0.37D or more.

By conservative estimate then, Keratometer readings will frequently be over or under power by 0.12D. When changes in K are measured, the effect may be compounded and yield a 0.25 D error in ΔK. This is not significant if the change in K is large. However, small changes can be greatly influenced. The problem may be further exacerbated by errors in the refraction where measurement is generally accurate to 0.25 D[35]. Consider the following hypothetical case:

	True K	Measured	True Refraction	Measured
1. Initial visit	44.50	44.37	-1.50	-1.75
2. Next visit	44.50	44.62	-1.50	-1.25
3. Net Change	0	0.25	0	0.50

While neither variable has in fact changed between visits, the finding is a 0.50 D "reduction in myopia" accompanying a 0.25 D "steeper K". This type of artifact would lead to a great deal of variability in the ΔRE/ΔK ratio for small changes as is evident in figure 4.

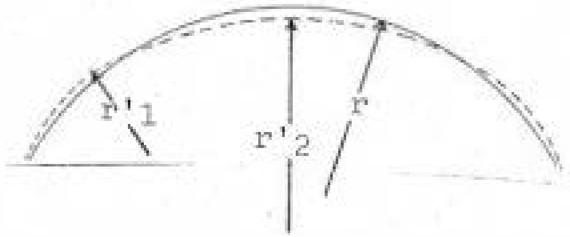
A systemic inflation of this ratio by this artifact would occur only if measurement procedures were biased to do so. Keratometer bias would be restricted to the examiner, while both examiner and patient could contribute to bias in refraction. An excellent compilation of the literature on this topic has been gathered by Rosenthal[36]. Experimenter effects upon data taking, data analysis and influence on patient responses are described.

F. Validity of the Keratometer

In addition to the problem of reliability, there is considerable question as to the validity of Keratometer measurements as an indicator of the corneal contribution to the refractive status of the eye. This issue has been considered in detail by Gullstrand[37] and more recently by Ludlam and Wittenburg[38]. The problems of validity of interest to the orthokeratologist are those principally associated with the size of the Keratometer mires. Since the majority of the entrance pupil is located inside the mire images, the majority of the light striking the retina passes through a corneal zone not measured by the Keratometer.

There is no present documentation of the actual topographical corneal changes accompanying corneal flattening. One hypothetical model which seems to have merit shows the cornea becoming applanated by the force of the lens on the cornea[39]. The cornea is part of a semi-rigid container, the eye. If we assume that the surface area of that container remains constant a decrease in curvature at one point must be accompanied by an increase in curvature adjacent to that point. Nolan[40] has presented some evidence that this may be occuring on the cornea. Thus a cornea which has flattened over a small central zone may actually show steepening at the zone measured by the Keratometer.

This phenomenon is illustrated by the following figure:



r = initial central radius of curv.
r'_2 = final central radius of curv.
r'_1 = final peri-central radius of curv.

Figure 6 (after Nolan[39])

The figure shows that $r'_2 > r > r'_1$. If the flattening is such that the Keratometer mire image is formed by the portion of the cornea where radius of curvature has steepened or flattened less than r'_2, the ΔK measured is invalid.

III. Intraocular Sources of Discrepancy

Several factors other than anterior corneal curvature have been proposed as possible contributers to decreases in myopia as found in orthokeratology. To provide a basis for consideration of the possible contribution of changes in other ocular components, the effects of changing each axial parameter in the schematic eye were calculated. Some of these effects had been previously examined[41] but the dioptric variations were not translated to a common practical reference point. For my calculations, the schematic eye was made to be initially myopic (2.5 D) by increasing the vitreous chamber depth of the eye. It must be realized that the dioptric effects of parameter changes will vary slightly with each eye. In addition, parameters are interrelated such that factors eliciting an ocular change in one must effect a change in another. Since the combinations of change are infinite, only limiting cases were determined, holding as many variables as possible constant. While the relationships plotted were not linear, data was fit to straight lines when errors of assumed linearity were small. Actual values used in determining the graphs are contained in appendix E. All changes in refractive error are translated to the anterior corneal surface.

A. Effects of radius of curvature change

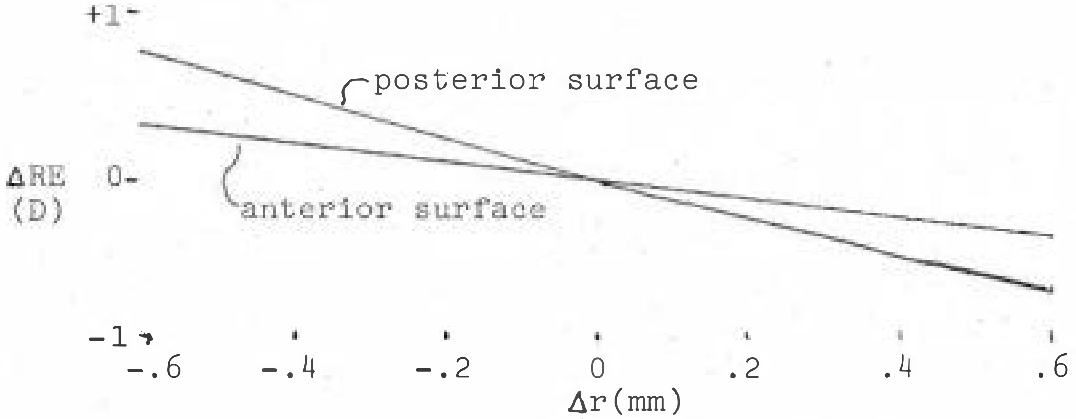


Figure 7 (crystalline lens)

Figure 7 shows that flattening at either lens surface would have a small effect upon reducing myopia. It is difficult to imagine a mechanism whereby a corneal contact lens would serve to flatten the crystalline lens. The possibility that such flattening would be found only with an orthokeratology lens seems even more remote.

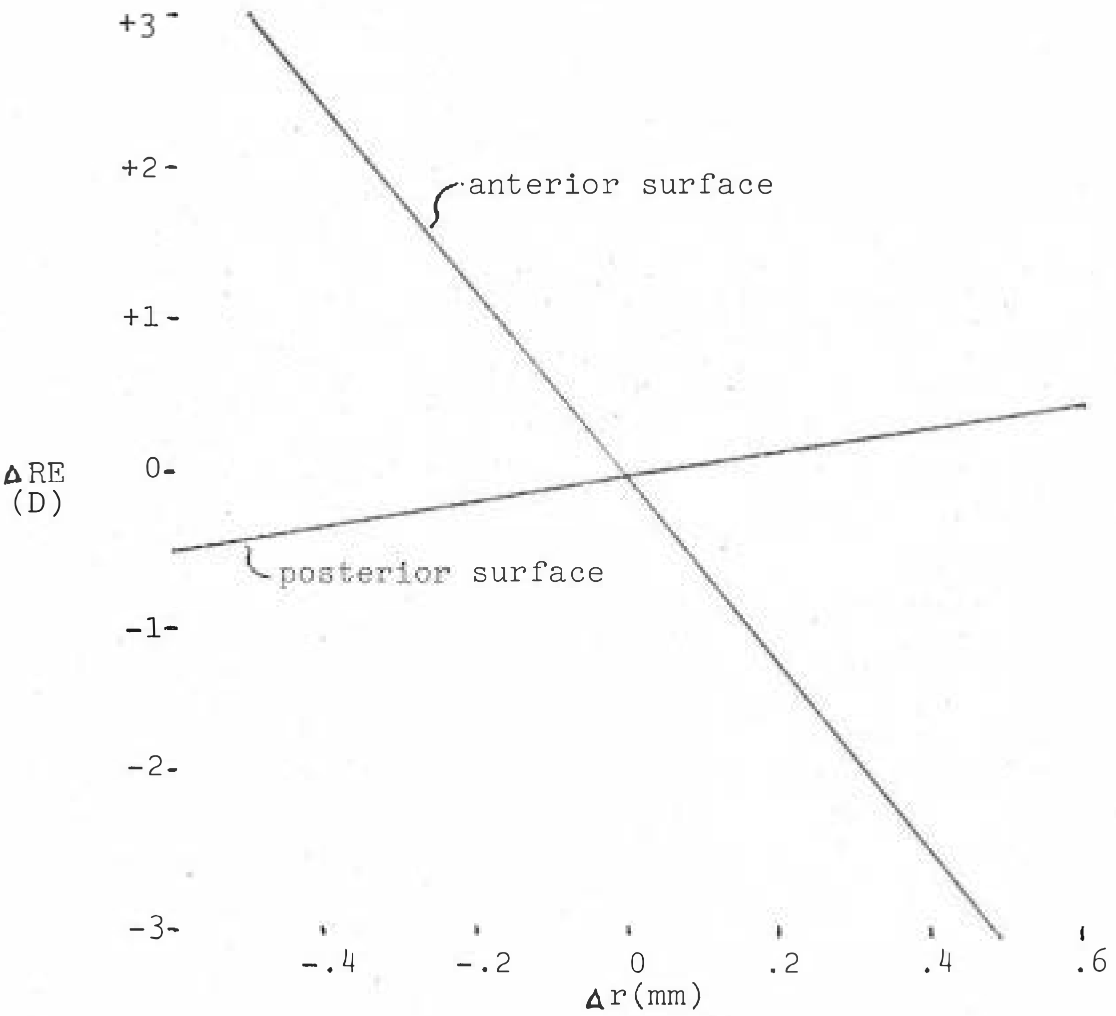


Figure 8 (cornea)

As the cornea flattens it might be expected that radii of curvature at both corneal surface would increase. Because of the small index change from cornea to aqueous, posterior curvature changes are extremely ineffective as compared to anterior changes of the same magnitude. Furthermore, in order to contribute to refractive changes enhancing those at the anterior cornea, the posterior cornea must steepen as the anterior surface flattens. This might be accomplished by peri-central corneal thickening and/or central thinning. No evidence for such a mechanism has been found.

B. Thickness and axial length changes

In considering the effects of cornea and lens thickness changes, one must specify the direction of the swelling (or thinning) relative to the retina. In one case, the posterior surface of the element may remain stationary with respect to the retina while the anterior surface is translated forward (thickening) or back (thinning). In the other case the anterior surface remains "stationary". This phenomena was not considered by Rengstorff and Arner[41] in their calculations of corneal thickness effects upon refraction.

Actual thickness changes probably follow a course somewhere between the two extremes. Thus RE resulting from thickness changes should lie somewhere between the plots of figures 9 and 10. A smaller range of thickness changes is shown for the cornea, since its total normal thickness is only 0.5 mm.

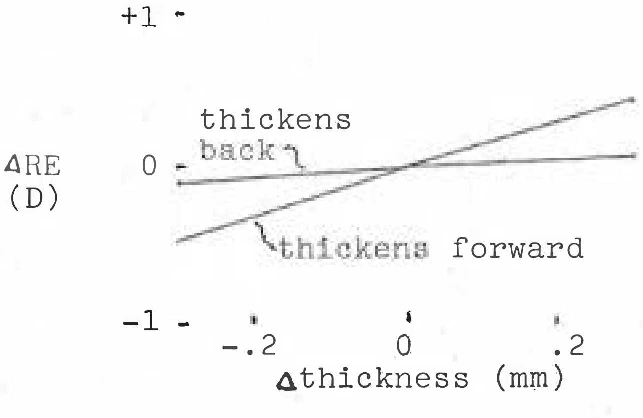


Figure 9 (corneal thickness)

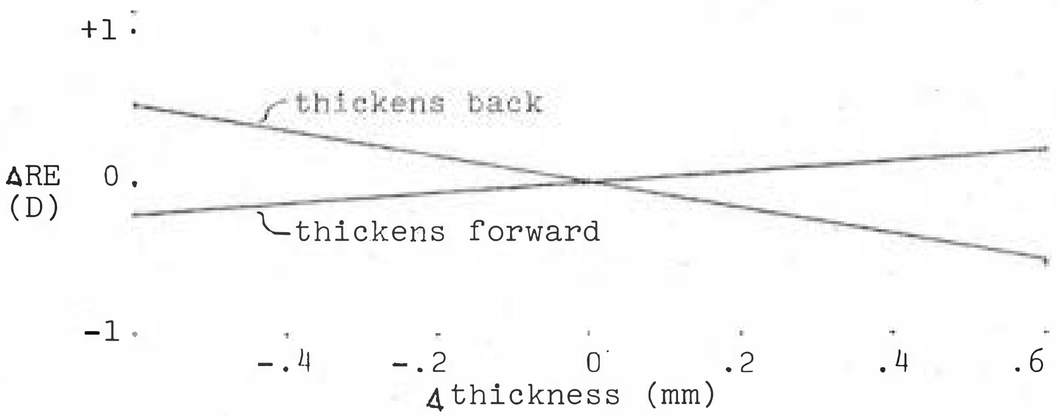


Figure 10 (lens thickness)

The method of accomplishing these variations with the computer is summarized below for thickness change "t":

Ocular Element	Surface Translated	Anterior Chamber Depth	Vitreous Chamber Depth	Axial Length
cornea	anterior	0	0	+t
cornea	posterior	-t	0	0
lens	anterior	-t	0	0
lens	posterior	0	-t	0

Table V

Corneal thickness (figure 9) is seen to have little effect upon refractive change. In the extreme case of anterior surface translation, only 0.5 D of myopia reduction occurs for a 60% thinning of the cornea.

Lens thickness changes would have an unpredictable effect upon refraction unless the direction of thickening were known, since anterior and posterior thickness translations tend to counteract one another. The net effect upon refractive error is probably negligible.

One possible effect of axial length change has been considered by Patterson[30]. The amount of anterior chamber shortening for a given amount of corneal flattening was calculated using the sagittal depth formula applied to Gullstrand's schematic eye. Patterson, however, introduced considerable by not differentiating the effects of anterior and vitreous chamber changes and not translating the effect to a clinically useful reference point. The calculations were based solely upon the total equivalent power of the eye.

Patterson's predicted value of average sagittal depth change (0.032 mm) was inserted in the computer program as a change in anterior chamber depth to determine the magnitude of error introduced by Patterson. This procedure resulted in a 0.0453 D decrease in power versus the 0.0785 D decrease reported by Patterson. The effect was inflated by 73%!

The effects of larger changes in both chambers are plotted in figure 11.

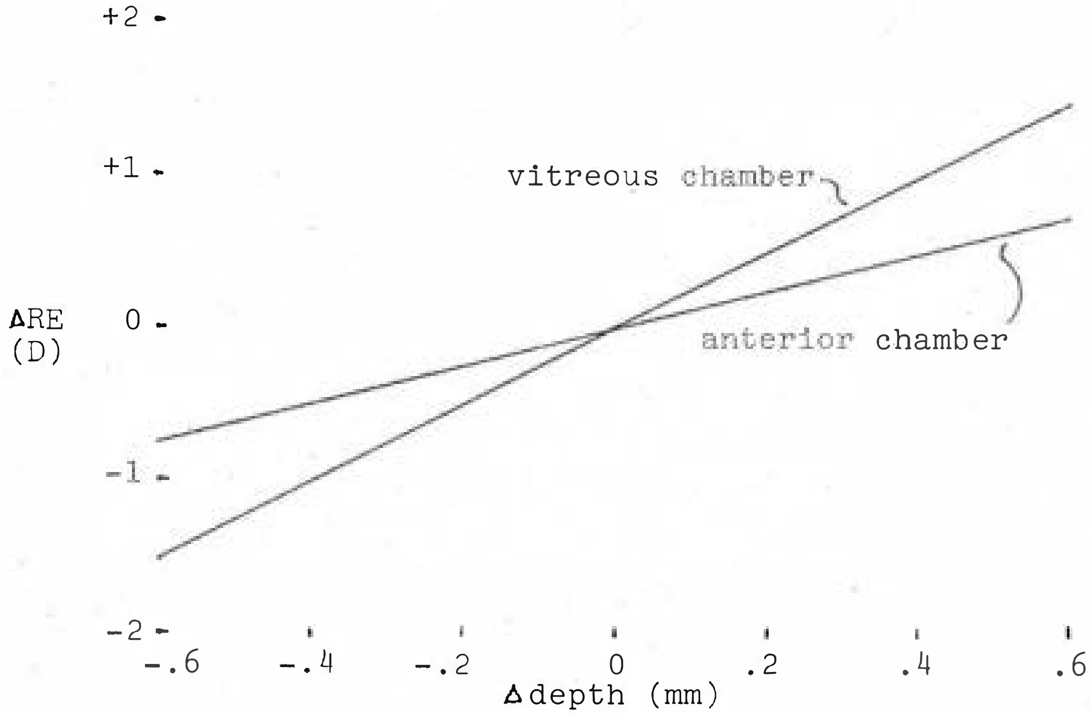


Figure 11 (chamber depth)

Decreases in vitreous chamber depth are more effective than decreases of the same magnitude in the anterior chamber in reducing myopia.

The myope corrected with contact lenses or by orthokeratology must accomodate more for a given near stimulus than when corrected with spectacles. Young[47] has concluded that the accomodative process causes the vitreous chamber depth to increase. By such a mechanism, orthokeratology might serve to enhance the increase in vitreous chamber depth of the developing myope.

C. Refractive index changes

Changes in the physiological processes of the eye might serve to alter the fluid content of ocular refractive elements and hence a change refractive index.

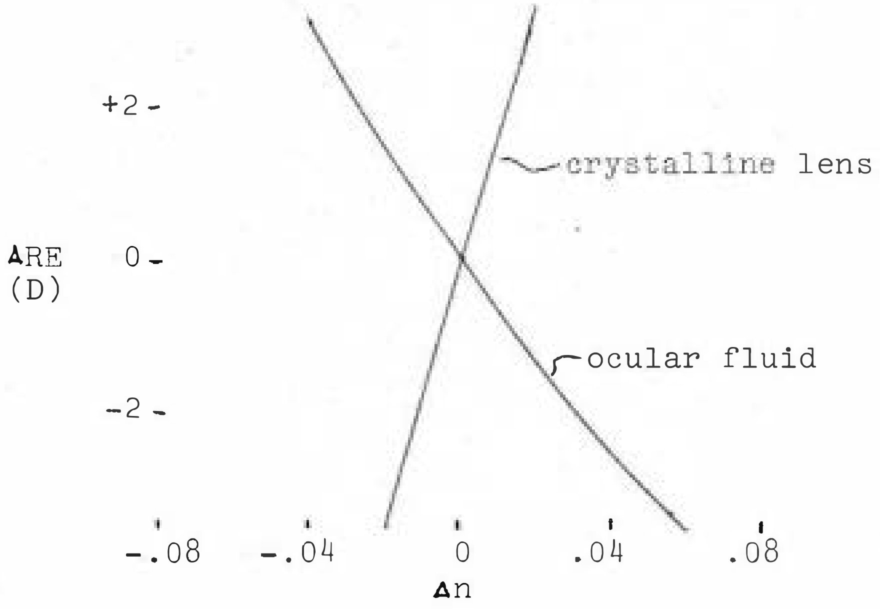


Figure 12 (lens and fluid index)

Obviously the refractive status of the eye is extremely sensitive to index changes of the intraocular fluid and the lens. Should the fluid become more opticly dense or the lens less dense, large reductions in myopia would ensue. Again, the probability of such a mechanism being effected exclusively by an orthokeratology lens seems quite small.

The cornea, on the other hand, would be much more susceptible to contact lens induced index changes. However, both the magnitude and direction of refractive changes caused by variations in corneal index may be somewhat unexpected to the casual observer.

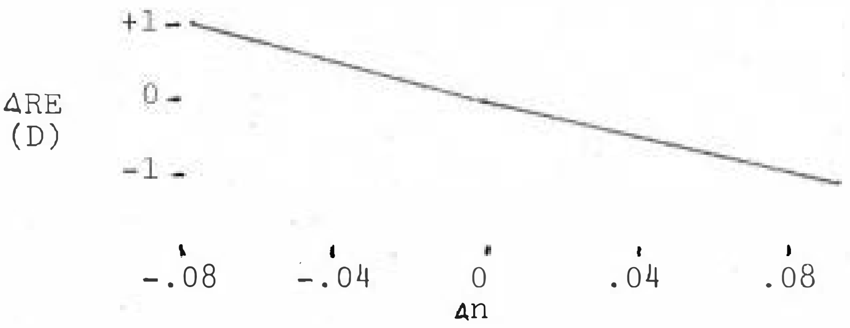


Figure 13 (corneal index)

As the refractive index of the cornea increases, myopia is reduced by small amounts. The reason that the refractive power of the cornea is inversely related to its refractive index is due to its physical form as a minus lens in air. The effect of index change is shown by the following proof.

Let: P = back vertex power of the cornea
n1 = refractive index of the medium adjacent to the anterior cornea (i.e. air)
n2 = refractive index of the cornea
n3 = refractive index of the medium adjacent to the posterior cornea (i.e. aqueous)
r1 = anterior radius of curvature
r2 = posterior radius of curvature
t = central corneal thickness

The refractive power of the cornea can be described by the thick lens equation: $P = \frac{n2-n1}{r1} + \frac{n3-n2}{r2} - \frac{t}{n} \cdot \frac{n2-n1}{r1} \cdot \frac{n3-n2}{r2}$

Expanding the equation:

$$P = \frac{n2}{r1} - \frac{n1}{r1} + \frac{n3}{r2} - \frac{n2}{r2} - \frac{t(n3n2-n3n1-n2^2+n1n2)}{n2r2r1}$$

$$P = \frac{n2}{r1} - \frac{n1}{r1} + \frac{n3}{r2} - \frac{n2}{r2} - \frac{n2tn3}{n2r2r1} + \frac{tn3n1}{n2r2r1} + \frac{tn2^2}{n2r2r1} - \frac{n2n1t}{n2r2r1}$$

Simplifying and rearranging:

$$P = n2\left(\frac{1}{r1} - \frac{1}{r2} + \frac{t}{r2r1}\right) + n2^{-1}\left(\frac{tn3n1}{r2r1}\right) + \frac{n1}{r1} + \frac{n3}{r2} - \frac{tn3}{r2r1} - \frac{tn1}{r2r1}$$

The relationship is now of the form P = f(n2). The change in P due to change in n2 can then be described by differentiating P with respect to n2.

$$\frac{dP}{dn2} = \frac{1}{r1} - \frac{1}{r2} + \frac{t}{r2r1} - n2^{-2}\left(\frac{tn3n1}{r2r1}\right)$$

$$= \frac{1}{r1} - \frac{1}{r2} + \frac{t}{r2r1}\left(1 - \frac{n3n1}{n2^2}\right)$$

The slope of the relationship P = f(n2) is described by dP/dn2. That is, as n2 changes, P will change as dP/dn2. Using Gullstrand's[11] values for the pertinent parameters, the three right hand terms of the deriviative have respective values of 130D, 147D, and 3D. Since the sign convention used in this deriviation was achieved by subtracting the refractive indeces from right to left (posterior to anterior), all radii are considered positive if convex to the left (anterior). The slope is then calculated to be 130 - 147 + 3 = -14D/ unit index. Since refractive index can physiologically change only by small amounts, a more useful relation is -0.14D/.01 unit of index change.

It can now easily be seen that the negative slope is due to the fact that the predominant factor is the posterior radius of curvature.

IV. Discussion

Evidence presented here indicates the reported large ratios of change in refraction versus change in Keratometer readings may reasonably be attributed to artifacts. These are associated principally with unreliability and invalidity of the Keratometer. Further evidence showed that the accepted ratio of 2 presents a misleading description of the $\Delta RE/\Delta K$ relation.

There are several precautions which the clinician may take to improve the reliability and validity of findings. Virtually all of the problems pointed out in this paper may be reduced or eliminated by more carefully gathering and handling data. The following considerations are recommended:

1. Translate all refractive power measurements to a common reference point. In orthokeratology, a logical point is the anterior corneal surface. This is important not only for phoroptor readings, but for hypothetical or measured changes in optical parameters posterior to the front corneal surface.
2. Dioptric power readings from the Keratometer are based upon an arbitrary index of refraction designed to represent the entire corneal system[12,13]. There is insufficient evidence to warrant the assumption that changes in K are valid measures of effective corneal power changes. Until a practical clinical instrument is available to the doctor which is reliable and capable of measuring corneal curvature within the area described by the entrance pupil, direct measures of corneal curvature will remain suspect. An

alternative method of determining anterior corneal power changes indirectly has been suggested[42,43]. The refraction is first done through the contact lens, then with the lens removed. The difference in the two values is due to the power in air of the contact lens and the lacrimal lens. Since all other refractive elements of the contact lens-lacrimal lens system are easily determined, the effective back surface power of the lacrimal lens can be readily determined. From this, the effective central corneal curvature can be calculated. Thus the Keratometer is eliminated as a source of error. Unequal changes in these two measurements could then validly be attributed to other ocular parameters.

3. Data from patients whose myopia has not yet stabilized, young adolescents in particular, should be considered separately from adults whose myopia has stabilized. This separate treatment may shed a great deal of light upon the orthokeratology mechanism in both groups.
4. Pseudo-myopic patients whose refractive measurements have been altered by training procedures[44,45] should be excluded from ΔRE/ΔK analysis, since their therapy probably has no relation to the contact lens application.
5. Great care should be taken to avoid bias in data collection. In the laboratory, this could be achieved by a "double blind" experimental design.
6. The most valid parameters to be used in evaluating refractive and corneal changes should be determined. The simplest method seems to be the use of spherical equivalents except

in the case of high astigmatism where principal meridians might be considered separately.

7. Reasonable and appropriate statistical methods should be followed in analyzing data. Medians, modes, and means are not meaning ful when variability is high or or when parameter relationships are not linear. If the mean is used, the value must be considered in light of the standard deviation and its limitations understood.

If these guidelines are followed, the "unexplained" changes in refraction generated by orthokeratology may well disappear. If differences between ΔRE and ΔK still exist, they will at least be amenable to a more meaning ful and orderly investigation.

It should be noted that ΔRE/ΔK ratio greater than unity is not unique to orthokeratology. Rengstorff[46] studied refractive and Keratometer changes in contact lens patients following removal of the contacts for extended periods. Although wide individual variations were found (just as in orthokeratology), the pattern for mean refractive and Keratometer changes is remarkably similar to those reported in the orthokeratology literature. That is, shortly after contact lens removal large refractive changes were accompanied by small Keratometer changes. This occured regardless of the direction (steepening and increased myopia, or flattening and decreased myopia) of the change. After about 3 weeks, the ratio had decreased to near unity. It appears that Keratometer reading required a period of time to "catch up" with the refractive changes.

A theory which could explain this phenomenon has been previously discussed. Assume that corneal curvature changes are first manifested in the central cornea inside the Keratometer mires. Over time this change "spreads" outward as the forces determining curvature are equalized across the entire corneal contour. The stabilized curvature is eventually reflected accurately by the Keratometer.

This could also explain the results of the linear regression curve (figure 5), which indicates that in general 0.75D of refractive change must occur before the change is reflected in the Keratometer measurements. As the cornea flattens further, more peripheral areas of the corneal contour become involved and at some point the Keratometer measured radius corresponds accurately to the effective radius within the entrance pupil. This can be seen intuitively by recalling the model of a semi-rigid sphere. The more the sphere is flattened the larger will be the area over which the flattening is manifested. As the sphere is allowed to return to its original shape, as in Rengstorff's[46] study, the inverse would occur.

Research on the effects of orthokeratology should concentrate upon this mechanism as the key to the "unexplained" refractive changes.

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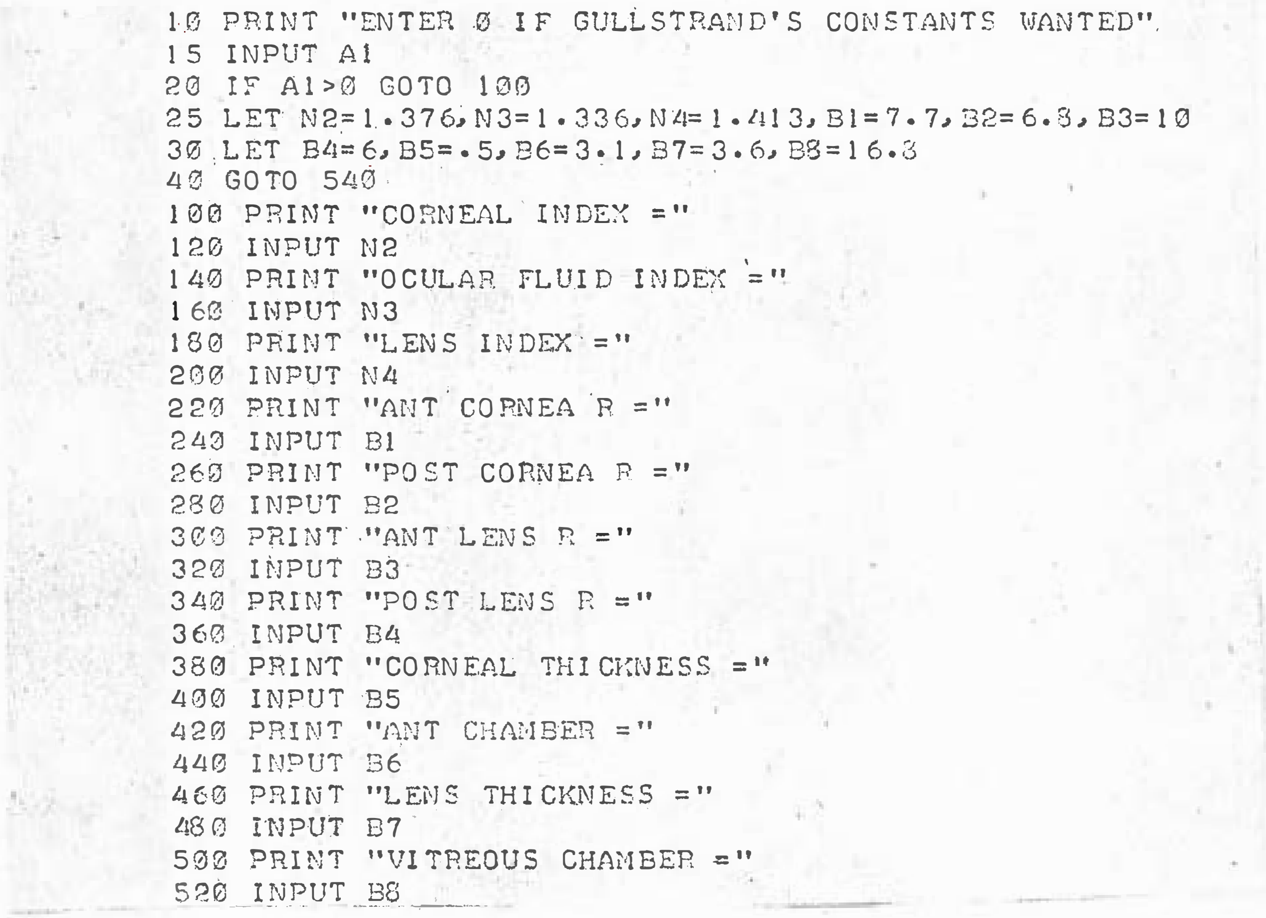
Appendix A

Schematic Eye Program

A program to calculate various refractive components of the schematic eye as well as changes in refractive error due to changes in various ocular parameters. Also calculated are powers of each ocular refractive component and total front vertex power of the eye. Gullstrand's values for ocular dimensions and refracting elements may be selected.

This program is available on file B of account 2001 at the Pacific University College of Optometry computer center. The program:



```
10 PRINT "ENTER 0 IF GULLSTRAND'S CONSTANTS WANTED".
15 INPUT A1
20 IF A1>0 GOTO 100
25 LET N2=1.376,N3=1.336,N4=1.413,B1=7.7,B2=6.8,B3=10
30 LET B4=6,B5=.5,B6=3.1,B7=3.6,B8=16.8
40 GOTO 540
100 PRINT "CORNEAL INDEX ="
120 INPUT N2
140 PRINT "OCULAR FLUID INDEX ="
160 INPUT N3
180 PRINT "LENS INDEX ="
200 INPUT N4
220 PRINT "ANT CORNEA R ="
240 INPUT B1
260 PRINT "POST CORNEA R ="
280 INPUT B2
300 PRINT "ANT LENS R ="
320 INPUT B3
340 PRINT "POST LENS R ="
360 INPUT B4
380 PRINT "CORNEAL THICKNESS ="
400 INPUT B5
420 PRINT "ANT CHAMBER ="
440 INPUT B6
460 PRINT "LENS THICKNESS ="
480 INPUT B7
500 PRINT "VITREOUS CHAMBER ="
520 INPUT B8
```

```
540 LET R1=B1/1000
560 LET R2=B2/1000
580 LET R3=B3/1000
600 LET R4=B4/1000
620 LET T1=B5/1000
640 LET T2=B6/1000
660 LET T3=B7/1000
680 LET T4=B8/1000
700 LET P1=(N2-1)/R1
720 LET P2=(N3-N2)/R2
740 LET P3=(N4-N3)/R3
760 LET P4=(N4-N3)/R4
770 LET P7=.3375/R1
780 LET P5=P1+P2-P1*P2*T1/N2
800 LET P6=P3+P4-P3*P4*T3/N4
810 LET A1=0
820 LET V1=P4-N3/T4+A1
840 LET V3=P3+N4/(N4/V1-T3)
860 LET V5=P2+N3/(N3/V3-T2)
880 LET V7=P1+N2/(N2/V5-T1)
890 IF V1>0 GOTO 1020
900 PRINT "REFRACTIVE ERROR AT ANT. CORNEA="V7
905 LET S1=V7
910 LET P8=1/(1/V7-.02)
911 PRINT "REFRACTIVE ERROR AT PHOROPTOR="P8
920 PRINT "ANT. CORNEA POWER="P1
930 PRINT "K READING="P7
940 PRINT "CORNEA POWER IN SITU="P5
960 PRINT "LENS POWER IN SITU="P6
980 LET A1=N3/T4
1000 GOTO 820
1020 PRINT "TOTAL POWER OF EYE="V7
1050 PRINT "IF THIS IS NOT REFERENCE EYE, ENTER 0"
1060 INPUT S5
1070 IF S5=0 GOTO 1140
1080 LET S6=S1
1090 LET S2=P8
1100 LET S3=P7
1110 LET S4=P1
1120 IF S5>0 GOTO 1300
1140 LET D1=S1-S6
1160 LET D2=P8-S2
1180 LET D3=P7-S3
1200 LET D4=P1-S4
1220 PRINT "CHANGE IN R.E. AT CORNEA="D1
1240 PRINT "CHANGE AT PHOROPTOR="D2
1260 PRINT "CHANGE IN K ="D3
1280 PRINT "CHANGE IN ANT. CORNEA POWER ="D4
1300 PRINT "ENTER PARAMETER CHANGE AS B VALUE, THEN 540 RUN"
```

Appendix B

Gullstrand's Constants

The constants are taken from Helmholtz's Treatise on Physiological Optics[11], pages 351 to 352.

1. Axial Dimensions:

Corneal thickness	0.5 mm
Lens thickness	3.6 mm
Anterior chamber depth	3.1 mm
Vitreous chamber depth	16.8 mm
Total axial length	24.0 mm

2. Radii of curvature

Anterior cornea	7.7 mm
Posterior cornea	6.8 mm
Anterior lens	10.0 mm
Posterior lens	6.0 mm

3. Refractive indeces

Cornea	1.376
Aqueous humor	1.336
Lens	1.413 (equivalent index to account for isoindecal layers of the lens)
Vitreous humor	1.336

Anterior focal length = 17.055 mm

Posterior focal length = 22.785 mm

Equivalent power = 58.64 D

Refractive error = -1 D

Appendix C

Spherical equivalents used in plotting figures 1 - 4

Doctor	Patient no.	Eye	ΔRE	ΔK
Shed[24]	1	OD	-2.00	-0.62
		OS	-2.00	-1.00
	2	OD	-0.75	-0.50
		OS	-0.37	-0.62
	3	OD	-1.50	-1.12
		OS	-1.87	-1.00
	4	OD	-1.00	-1.12
		OS	-1.37	-0.75
	5	OD	-2.75	-0.87
		OS	-2.25	-0.50
Ziff[25]	1	OD	-1.12	-0.62
		OS	-1.50	-0.37
	2	OD	-1.62	-1.50
		OS	-2.50	-2.12
	3	OD	-2.75	-2.12
		OS	-3.25	-2.37
	4	OD	-2.50	-0.87
		OS	-2.37	-1.00
	5	OD	-2.25	-0.62
		OS	-1.75	-0.75
Harris[26]	1	OD	-2.00	-2.62
		OS	-2.00	-2.62
	2	OD	-1.00	-0.75
		OS	-1.50	-1.00
	3	OD	-2.25	-1.37
		OS	-1.25	-2.50
Nolan[27]	1	OD	-1.75	-0.75
		OS	-1.50	-0.87
	2	OD	-1.25	-1.12
		OS	-1.00	-0.62
	3	OD	-1.50	-0.87
		OS	-1.75	-1.25
	4	OD	-2.62	-1.62
		OS	-2.25	-1.50
	5	OD	-1.25	-0.62
Ziff[28]	1	OD	-1.75	-1.37
		OS	-2.00	-1.62
	2	OD	-1.75	-1.62
		OS	-1.75	-1.75
	3	OD	-0.87	-1.25
		OS	-2.00	-1.87
	4	OD	+0.25	+0.12
		OS	+0.62	+0.37
	5	OD	-2.25	-1.12
		OS	-1.75	-0.37
	6	OD	-2.25	-1.12
		OS	-3.00	-0.62
	7	OD	-1.50	-1.00
		OS	-0.75	-0.50

Doctor	Patient no.	Eye	ΔRE	ΔK
Nolan[29]	1	OD	-1.00	-0.62
		OS	-0.50	-0.25
	2	OD	-0.87	-1.87
		OS	-0.87	-1.12
	3	OD	-1.25	-0.75
		OS	-1.25	-0.75
	4	OD	-0.75	-0.62
		OS	-0.50	-0.75
	5	OD	-0.37	-0.50
		OS	-0.25	-0.12
	6	OD	-1.37	-1.75
		OS	-1.12	-2.12
	7	OD	-1.50	-1.87
		OS	-1.62	-1.62
	8	OD	-0.87	-0.25
		OS	-0.87	-0.62
	9	OD	-0.75	0
		OS	-0.75	-0.25
	10	OD	-1.25	-0.37
		OS	-1.50	-1.12
	11	OD	-1.50	-0.37
		OS	-1.50	-0.62
	12	OD	-0.12	-0.25
		OS	0	-0.25
	13	OD	-0.62	-0.87
		OS	-1.00	+0.37
	14	OD	-0.50	-0.12
		OS	-0.62	+0.37
	15	OD	-1.50	-0.37
		OS	-2.00	-1.25
	16	OD	-0.50	-0.12
		OS	-0.75	-0.12
	17	OD	-0.75	-1.12
		OS	-1.25	-1.50
	18	OD	-0.75	-0.75
		OS	-0.25	-0.37
	19	OD	-1.50	-0.50
		OS	-1.12	-0.75
	20	OD	-0.62	-0.87
		OS	-1.00	-1.25
	21	OD	0	0
		OS	-0.50	-0.75
	22	OD	-1.00	-0.25
		OS	-1.00	-0.25
	23	OD	-1.75	-0.12
		OS	-1.75	-0.87
	24	OD	0	+0.12
		OS	0	-0.87
	25	OD	-1.25	-0.75
		OS	-1.50	-0.25
	26	OD	-2.00	-0.62
		OS	-1.87	-0.75
	27	OD	-1.00	-1.00
		OS	-0.87	-0.75

28	OD	-1.87	-0.62
	OS	-1.37	-1.25
29	OD	-1.12	-1.00
	OS	-1.37	-0.75
30	OD	-0.12	-0.12
	OS	-0.50	-0.25
31	OD	-1.37	-0.25
	OS	-1.50	-0.37
32	OD	-0.75	-0.50
	OS	-0.75	-0.50
33	OD	-0.62	-0.25
	OS	-0.37	-0.50
34	OD	-1.25	-0.25
	OS	-0.50	-0.12
35	OD	-0.75	-0.87
	OS	-0.50	-0.37
36	OD	-0.25	0
	OS	-0.25	+0.12
37	OD	-0.50	-0.37
	OS	-0.37	-0.37
38	OD	-1.25	-0.12
	OS	-0.75	-0.37
39	OD	+0.12	+0.12
	OS	+0.25	+0.25
40	OD	-0.75	-1.12
	OS	-0.87	-0.87
41	OD	-0.50	-1.25
	OS	-0.37	-1.25
42	OD	-1.75	-1.50
	OS	-1.75	-1.12
43	OD	-0.75	-1.00
	OS	-0.75	-0.62
44	OD	-0.75	-0.37
	OS	-0.37	-0.37

Appendix D

Linear regression calculations

Linear regression establishes an equation of the form $y = a + bx$. y in this case is ΔRE and x is ΔK. The solutions for a and b are obtained by the following equations:

$$a = \frac{(\Sigma y)(\Sigma x^2) - (\Sigma x)(\Sigma xy)}{n(\Sigma x^2) - (\Sigma x)^2}$$

$$b = \frac{n(\Sigma xy) - (\Sigma x)(\Sigma y)}{n(\Sigma x^2) - (\Sigma x)^2}$$

I. $\Delta K > 1D$

$n = 55$
$\Sigma x = 86.9899$
$\Sigma x^2 = 148.308$ — $a = 0.35$
$\Sigma y = 96.9499$
$\Sigma xy = 162.894$ — $b = 0.89$

II. $K \leq 1D$

$n = 137$
$\Sigma x = 71.6998$
$\Sigma x^2 = 51.2739$ — $a = 0.80$
$\Sigma y = 150.25$
$\Sigma xy = 86.545$ — $b = 0.58$

III. Combined data

$n = 192$
$\Sigma x = 158.70$ — $a = 0.74$
$\Sigma x^2 = 199.58$
$\Sigma y = 247.20$ — $b = 0.66$
$\Sigma xy = 249.439$

Appendix E

Data used to plot figures 7 - 13

I. Radius of curvature

A. Cornea

	r (mm)	RE (D)		r (mm)	RE (D)
	8.3	-3.53		7.4	+0.46
anterior	8.1	-2.41	posterior	7.2	+0.32
	7.9	-1.24		7.0	+0.16
	7.7	0		6.8	0
	7.5	+1.30		6.6	-0.17
	7.3	+2.68		6.4	-0.36
	7.1	+4.13		6.2	-0.55

B. Lens

	10.6	-0.34		6.6	-0.68
	10.4	-0.23		6.4	-0.47
anterior	10.2	-0.12	posterior	6.2	-0.24
	10.0	0		6.0	0
	9.8	+0.12		5.8	+0.26
	9.6	+0.25		5.6	+0.54
	9.4	+0.39		5.4	+0.85

II. Axial thickness and chamber depth

A. Cornea

	t (mm)			t (mm)	
	.65	+0.23		.65	+0.05
	.60	+0.16		.60	+0.03
	.55	+0.08		.55	+0.02
"forward"	.50	0	"back"	.50	0
	.40	-0.16		.45	-0.02
	.30	-0.32		.30	-0.07

B. Lens

	4.2	+0.22		4.2	-0.51
	4.0	+0.14		4.0	-0.34
"forward"	3.8	+0.07	"back"	3.8	-0.17
	3.6	0		3.6	0
	3.4	-0.07		3.4	+0.17
	3.2	-0.14		3.2	+0.35
	3.0	-0.21		3.0	+0.52

C. Anterior Chamber

3.7	+0.73
3.5	+0.49
3.3	+0.25
3.1	0
2.9	-0.25
2.7	-0.50
2.5	-0.75

D. Vitreous Chamber

18.5	+1.44	17.7	-0.50
18.3	+0.97	17.5	-1.00
18.1	+0.49	17.3	-1.51
17.9	0		

III. Refractive index

	n	RE (D)
A. Cornea	1.46	-1.05
	1.43	-0.68
	1.40	-0.31
	1.376	0
	1.35	+0.34
	1.32	+0.73
	1.30	+1.00
B. Lens	1.50	+16.26
	1.47	+10.37
	1.44	+ 4.79
	1.413	0
	1.38	- 5.56
	1.36	- 8.78
C. Ocular fluids		
	1.39	-3.41
	1.36	-1.62
	1.336	0
	1.30	+2.77