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Assessing the relationship of the rigidity/pliability of the cornea to its ability to maintain an induced flattening

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Assessing the relationship of the rigidity/pliability of the cornea to its ability to maintain an induced flattening

Abstract
The purpose of this study was to evaluate the ability of the cornea to adapt to and maintain an induced flattening. That is, which cornea is more likely to maintain an induced flattening longer, a cornea that readily flattens or one that is more resistant? The aim was also to develop a clinically feasible test to predict the suitability of a given patient for orthokeratology. We selected twenty low myopes who had healthy corneas, minimal astigmatism, and no recent history of rigid contact lens wear. Baseline corneal maps were taken with the EyeSys and acuities were recorded. The cornea of one eye was appplanation three millimeters inward with a Tonomat endplate and held in place for ten seconds. Immediately following appplanation, acuities and another map were taken; then again at five, ten, and fifteen minutes. The baseline map and acuity were compared to each of the four post-appplanation maps and acuities and analyzed for patterns. The group of subjects as a whole did not show significant change in K values pre- versus post-appplanation. An improvement in acuity was seen in most of the subjects at some point, but in a variety of patterns. The group was broken down into smaller groups that displayed similar patterns. No statistical significance in average K values over time could be shown. There was statistical significance seen in visual acuities over time, although these changes could not be statistically linked to any change in K values. As clinically applied to orthokeratology, our study suggests the following: 1) A provocative test such as minor indentation of the cornea (perhaps with a Goldmann probe or a flat trial contact lens) may be a useful procedure for assessing short term pliability of the cornea. 2) Different corneas respond differently, suggesting that orthokeratology may never be successful on all potential candidates. 3) Visual acuity change is a better indicator of potential success than corneal curvature changes. 4) Individuals who show improved or stable short term acuity improvements may be good ortho-k patients.

Degree Type
Thesis

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ASSESSING THE RELATIONSHIP OF THE
RIGIDITY / PLIABILITY OF THE CORNEA TO ITS
ABILITY TO MAINTAIN AN INDUCED FLATTENING

By

DAWNE RIME
GINA SEYMOUR

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A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, OR
for the degree of
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May, 1995

Advisor: DR. CRISTINA M. SCHNIDER, O.D., MSc
ASSESSING THE RELATIONSHIP OF THE
RIGIDITY / PLIABILITY OF THE CORNEA TO ITS
ABILITY TO MAINTAIN AN INDUCED FLATTENING

Dawne Rime, Investigator

Gina Seymour, Investigator

Cristina M. Schnider, O.D.
ABOUT THE AUTHORS

Dawne Rime received her Bachelor's degree in Chemistry with a minor in Spanish at Southwest State University in Marshall, Minnesota. She is currently completing her work for the degree of Doctor of Optometry at Pacific University College of Optometry in Forest Grove, Oregon. Dawne has a strong interest in challenging contact lens fits and will be working in private practice in the Portland area.

Gina Seymour began her undergraduate work at Viterbo College in LaCrosse, Wisconsin, majoring in biology. She received her degree in Visual Science, and is currently completing her work for the degree of Doctor of Optometry at Pacific University College of Optometry in Forest Grove, Oregon. Gina is interested in primary care and plans to be in private practice following graduation.
ABSTRACT

The purpose of this study was to evaluate the ability of the cornea to adapt to and maintain an induced flattening. That is, which cornea is more likely to maintain an induced flattening longer, a cornea that readily flattens or one that is more resistant? The aim was also to develop a clinically feasible test to predict the suitability of a given patient for orthokeratology.

We selected twenty low myopes who had healthy corneas, minimal astigmatism, and no recent history of rigid contact lens wear. Baseline corneal maps were taken with the EyeSys and acuities were recorded. The cornea of one eye was applanated three millimeters inward with a Tonomat endplate and held in place for ten seconds. Immediately following applanation, acuities and another map were taken; then again at five, ten, and fifteen minutes.

The baseline map and acuity were compared to each of the four post-applanation maps and acuities and analyzed for patterns. The group of subjects as a whole did not show significant change in K values pre- versus post-applanation. An improvement in acuity was seen in most of the subjects at some point, but in a variety of
patterns. The group was broken down into smaller groups that displayed similar patterns.

No statistical significance in average K values over time could be shown. There was statistical significance seen in visual acuities over time, although these changes could not be statistically linked to any change in K values.

As clinically applied to orthokeratology, our study suggests the following:

1) A provocative test such as minor indentation of the cornea (perhaps with a Goldmann probe or a flat trial contact lens) may be a useful procedure for assessing short term pliability of the cornea.

2) Different corneas respond differently, suggesting that orthokeratology may never be successful on all potential candidates.

3) Visual acuity change is a better indicator of potential success than corneal curvature changes.

4) Individuals who show improved or stable short term acuity improvements may be good ortho-k patients.
We would like to express our sincere thanks to the following persons for their contributions to this study:

Dr. Cristina Schnider for the idea, the game plan, and the know-how to make this project clinically useful. Her knowledge has been invaluable.

Ciba Vision Corporation and Sally Dillehay for generously providing complementary Focus and NuVue contact lenses both for the applanation procedure and for compensation for the subjects for their time.

Beta Sigma Kappa optometric fraternity for providing funding for the project.

EyeSys Laboratories for having the technology available to more accurately record, compare, and analyze corneal curvatures.
Assessing the Relationship of the Rigidity/Pliability of the Cornea to Its Ability to Maintain an Induced Flattening

History

Eye care practitioners, as early as the 1950's and 1960's, have noted and recorded a relationship between rigid contact lens wear, keratometric readings, and refractive errors that varied between examinations. The most common finding revealed an association between flattened corneas and reduced myopia.\(^1,2,3,4,5,6,7\) However, this was not the only data reported. Some patients experienced an increase in myopia along with a steeper corneal curvature\(^3,8,9,10,11\) while other rigid lens wearers discontinued myopic progression.\(^1,2,3,6,12\) Although the data was contradictory, there was evidence of a relationship between corneal curvature, refractive status, and rigid contact lens wear.

This set the stage for more intense research into the field that would come to be known as orthokeratology. Ziff was the first to initiate an orthokeratology study that was meant to establish whether or not "emmetropization of the cornea can be predicted or accomplished partially or completely, depending on the original existing degree of corneal curvature."\(^{11}\) The results of his study
demonstrated a greater degree of flattening among those with steeper corneas to begin with. Freeman's work in orthokeratology supported the conclusions drawn from Ziff's study. According to Freeman, the corneas that are initially more steep centrally than peripherally will demonstrate more significant reductions in myopia.\textsuperscript{13} Freeman advocated the use of the corneascope to follow the marked corneal changes between the third and ninth corneascope rings.\textsuperscript{14} The reason for this is Freeman believes that the induced corneal changes occur in the paracentral corneal region.\textsuperscript{14} PEK (photoelectric keratoscope) analysis\textsuperscript{15,16,17,18,19} supports corneascopic orthokeratology data by objectively producing results that indicate central flattening with paracentral corneal steepening. According to the American Optometric Association, controlled studies were the next step towards confirming the effectiveness of orthokeratology.\textsuperscript{20}

Kerns performed the first controlled study.\textsuperscript{21-28} Kerns' study compared non-contact lens wearers, conventional lens wearers, and orthokeratology lens wearers. The results of the study revealed a statistically significant improvement in visual acuity and reduction in refractive errors among the orthokeratology group. However, Kerns' orthokeratology data also revealed discrepancies in the magnitude and direction of the procedural effects such that the precision of control and predictability of the response was
questionable at best.\textsuperscript{23-28} Although the orthokeratological effects were not predictable, Kerns was able to establish that the initial corneal shape as measured by the PEK was more relevant to the direction and magnitude of myopia than was the base-curve-to-cornea relationship.\textsuperscript{28} Initial corneal shape was not the only factor Kerns considered to affect the orthokeratological response. Kerns also felt corneal rigidity was primarily involved in the degree of response.\textsuperscript{27} Kerns study did not specifically evaluate corneal rigidity. However, corneas with similar parameters did not respond identically to the same lenses. Obviously, more controlled studies were needed.

Binder performed the second controlled orthokeratology study.\textsuperscript{29,30} He compared conventional rigid contact lens wearers with orthokeratology lens wearers. The results from Binder's study confirmed Kerns' analysis of the orthokeratological response: "variable, unpredictable, and uncontrollable."\textsuperscript{29,30}

The next to contribute to the study of orthokeratology was Pacific University.\textsuperscript{31} The Pacific University study used the Tabb method of orthokeratology to evaluate the process and mode of reducing myopia with contact lens use.\textsuperscript{31} The study monitored the following ocular parameters: axial length, anterior chamber depth, vitreous depth, crystalline lens power and curvature, anterior corneal curvature and shape factor, corneal thickness, intraocular
pressure, unaided visual acuities, and refractive error. These ocular parameters were routinely measured throughout the procedure. The conclusion drawn from this study was that “the site of tissue changes appears to be entirely the cornea, with changes in central corneal curvature, shape factor, and thickness all contributing significantly to the process.”¹ The Pacific University study pinpointed the corneal tissue as the source of the orthokeratological response. However, the predictability factor, permanency factor, contact lens parameters, and corneal fitting relationship are all areas that need further exploration.

Another study at UC Berkeley was the first to evaluate relative efficacy of orthokeratology by assessing changes in refractive error, visual acuities, and corneal curvature. Second, to evaluate the safety of the procedure by assessing changes in corneal staining, corneal thickness, visual acuities, astigmatism, and endothelial cell density. In their comparison of conventional rigid contact lenses versus ortho-k lenses, they showed a greater reduction in myopia in the ortho-k wearers than conventional lens wearers. Reduction of myopia, according to Polse, was largely temporary. refractive error, visual acuities, and corneal curvature all drifted back toward pre-treatment levels as lens wear was decreased. This rebound effect, as the Berkeley study suggests, indicates the high degree of corneal elasticity present in all individuals no matter the magnitude
of change due to ortho-k wear or the baseline characteristics. A complete return to original levels did not occur even when contact lens wear was completely discontinued.\(^{32}\)

It is the purpose of this study to evaluate the ability of the cornea to adapt to and maintain an induced flattening. Also, to develop a clinically feasible test to predict the suitability of a given patient for orthokeratology. By establishing this, orthokeratology could become a more predictable method of myopic correction and control.
Materials and Methods

I. Subjects:

Twenty subjects were recruited for participation in this study. Subjects had a myopic refractive error in one eye between -0.50 and -4.00 D with refractive astigmatism no greater than 0.75 D. Subjects must not have a history of rigid lens wear. The subjects were correctable to at least 20/20. They had intraocular pressures below 20mmHg. Their corneas were normal with no apparent pathology. There were ten or fewer corneal microcysts/vacuoles. Corneal striae was not present, and corneal mires were undistorted. Corneal staining with sodium fluorescein was graded at least a two or better on the following scale:

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<td>0</td>
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<td>1</td>
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<tr>
<td>2</td>
<td>Macropunctate</td>
</tr>
<tr>
<td>3</td>
<td>Coalescent macro</td>
</tr>
<tr>
<td>4</td>
<td>Patch</td>
</tr>
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</table>

II. Experimental Method:

The study was randomized to incorporate only the right or left eye of a given subject, because of inter-eye correlation as shown by Ray and O'Day.\textsuperscript{34}
The baseline evaluation included:
1) Aided and unaided visual acuities, taken with LogMar.
2) Biomicroscopy exam with and without fluorescein.
3) Two corneal maps taken with the EyeSys to establish the consistency of the readings.
4) Goldmann tonometry, performed with proparacaine and a sodium fluorescein strip. This procedure was performed exclusively by one researcher for the sake of consistency.

III. Experimental Visit:
1) Unaided visual acuities were taken with LogMar to establish a baseline for comparison with post-applanation unaided visual acuities.
2) Biomicroscopic reverification of corneal health.
3) Two pre-applanation baseline corneal maps taken with the EyeSys. These were compared to the initial maps to further establish the consistency of the instrument. The EyeSys was programmed to map and analyze the area of the cornea that corresponded with the diameter of the applanator. The data from this baseline map was compared to post-applanation maps to measure diopters of corneal flattening and to monitor the rate of regression of the cornea to its original curvature.
4) A +2.00 disposable contact lens (Ciba NuVues 8.6/14.0 +2.00) was placed on the subject’s eye for desensitization and protection purposes. Topical anesthetic was not chosen for this purpose due to its softening effect on the cornea. However, proparacaine was used to suppress the blink reflex in the untested eye. The subject was aligned in the instrument for applanation. The apparatus consisted of a Tonomat endplate, which was attached to an arm whose forward or backward movement is measurable in millimeters (see Photo 1). The disposable endplate was to just make contact with the apex of the contact lens. The arm was moved to depress the cornea three millimeters and left in position for ten seconds (see Photo 2). The apparatus was backed away from the subject and the contact lens disposed of.

5) Immediately post-applanation, a corneal map was taken with the EyeSys, followed by unaided visual acuities. This point was considered the zero mark in time, and a map and unaided visual acuities were taken at five, ten, and fifteen minutes from the zero mark. Different LogMar visual acuity charts were used for each measure to avoid chart familiarization. The subject was then released, as no further data was required.
Results

The average K value was calculated using the EyeSys "absolute color map" function. A grid overlies the color map, and the central intersection of this grid lies at the corneal apex. The central five by five square millimeter area was used to collect and average data points for this study, as many subjects' data did not project outside this area.

Twenty-four data points were collected and averaged from each map. Each intersection in the described area was considered one data point except for the centralmost point, which served as a reference. See Map 1.

Map 2 shows a pre-indentation map and immediately post-indentation map, with a difference map, demonstrating the change in corneal curvature and dioptric power.

Map 3 shows the post indentation map sequence of one subject. Note the slight resteepeening of the cornea over time as it regresses to baseline values.

Graph 1 demonstrates the effect of Tonomat indentation on visual acuity over time. The graph represents raw data plots of actual acuity variances. The first data point represents the initial visual acuity before indentation. Data point two is the visual acuity immediately after indentation. Data point three is the visual acuity
five minutes after indentation. Data point four is the visual acuity ten minutes after indentation. Data point five is the visual acuity fifteen minutes after indentation.

Since the subjects as a group did not display any similarities of visual acuity change after indentation, the subjects were sorted into smaller groups with similar patterns. Four of these smaller groups resulted, as represented by Graphs 2-5.

Nine subjects showed an initial decrease in visual acuity which then improved to better than the original acuity before indentation. See Graph 2.

Two subjects showed increasingly improved visual acuity over the fifteen minute timespan. See Graph 3.

Four subjects showed improved visual acuity initially which drifted back towards the original acuity before indentation. See Graph 4.

Five subjects showed no distinct pattern in visual acuity changes. Erratic fluctuations of improved and decreased acuities over time were seen. See Graph 5.

Graph 6 demonstrates the actual acuity change between pre indentation as compared to each acuity measure taken post indentation. Positive numbers represent an improvement in acuities. Negative numbers represent a decrease in acuities.
An analysis of variance (ANOVA) as demonstrated by Table 1 shows statistical significance of fluctuation of acuity over time.

Table 2 is an analysis of variance which indicated that there was no statistically significant variance in K values over time.

Table 3 is a correlation analysis of the natural log change of visual acuity as compared to the natural log change of corneal map values. There was no statistically significant correlation between the two.

A descriptive analysis was run to attempt to elicit a reason why some subjects demonstrated greater visual acuity changes as compared to others. No statistically significant correlations were found.
Discussion

Evaluation of the ability of the cornea to adapt to and maintain an induced flattening is represented by the corneal map values. An analysis of variance (Table 2) shows no statistically significant corneal map change over time. 

Table 3 demonstrates no significant correlation between visual acuity and corneal maps over time after indentation. However, visual acuities were significantly affected by indentation of the cornea.

Erickson, et al. studied refractive error changes versus keratometric changes. The results disproved the notion that dioptically, refractive error changed twice as fast as corneal curvature. In fact it showed that approximately a 0.75 D change in refractive error resulted despite no measurable change in corneal curvature. However, once a change in corneal curvature was detectable, only 2/3 of a diopter change in refractive error was seen for each diopter of change in corneal curvature.\textsuperscript{36}

Woo, et al. studied the central and peripheral refractive power of the cornea.\textsuperscript{37} The results of the Woo study and this study were similar in that both found no significant central corneal refractive power change (central 3.3mm) after orthokeratology (indentation). The Woo study went on to show that the primary site of corneal
refractive power change occurred approximately 2.95mm temporal of the corneal apex. In our study, the data points collected from the corneal maps did not extend beyond 2.54mm from the corneal apex, nor did they analyze central versus peripheral corneal changes.

A suggestion for similar studies in the future: consider incorporating data points beyond the central 3mm, and separate the data points into two categories: central, which tend to flatten post indentation, and peripheral which tend to steepen post indentation.

As clinically applied to orthokeratology, our study suggests the following:

1) A provocative test such as minor indentation of the cornea (perhaps with a Goldmann probe or a flat trial contact lens) may be a useful procedure for assessing short term pliability of the cornea.

2) Different corneas respond differently, suggesting that orthokeratology may never be successful on all potential candidates.

3) Visual acuity change is a better indicator of potential success than corneal curvature changes.

4) Individuals who show improved or stable short term acuity improvements may be good ortho-k patients.
Map 1.
COMPARATIVE ISODIOPTRIC MAPPING

Press C to change Plot parameters

EyeSys Corneal Analysis System
Map 2.
COMPARATIVE ISODIOPTRIC MAPPING

Press C to change Plot parameters
EyeSys Corneal Analysis System

Map 3.
Graph 2

![Graph 2]
Graph 3

![Graph 3](image-url)
Graph 5

Va Change

Time

1 2 3 4 5
## ANOVA - VAs

**Table 1**

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<th>Source of Variation</th>
<th>SS</th>
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<th>MS</th>
<th>F</th>
<th>P-value</th>
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## ANOVA - Maps

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### Va improvement of three hundredths of a digit or more. (significant VA improvement)

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### Va improvement of less than three hundredths of a digit.

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Bibliography


