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## A clinical method for predicting the success of orthokeratology treatment phase II

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## **A clinical method for predicting the success of orthokeratology treatment phase II**

### **Abstract**

Orthokeratology is a method of fitting rigid contact lenses in a progression in order to change the cornea's radius of curvature, resulting in an improvement in uncorrected visual acuity. The usefulness of orthokeratology for most patients will depend on both the magnitude of myopia reduction and the amount of time he or she must wear a "retainer lens" to maintain that change. This study is an attempt to create a simple and clinically practical procedure to predict which patients will require the least amount of retainer lens wear while maintaining optimal visual acuity, and is divided into two phases. Phase I of this study revealed a significant difference between subjects' refractive error changes after undergoing short-term orthokeratology lens wear. In Phase II, ten patients from Phase I were selected to receive the orthokeratology treatment. After patients achieved minimal wear time of their orthokeratology retainer lenses, a comparison of visual acuity retention time and the initial changes in refractive condition found in Phase I was statistically correlated. Statistical analysis revealed no significant difference between visual acuity retention time and the changes in refractive condition found in Phase I. However, the results of this study might be more promising if a larger and more controlled subject pool was incorporated.

### **Degree Type**

Thesis

### **Degree Name**

Master of Science in Vision Science

### **Committee Chair**

Katherine Hinshaw

### **Subject Categories**

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**A CLINICAL METHOD FOR PREDICTING THE SUCCESS**  
**OF ORTHOKERATOLOGY TREATMENT**  
**PHASE II**

By

BART LOTTON  
MITCH MARTIN  
JOEL NEUMILLER

A thesis submitted to the faculty of the  
College of Optometry  
Pacific University  
Forest Grove, Oregon  
for the degree of  
Doctor of Optometry  
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Adviser:

Katherine Hinshaw, O.D.

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## **Biographical Sketches**

### **Bart Lotton**

Bart lotton is a fourth year intern at Pacific University College of Optometry. He received his B.S. in biological sciences from Montana State University in 1991 and will receive his doctorate in optometry in 1996.

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### **Achnowledgments**

The authors would like to thank the many people who have helped plan, organize and execute this project. First we would like to thank Dr. Katherine Hinshw and Dr. James Peterson for supporting us and taking the time to teach us the basics as well as the more complex aspects of contact lenses.

A special thanks goes to Contex Inc., and its owner Mr. Nick Stoyan who, with the help of Launa Kind, provided us with unlimited contact lenses for both phases of our study.

We would also like to thank Dr. Bradley Coffey for his help with statistical analysis, and Dr. Roger Tabb for his counsel. Finally, we again would like to thank Launa Kind for her unyielding kindness and patience.

## **Abstract**

Orthokeratology is a method of fitting rigid contact lenses in a progression in order to change the cornea's radius of curvature, resulting in an improvement in uncorrected visual acuity. The usefulness of orthokeratology for most patients will depend on both the magnitude of myopia reduction and the amount of time he or she must wear a "retainer lens" to maintain that change. This study is an attempt to create a simple and clinically practical procedure to predict which patients will require the least amount of retainer lens wear while maintaining optimal visual acuity, and is divided into two phases.

Phase I of this study revealed a significant difference between subjects' refractive error changes after undergoing short-term orthokeratology lens wear. In Phase II, ten patients from Phase I were selected to receive the orthokeratology treatment. After patients achieved minimal wear time of their orthokeratology retainer lenses, a comparison of visual acuity retention time and the initial changes in refractive condition found in Phase I was statistically correlated. Statistical analysis revealed no significant difference between visual acuity retention time and the changes in refractive condition found in Phase I. However, the results of this study might be more promising if a larger and more controlled subject pool was incorporated.



## **Introduction**

Orthokeratology can be defined as the manipulation of the fitting characteristics of a rigid contact lens to flatten the anterior surface of the cornea and decrease the amount of myopia and/or astigmatism. The procedure started in the 1950's and 1960's when eyecare practitioners began to notice that their contact lens patients' keratometric readings and refractions changed after several years of contact lens wear. Most myopic patients became less myopic with flatter corneas as a result of rigid contact lens wear. In 1962 Dr. George N. Jessen reported on a "deliberate effort" to encourage corneal shape changes with his "orthofocus techniques" using contact lenses.<sup>1</sup> In that same year Dr. Jessen helped found the Society Of Orthokeratology and Ortho-K was born.

Since orthokeratology's inception, practitioners have tried to devise a method of predicting whether or not a patient will be successful with the procedure.. In this way, practitioners would decrease their failure rate and increase their percentage of success. The researchers in phase I of this study set out to do just that: find a method for predicting which patients would be good candidates versus which would be poor candidates for the orthokeratology procedure.

In phase I the researchers attempted to create a simple and clinically practical procedure to predict those patients that would require the least amount of retainer lens wear while maintaining optimal visual acuity. Phase I was devoted to an assessment of the efficacy and duration of refractive changes induced by short-term OK lens wear and whether or not different individual refractive errors respond differently to the OK lens effect. Statistical analysis revealed

## **Apparatus and Procedures**

On initial examination of each of the 10 subjects, baseline characteristics were recorded, including: aided and unaided visual acuity, refractive error, and keratometry readings with both the AO keratometer and the EyeSys corneal topographer. Next, the first orthokeratology lens (OK-3 lens Contex Inc.) was fit 1.5D flatter than the flattest corneal curve read from the AO keratometer. The fitting characteristics of the lens were evaluated with a biomicroscope confirming that the following aspects were present: 2-3 mm of apical touch, intermediate pooling, light peripheral touch or liftoff, movement of 1-2 mm before and after the blink. If the lens met the fitting criterion, then an over-refraction was performed to determine the lens power needed. If it was determined by over-refraction that the patient needed a lens power change, then the patient was provided with the corrected power lens and the fit evaluation along with the over-refraction was repeated. At this point the patient was allowed to leave with the lenses in place and asked to return in five hours, when a full exam would be performed.

At each visit the same examination protocol was followed. First the specifications of each lens were transferred from the previous exam form: base curve (diopters), diameter, power, and cleaning care regimen. The amount of time the lenses were worn on the day of the visit was also recorded. The patient was then asked about any symptoms experienced. Next monocular visual acuities, with the lenses on were taken using a projected Snellen chart. A spherical over-refraction along with visual acuities was then performed. If 20/20 acuity was not attainable with the spherical over-refraction, a sphere-cylinder over-refraction was done with visual acuity results following. Next, slit lamp examination was used to evaluate the lens fit. The lenses were observed without fluorescein and again with fluorescein for the fitting characteristics listed

a significant difference between subjects' refractive error changes. That is, patient refractive errors did respond differently from each other when subjected to the OK lenses.<sup>2</sup>

In a double blind study consisting of three researchers and ten subjects, the method used by the researchers in phase I to predict good versus poor candidates was put to the test. In phase II of the study, ten subjects, five predicted good candidates, and five predicted poor candidates were given orthokeratology treatment over a six month period.

This paper addresses Phase II of the study.

## **Methods - Phase II**

### **Subjects**

Of the original 19 subjects participating in Phase I of the study, 10 were selected to participate in Phase II. The 10 subjects were separated into two groups, good orthokeratology candidates and poor orthokeratology candidates, based on criteria set by the researchers in Phase I. Unfortunately of the 10 subjects selected to complete Phase II, 4 dropped out of the study.

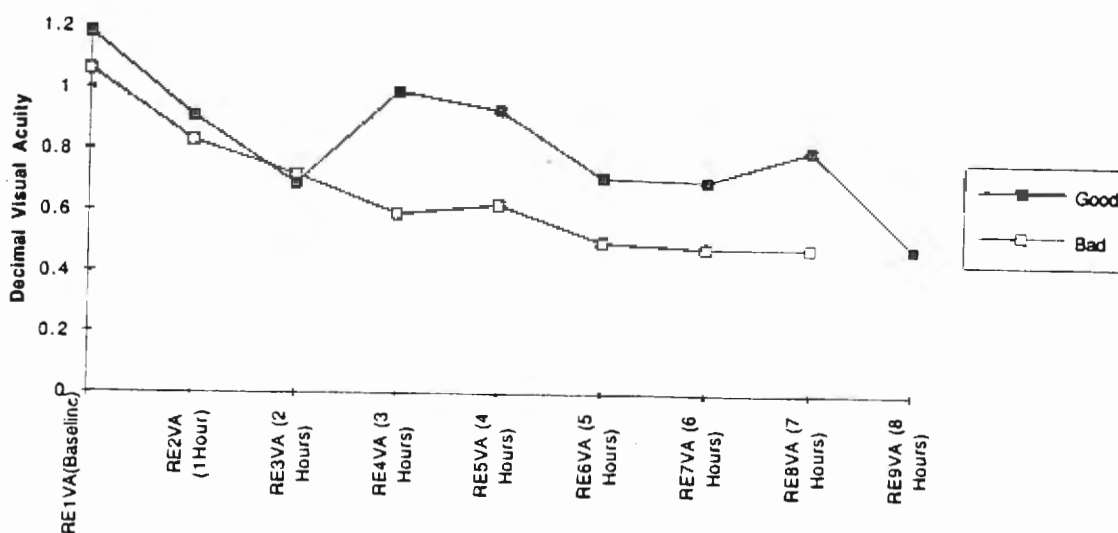
For information on the original subject pool and the selection process see Methods - Phase I, appendix I.

previously. After observing the lens on the eye, the lenses were removed. Central, as well as temporal corneal curvature was measured as soon as the lenses were removed using an AO keratometer. Unaided monocular visual acuities were then taken, followed by a monocular subjective to best visual acuity. Anterior segment health was assessed using a slit lamp and fluorescein to check for staining. If a lens change was required, new lenses were tried. If the correct parameters were not in stock, the correct lens was ordered and dispensed at the next visit.

Corneal topography readings were also taken routinely using the EyeSys program. A baseline reading was done before any lenses were put on the eye. Following readings were performed after the five hour follow-up, after every two lens changes, and if an signs or symptoms of corneal distortion occurred. For a copy of the examination protocol outline and examination form, see appendix II.

## Results

Figure 1. shows the decimal visual acuity plotted against time for both the good ortho-k candidates and the poor ortho-k candidates.



By means of extrapolation one can see a trend of better visual acuity over time for the good candidates as compared to the poor candidates. The better visual acuity comparison is to the degree of around 0.2 decimal acuity, which is approximately equal to a one line difference in Snellen visual acuity measurement. The graph also indicates a better retention time for the good candidates, approximately two and one-half to three more hours of visual acuity retention before dropping below the cut-off acuity of 20/40.

## **Discussion**

As researchers we were asked to test a procedure that would allow a practitioner to predict the success of an orthokeratology candidate. Many problems were encountered during the course of the study, the most devastating being the drop out rate of subjects. In spite of this, our data does show some promising results for this orthokeratology screening procedure. We believe that these results warrant further testing with a larger subject pool and more stringent guidelines for subject entry into the study.

We can attribute most of the large drop-out rate of our subjects to the fact that they were predominately optometry students, engulfed with large amounts of visually demanding tasks, with very strict class schedules. Understandably, they are extremely critical about their vision. In addition, optometry students are more apprehensive and inquisitive toward the procedures than the average layperson would be. Because of these factors the subject pool was in jeopardy concerning loyalty to the study, and this of course lead to poor subject numbers at the end of the study. Of the beginning ten subjects, six remained at the finish, including four good candidates

and two poor candidates. One of the four good candidates was dropped from the statistical analysis, because this subject was an extreme outlier and would have altered the data immensely. This leaves us with statistical analysis of three good candidates versus two poor candidates, and it brings us to the next subject of concern.

Consideration of candidate beginning refractive error would seem to be important for further exploration of this screening procedure. The one candidate whose data was not included in our final statistical analysis had a beginning refractive error of less than -1.00 diopter, and, in fact was the only subject with such a low refractive error.

In spite of the low number of subjects, we still were impressed by the results. The "good" candidates, as predicted by the researchers' method in phase I, did indeed show a better visual acuity over time and have a longer retention time of their superior acuity. In addition, there did exist a larger drop-out rate in the poor candidate group. Therefore, we believe the procedure is worthy of notice and deserving of further investigation. We suggest that the beginning subject pool be much larger, and that more stringent guidelines are used to determine qualification of subjects for study, particularly refractive error.

As most orthokeratologists know, the biggest concern in choosing a "good" candidate for orthokeratology is the candidate's goal. One patient may wish to have good vision without lenses for only two hours, to play a basketball game or to read sheet music in a recital; another patient may wish to have good vision without lenses for more than a week at a time. In the first example, all of our subjects would have been "good" candidates, whereas in the latter example

only one of our beginning ten subjects would have been a good candidate. Nevertheless, we think that the screening procedure proposed by the researchers in phase I is a good one, worthy of further testing, giving the orthokeratologist a good idea of how well he/she can do with each patient. Further, we believe that the screening procedure would be particularly good for beginning orthokeratologists, who are not able to rely on years of experience to help them determine which candidates are likely to be successful with the orthokeratology procedure.

## References

1. Binder, PS., May, CH., Grant, SC.: An evaluation of orthokeratology. *Am Academy of Ophthal* 87:729-745, 1980.
2. Brand, RJ., Polse, KA., Schwalbe, JS.: The Berkely Orthokeratology Study, Part I. *American Journal of Optometry and Physiological Optics* 60:175-185, 1983.
3. Brand, RJ., Polse, KA., Schwalbe, JS.: The Berkely Orthokeratology Study, Part III. *American Journal of Optometry and Physiological Optics* 60:321-328, 1983.
4. Bryant, MK., Horner, DG.: Take another look at Today's Ortho-K. *Review of Optometry*. June 15, 1994. pg. 43.
5. Buffington, RD., Lilly, JY.: A predictable approach to orthokeratology. *Contact Lens Spectrum* 1:24-8, 1986.
6. Contex, Inc.: OK™ Lens Fitting Guide. Copyright 1994.
7. Coon, LJ.: Orthokeratology: Part I Historical Perspective. *J Am Optom Assoc* 53:#3:3/82.
8. Curtin, BJ.: Myopias. Philadelphia: Harper & Row, 1985; 203-34.
9. Ederer, F.: Shall we count the numbers of eyes or numbers of subjects? *Arch Ophthalmol* 89:1-2, 1973.
10. Freeman, RA.: Orthokeratology and the corneascope computer. *Opt Weekly* 67:90-92, 1976.
11. Kerns, RL.: Research in orthokeratology: I. Introduction and background. *J Am Optom Assoc* 47:1047-51, 1976.
12. Kerns, RL.: Research in orthokeratology: V. Results and observations--recovery aspects. *J Am Optom Assoc* 48:345-359, 1977.
13. King, P.: Orthokeratology: seeing is believing. *Sci Technol Dimen* 1:21-6, 1987.
14. Lakin, D., Estes, S.: Reshaping your ideas. *Contact Lens Spectrum* pg. 25, April 95'.
15. Nolan, JA.: Myopia control with contact lenses. *Contacto* 11(4):24-27, Dec. 1967.
16. Tredici, TJ.: Role of orthokeratology: a perspective. *Ophthalmology* 86:698-705, 1979.
17. Wesley, RKA.: Orthokeratology, a practical fitting method. *Global Contacto* 35(2):25-35, 1992.



**Informed Consent Form**  
Pacific University College of Optometry

- A. Title of Project:     **A Clinical Method for Predicting the Success of Orthokeratology Treatment: Phase I**
- B. Principal Investigators:     Eli Ben-Moshe     357-5441  
  Troy Bailey         357-4484  
  Christine Dorn     626-1183
- C. Advisers:                     Katherine Hinshaw, O.D. 357-2371  
  James Peterson, O.D.    357-6151
- D. Project Location:            Pacific University
- E. Project Dates:                December, 1993 through May 1994

**1. DESCRIPTION**

In Phase I the subjects' refractive error will be determined and they will be screened using keratometry and biomicroscopy. Each subject will be fit with RGP lenses that are 2.00 D to 2.50 D flatter than the average of the two meridians of the cornea. After wearing the lenses for two hours they will be removed and an autorefractometer will be taken every hour until the refractive condition returns to the initial readings. The change in refraction as a function of time will be recorded. After all the data is collected the five subjects whose corneas take the longest time to return to baseline and the five subjects whose corneas take the least amount of time to return to baseline will be selected to participate in Phase II. In this second phase the patients from each group will be assigned to a doctor who will perform OK for 18 months. After patients have achieved minimal wear time of their retainer lenses a comparison of the retainer lens wearing time and the initial rate of change of the corneal curvature will be compared. The project is designed to establish a procedure which will allow the prediction of which patients will require the least amount of retainer lens wear while retaining optimal visual acuity.

**2. RISKS**

No unusual or invasive techniques will be used during the visual exams, only routine optometric tests. Some individuals may experience mild headaches or fatigue after these tests, mild discomfort associated with new contact lens wear, induced astigmatic change due to contact lens wear or allergic reactions to solutions.

**3. BENEFITS**

Patients will receive the Orthokeratology procedure at no cost and will keep the retainer lenses at the end of the project.

**4. ALTERNATIVES ADVANTAGEOUS TO SUBJECTS**

Not applicable.

## **Appendix A**

## Introduction

Orthokeratology (OK) has been used as a means to reduce myopia for many years. It involves fitting progressively flatter RGP or PMMA lenses to flatten the curvature of the cornea, which reduces the refractive power of the eye and improves unaided visual acuity. The success rate of OK, or any other health care procedure, can be greatly increased with better patient selection. The usefulness of OK for most patients will depend on both the magnitude of myopia reduction **and** the amount of time he or she must wear a retainer lens to maintain that change. For example, a practitioner who reduces a patient's myopia from -4.00 to plano may find that the patient is very unhappy when he/she realizes a considerable amount of time and money has been spent to get perfect vision that lasts only a few hours without contact lenses.

Throughout the years OK practitioners have found that the degree of myopia reduction is largely dependent on characteristics of the patient's cornea and complete visual system. Although Kerns<sup>1</sup> states that there is nothing to indicate which patients will respond optimally to OK from the pre-fit examination and that one can not offer a solid prognosis of the procedure, many practitioners seem to disagree. Wesley states that the best OK candidates are those with less than 3.00 D of myopia and less than 1.5 D of corneal astigmatism<sup>2</sup>. Freeman<sup>3</sup> believes that corneal astigmatism is a must to successfully treat myopia with OK. May<sup>4</sup>, a pioneer in the field, explains that patients with corneas that are steeper centrally than peripherally show the greatest reduction in myopia. Contex, Inc, the manufacturer of OK<sup>TM</sup> lenses, states that the likely amount of myopia reduction that can be achieved is two times the difference between flat central K and temporal K readings<sup>5</sup>.

Most doctors predict the success of OK based only on the amount of myopia reduction attainable and do not take into account the time of retainer lens wear in the definition of success. According to Kerns<sup>6</sup>, the manner in which the eye responds after the removal of a contact lens is highly individualistic in nature.

It has been shown that the cornea is either highly elastic or has some other memory mechanism to return it to its original curvature after lens wear is discontinued<sup>6,7</sup>, and that OK patients must wear retainer lenses some of the time to stabilize the corneal flattening and prevent regression of refractive error<sup>8,9,10,11</sup>, but present reports do not provide substantial information about the amount of time patients must wear retainer lenses to maintain the corneal curvature change induced by OK. This study attempts to devise a simple and clinically practical procedure to predict which patients will require the least amount of retainer lens wear while retaining optimal visual acuity, and is divided into two phases.

Phase I of this study is devoted to an assessment of the short-term efficacy and duration of refractive changes induced by short-term OK lens wear in order to find out if differences in refractive error (RE) changes do exist between individuals. In Phase II, five patients who showed the greatest change in RE and the five patients who showed the least amount of change in RE from Phase I were selected to receive the OK treatment. Neither the subjects or the interns performing the OK procedure know from which group the subjects came in this double-blind study.

After patients have achieved minimal wear time of their OK retainer lenses, a comparison of the retainer lens wearing time and the initial changes in refractive condition found in Phase I will be statistically correlated. Phase II is currently under way, with completion anticipated sometime in 1995. We hypothesize that differences

in RE changes do exist and that those patients whose refractive condition changed the least in two hours after removal of OK lenses will require the least amount of lens wear at the end of the OK procedure.

This paper addresses Phase I of the study.

## **Methods - Phase I**

### **Subjects**

The subject pool was selected from 48 volunteers interested in having the OK treatment and motivated to participate in the study by offering the OK procedure to those selected from Phase I at no cost.

All volunteers were Pacific University Optometry or undergraduate students and all had a complete eye examination at the Pacific University Optometry Clinic within the previous year. The clinic's patient files were used to screen the subjects using visual acuities, refractive condition, keratometry, biomicroscopy, ophthalmoscopy and tonometry. Only those myopes who met the following criteria were asked to participate in the study:

1. Best corrected visual acuity of 20/20 or better.
2. Refractive condition of both eyes between .75 D and 3.75 D sphere with no more than 1.25 D of corneal astigmatism.
3. No ocular pathologies which would impede normal contact lens wear.

Twenty of the volunteers were eliminated by the screening and nine more were unable to participate due to scheduling conflicts or a change of mind, leaving 19

subjects (10 males and 9 females) between the ages of 18 and 29 to participate in Phase I of the study. All volunteers were asked to sign an informed consent form.

### **Apparatus and Procedures**

Each subject's refractive error (RE) was determined by taking an average of the equivalent spheres of six readings from an Allergan Humphry autorefractor and corneal curvature was measured with a standard B&L keratometer. The same instruments were used throughout the study and the keratometer was calibrated using steel balls of known radius.

The subjects were then fit with plano lenses from an OK-3™ trial lens set from Contex, Inc. The lenses were fit approximately 2.00 D flatter than the average of the two principal meridians of the cornea. Lens modifications were performed to ensure a well-centered lens with 1 - 2 mm of movement after each blink. Fluorescein patterns were checked for 2 - 3 mm of apical touch, intermediate pooling and light peripheral touch or lift off.

The subjects were then allowed to leave while wearing the lenses and instructed to return in two hours, or sooner if they experienced any discomfort. After two hours the lenses were removed and the RE determination was repeated. The RE was measured again one hour after the removal of the lenses and once more two hours after the removal of the lenses.

The difference between the initial RE and the RE immediately after the removal of the lenses, as well as the difference between the RE immediately after lens removal and the RE one and two hours after lens removal was calculated and used in statistical analysis. Since we are not comparing different treatments applied

to the two eyes of an individual and because the RE of each eye of an individual has been found to be highly correlated, all calculations were based on the results from the right eyes only. As Ederer<sup>12</sup> states, the second eye adds little information and, if included, may invalidate any statistical inference drawn from the data.

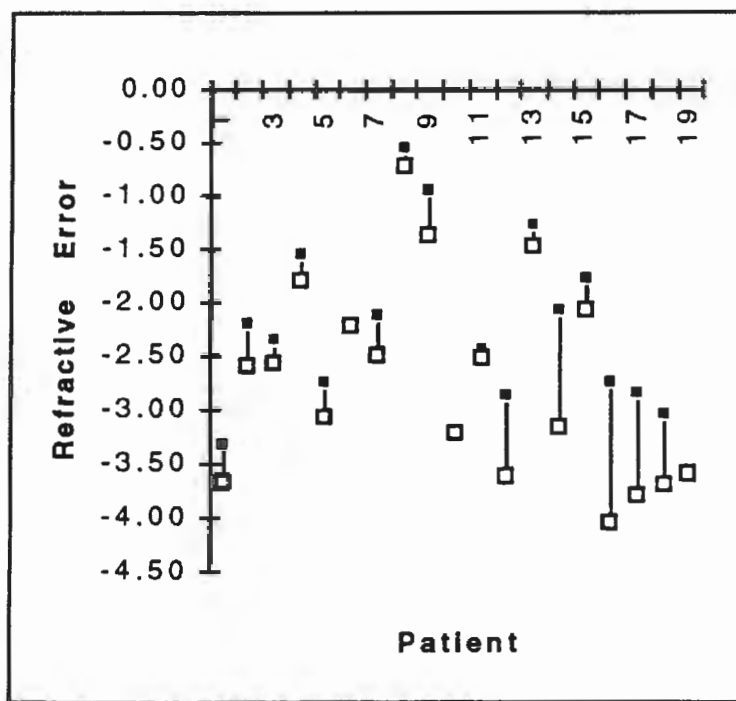
## Results

The amount of change in each subject's RE is shown in Table 1. After two hours of contact lens wear, the subjects showed an overall mean reduction in the initial RE of .35D. Two hours after removing the lenses the subjects showed a mean increase in RE of .41D.

**Table 1.** Changes in refractive error (RE) after wearing OK-3<sup>TM</sup> contact lenses for two hours.

<b>Patient</b>	<i>Refractive Error (A)</i>	<i>RE after lens wear (B)</i>	<i>Change in RE due to lens wear (B-A)</i>	<i>RE 1Hr after lens removal (C)</i>	<i>Change in RE 1 Hr after lens removal (C-B)</i>	<i>RE 2Hrs after lens removal (D)</i>	<i>Change in RE 2Hrs after lens removal (D-B)</i>	<i>Rank (Top, Middle, Bottom)</i>
1	-3.63	-3.33	0.30	-3.56	-0.23	-3.67	-0.34	M
2	-2.90	-2.20	0.70	-2.65	-0.45	-2.60	-0.40	M
3	-2.45	-2.35	0.10	-2.15	0.20	-2.58	-0.23	M
4	-2.05	-1.55	0.50	-1.55	0.00	-1.80	-0.25	M
5	-2.80	-2.75	0.05	-3.05	-0.30	-3.08	-0.33	M
6	-2.18	-2.25	-0.07	-2.33	-0.08	-2.23	0.02	T
7	-2.50	-2.13	0.37	-2.25	-0.12	-2.50	-0.37	M
8	-0.73	-0.55	0.18	-0.70	-0.15	-0.73	-0.18	T
9	-1.30	-0.95	0.35	-1.23	-0.28	-1.38	-0.43	M
10	-2.23	-3.25	-1.02	-3.38	-0.13	-3.23	0.02	T
11	-2.38	-2.45	-0.07	-2.90	-0.45	-2.52	-0.07	T
12	-3.87	-2.87	1.00	-3.27	-0.40	-3.62	-0.75	B
13	-1.37	-1.28	0.09	-1.37	-0.09	-1.47	-0.19	M
14	-3.15	-2.07	1.08	-3.37	-1.30	-3.17	-1.10	B
15	-2.23	-1.78	0.45	-2.18	-0.40	-2.07	-0.29	M
16	-3.17	-2.75	0.42	-3.57	-0.82	-4.05	-1.30	B
17	-3.82	-2.85	0.97	-3.30	-0.45	-3.80	-0.95	B
18	-4.08	-3.06	1.02	-3.54	-0.48	-3.70	-0.64	B
19	-3.73	-3.58	0.15	-3.79	-0.21	-3.60	-0.02	T
<b>AVE</b>	-2.66	-2.32	0.35	-2.64	-0.32	-2.73	-0.41	
<b>MEDIAN</b>	-2.50	-2.35	0.35	-2.90	-0.28	-2.60	-0.33	

The changes in RE between the time of lens removal and two hours after lens removal for each subject are illustrated in Figure 1. The five subjects whose RE changed the greatest amount between lens removal and two hours after removal were assigned to group B and showed a mean increase in myopia of .95D. The five subjects whose RE changed the least between lens removal and two hours after removal were assigned to group T and showed a mean increase in myopia of only .05D. The remaining subjects were assigned to Group M and showed a mean increase in myopia of 0.31D. Using a One Factor ANOVA test, a statistically significant difference between these three groups was found ( $p=.0001$ ).



**Figure 1.** Change in refractive error after removal of OK lenses.

The mean RE of the groups T, M, and B plotted against time are shown in figure 2. "0" refers to the time before the OK lenses were put on the eyes, "P0" refers to the time at which the OK lenses were first removed, "P1" refers to one hour post lens removal, and "P2" refers to two hours post lens removal.



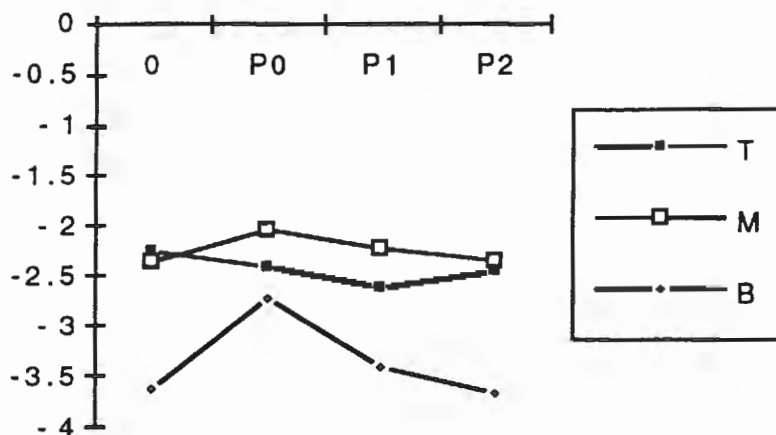


Figure 2. Mean RE of groups T, M, B vs. Time.

## Discussion

Although current practitioners talk about the success of Orthokeratology in relation to the amount of RE that can be reduced, the final amount of retainer lens wear time should also be taken into account. If a patient must wear his/her retainer lenses 6 or 8 hours per day, the benefit of this procedure is greatly reduced. Therefore a practical method of determining the retainer lens wear time would be useful to the practitioner when discussing the benefits of OK with the patient.

In this study a group of volunteers interested in having the OK treatment was fit for two hours with OK lenses. The lenses were removed and RE measurements were taken several times afterwards. A One Factor ANOVA statistical analysis was applied to the groups T, M, and B with several conclusions becoming evident.

Before any lenses were put on the eyes a statistical difference existed between each group's REs ( $p=.0182$ ). After two hours of lens wear the differences in REs between the three groups had collapsed. That is to say, the wearing of the OK

lenses brought all subjects towards emmetropia, and that after the lenses were removed no statistical difference between the groups' REs existed ( $p=.3275$ ).

Our analysis showed that two hours after lens removal a significant difference between each group's REs did exist ( $p=.0217$ ). However, no significant difference was found one hour after lens removal. Therefore, a minimum of two hours is required to find a significant difference between each group's REs.

A One Factor ANOVA-Repeated Measures analysis showed a significant difference between the three groups' REs over time ( $p=.0001$ ). The mean changes of each group's REs are illustrated in Figure 2. Group B showed the most change in RE due to wearing the lenses for two hours and also after lens removal. Group T's REs changed very little over the two hours of wearing the lenses and changed very little over the two hours after the lenses were removed. These different responses to the OK lenses were what we expected to find.

When looking at Figure 2 it is apparent that group T actually became slightly more myopic after wearing the OK lenses. This myopic shift is most likely due to the lenses inducing mild corneal edema and does not change the fact that group T's REs changed significantly less than did group B's, over time.

In conclusion, because group T's REs remained relatively stable over time compared to group B's REs, we hypothesize that Phase II will show a correlation between the retainer lens wear time and the initial changes in refractive conditions found in Phase I such that the subjects in group T will require less retainer lens wear time than those in group B.

We anxiously await the results of Phase II; the possibility of a predictor for successful OK is of interest to practitioners everywhere.