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A clinical method for predicting the success of orthokeratology treatment phase I

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phase I

Abstract
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cornea's radius of curvature, resulting in an improvement in uncorrected visual acuity. 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. 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 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 a significant difference between subjects' RE changes. That is,
patient refractive errors did respond differently from each other when subjected to the OK lenses.

In Phase II, ten patients from Phase I were selected to receive the OK treatment. 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. We hypothesize that those
patients whose refractive condition changed the least in the two hours post OK lens removal will require the
least amount of retainer lens wear at the end of the OK procedure. Phase II is currently under way, with
completion anticipated sometime in 1995.

Degree Type
Thesis

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A CLINICAL METHOD FOR PREDICTING THE SUCCESS OF ORTHOKERATOLOGY TREATMENT
PHASE I

By

ELI BEN-MOSHE
TROY BAILEY
CHRISTINE DORN

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

Katherine Hinshaw, O.D.
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Biographical Sketches

Troy Bailey

Troy Bailey is a fourth year intern at Pacific University College of Optometry. He received his B.S. in visual science from Pacific University in 1993 and will receive his doctor of Optometry in 1995. After graduation he plans to open a practice in the Northwest. He is a current member of the AOA contact lens section and a member of the Association of Seventh Day Adventist Optometrists (ASDAO).

Eli Ben-Moshe

Born in Israel, Eli Ben-Moshe came to the United States at the age of 11. He received his baccalaureate in visual science at Pacific University in 1993. He expects to receive his doctorate in May of 1995 from Pacific University College of Optometry. Throughout his academic career, Eli has developed a strong interest in the study of Orthokeratology. This interest was fueled by extensive research and case studies on the subject. He is currently a member of the AOA contact lens section, the International Orthokeratology Society and the National Eye Research Foundation. He plans to continue his work by serving his community in San Diego.

Christine Dorn

Christi Dorn is a second year optometry student at the Pacific University College of Optometry. She was born and raised in Minnesota and received a Bachelor of Arts degree from Hamline University where she graduated magna cum laude and was elected to the Phi Beta Kappa, Pi Gamma Mu and Kappi Phi Honor Societies. Upon receiving her O.D. degree she plans to return to Minnesota to work in a private practice setting.
Abstract

Orthokeratology (OK) 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 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. 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.

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In Phase II, ten patients from Phase I were selected to receive the OK treatment. 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. We hypothesize that those patients whose refractive condition changed the least in the two hours post OK lens removal will require the least amount of retainer lens wear at the end of the OK procedure. Phase II is currently under way, with completion anticipated sometime in 1995.
Acknowledgments

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 Hinshaw 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 the doctors around the country who helped shape our ideas, most notably Dr. Charles May, who supplied us with his contact lenses and shared his knowledge and vast experience about the subject with us, Dr. Jeffrey Eger who enriched us with his fitting techniques, and Dr. Helton Hanono, who sparked our interest in the subject of Orthokeratology.

We also greatly appreciate Contex, Inc. and its owner Nick Stolian who, with the help of Launa Kind, provided us with unlimited contact lenses for both phases of our study, and Dr. Bradley Coffey and Dr. Robert Yolton without whom we would have drowned in the confusion of statistical analysis.
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\textsuperscript{1} 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\textsuperscript{2}. Freeman\textsuperscript{3} believes that corneal astigmatism is a must to successfully treat myopia with OK. May\textsuperscript{4}, 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\textsuperscript{TM} 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\textsuperscript{5}. 
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\textsuperscript{6}, 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\textsuperscript{6,7}, and that OK patients must wear retainer lenses some of the time to stabilize the corneal flattening and prevent regression of refractive error\textsuperscript{8,9,10,11}, 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\textsuperscript{12} 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>
<thead>
<tr>
<th>Patient</th>
<th>Refractive Error (A)</th>
<th>RE after lens wear (B)</th>
<th>Change in RE due to lens wear (B-A)</th>
<th>Change in RE 1Hr after lens removal (C)</th>
<th>Change in RE 2Hrs after lens removal (D)</th>
<th>Change in RE 2Hrs after lens removal (D-B)</th>
<th>Rank (Top, Middle, Bottom)</th>
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<td>-2.90</td>
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<td>B</td>
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</table>
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](image)

**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.
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.
References


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 autorefraction 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.
5. CONFIDENTIALITY
   Records of this project will be maintained in a confidential manner and no
   name identifiable information will be released without written consent.

6. COMPENSATION AND MEDICAL CARE
   All efforts have been made to eliminate risk of injury to subjects. In the
   unlikely event that you are injured in this study, it is possible that you will not receive
   compensation or medical care from Pacific University, the investigators or any
   organization associated with the study.

7. OFFER TO ANSWER INQUIRIES
   The investigators will be happy to answer any questions that you may have at
   any time during the course of the study. If you are not satisfied with the answers you
   receive, please call Dr. James Peterson at 357-0442. As a result of your
   participation in the project, you are not a Pacific University clinic patient. All
   questions should be directed to the researchers and/or the faculty advisor who will
   be solely responsible for any treatment (except for an emergency). You will not be
   receiving complete eye, vision, or health care as a result of participation in the
   project; therefore, you will need to maintain your regular program of eye, vision and
   health care.

8. FREEDOM TO WITHDRAW
   You are free to withdraw your consent and to discontinue participation in this
   project or activity at any time without prejudice to you.

I have read and understood the above. I am 18 years of age or over (or this form is
signed by my parent or guardian). I am in agreement with the personal obligations of
the consent.

Printed name___________________________ Date of birth:____________
Signed name___________________________ Date:____________
Address________________________________ Phone:____________

Name and address of a person not living with you who will always know your
address:

______________________________________