

**ORTHOKERATOLOGY
PROJECT
and
SUBJECTIVE RESPONSE
STUDY of PATIENT
WEARING RETAINER
LENSES**

~~Paul Ware~~
March 19, 1994

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SECTION

ONE

Ferris State University

College of Optometry

February 3, 1993

John Pole O.D., Chairperson
Human Studies Committee
Ferris State University
Big Rapids MI, 49307

Dear Dr. Pole,

I request approval from your committee for the attached informed consent document to be used for a contact lens study. A brief description is enclosed outlining the purpose of this study.

All materials that will be used have been approved by the FDA and the procedures have been successful for the past two decades. We will be primarily using subjects from the student body from the college of optometry. If you have any questions please feel free to contact me at the Ferris State University College of Optometry.

Sincerely,



Donald H. Lakin O.D.
Associate Professor

Evaluation of Retainer Lens Wear
Following Orthokeratology Contact Lens Therapy

The main purpose of the study is to compare the practicality of using an FDA approved extended wear RPG for overnight retaining lens as compared to the more traditional Orthokeratology (Ortho-K) retainer lens schedule. The goal of Ortho-K therapy is to provide usable vision in the absence of a corrective lens. Now that rigid gas permeable (RPG) lenses are available for extended wear it offers a new opportunity for retainer lens wear during sleeping hours. Grant, and others have reported success by combining orthokeratology techniques with over night wear. Traditional orthokeratology techniques recommend a gradual decline in daily wearing time of the lens once the optimum VA is achieved. This approach and actual retaining lens wear time is individualized to suit patient needs. By using a retainer lens during non waking hours usable uncorrected visual acuity may be maintained without the inconvenience of lens wear during the waking hours.

Orthokeratology cannot be done on a random bases. The study is an attempt to evaluate person who have exhibited success in ortho-K corneal changes and are candidates for extended wear RGP wear. Twenty subject are sought with 3.00 or less diopters of myopia, and 1.00 or less diopters of corneal astigmatism. No pathological condition must be present. Prior entry into the study, optimal VA must be achieved using ortho-K therapy.

Informed Consent
Evaluation of Night Retainer Lens Wear
Following Orthokeratology Contact Lens Therapy

Patient: _____ Date: _____

I consent to be in this study which involves nearsighted control through Orthokeratology (Ortho-K) therapy. The therapy consist of fitting a series Rigid Gas Pearmeable (RGP) contact lenses in which the cornea become more round and flat. After the optimum shape reached a retainer lens will be required to maintain the corneal shape. These retainer lens will be a RGP lens which has been FDA approved for extended (overnight) wear. The study is being carried out to compare overnight wearing schedule to a traditional Ortho-K retainer daytime wearing schedule.

No discomfort or adverse reactions are expected with the use of these lenses, other than those normally associated with contact lens wear, if used according to the instructions. The complications that may occur with daily and extended contact lens wear can include mild discomfort, irritation, corneal abrasion, infection and/or temporary blurred vision. There is an increased risk of these problems when the lenses are worn at night.

The fitting of these lenses and the follow-up evaluations will be performed by Dr. Lakin or Dr. Pole who are authorized to use the services of other qualified personnel in the performance of the study.

I understand that at least 16 visits will be required over the course of the first year of the study period. I also agree to follow the lens wearing and care instructions given me and to report any problems to the investigators immediately.

The above items have been orally explained to me by _____ and I understand them. I understand any further inquiries I may make concerning the procedures will be answered. I understand I am free to withdrawal my consent and discontinue participation in the study at any time after notifying the project director and without prejudicing my future care. No guarantee has been given me concerning the clinical safety or effectiveness of this procedure.

If I am a student or employee at Ferris, I understand participating or withdrawing from the study will not effect my status as a student or employee.

If any problems occur or any other questions please call:

FSU Clinic: 592-2222

Dr. Lakin: 592-2189 Res. 775-1872

In case of no answers or emergency:

Pager 339-0087, leave a display number.

Signed: _____ Witness: _____
(subject)

SECTION

TWO

Protocol for Retainer Lens Study

Submitted February 4, 1993

The practice of orthokeratology involves a systematic approach of myopia control through the use of rigid contact lenses to change the corneal curvature topography. Over the past thirty years techniques have been sought and found to improve visual acuity of the myopic patient. Using orthokeratology techniques temporary changes in corneal curvature and improved visual acuity has been reported.¹ The need for maintaining positive changes is obvious. Optometrist practicing orthokeratology recognize the need for the use of retaining lenses to maintain optimum visual acuity. Other than limited clinical experiences and anecdotal information, no large body of knowledge exist in the recommended use of retainer lenses for myopia control.

Now that rigid gas permeable (RPG) lenses are available for extended wear it offers a new opportunity for retainer lens wear during sleeping hours. Grant, and others have reported success by combining orthokeratology techniques with extended wear schedule.^{2,3} Traditional orthokeratology techniques recommend a gradual decline in daily wearing time of the lenses once the optimum acuity is achieved. This approach and actual retaining lens wear time is individualized to suit patient needs. By using a retainer lens during non waking hours usable uncorrected visual acuity may be maintained without the inconvenience of lens wear during the waking hours.

The purpose of this study is to evaluate traditional orthokeratology retainer wear to a night time retainer

schedule. The criteria used will be based on visual acuity corneal topography, bio-microscopic examination and subjective responses by the subjects involved. By using these criteria night retainer lens wear may prove to be an alternative to traditional retaining lens wear schedules.

SUBJECT SELECTION

Orthokeratology cannot be done on a random bases. The study is an attempt to evaluate persons who have exhibited success in orthokeratology corneal changes and are candidates for extended wear RGP wear. Approximately Twenty subjects are sought with 3.00 diopters or less of myopia, and less than 2.00 diopters of astigmatism. No pathological condition must be present in which RGP extended wear is contraindicated. Prior into the study optimal visual acuity must be achieved using orthokeratology therapy.

LENS SELECTION

The lenses used may be of two design models:

1. A traditional tri-curve design.
2. An aspheric back surface design in which the lens steepens after a spherical optic zone. These included the MCL design by Art Optical, and the O-K series by Kontex.

Materials used are to be extended wear approved materials.

EXPERIMENTAL DESIGN

The subjects after initial orthokeratology therapy will be divided into two groups. Group I will the traditional retainer wear schedule. Lens wear is decrease on an individual bases, usually starting full days then decreasing hours until optimum schedule is achieved. Group II will be a night retainer lens wear schedule. The lenses will be worn at non waking hours nightly, and one hour upon waking with the instillation of lubricating agents.

Each groups measurements will be recorded once in the first week of retainer therapy in the AM and PM. Then bimonthly in AM and PM until the conclusion of the study.

EXAMINATION OF SUBJECTS

Exam Protocol

AM:	1. VA with lenses on	PM :	1. VA with lenses off
	2. Bio-microscopy		2. Bio-microscopy
	3. VA with lenses off		3. Corneal Topography
	4. Corneal Topography		

Visual Acutities

Measurement is in Snellen Acutities. During the AM examination the VA is measured with the lenses on then off. Care must be taken to alternate charts to prevent the subjects memorizing the responses.

During the PM evaluation if the subject in group I normally wears the lens at this time then proceed the same as the AM exam. Group II and Group I subjects not wearing

the lenses in the PM need only the unaided VA only. Again Alternate the charts to prevent memorization.

Bio-microscopy

Corneal integrity will be evaluated with various illuminations and visualizations . Any condition in the integrity of the cornea will be recorded. Flouroskien will be added to aid in evaluation of the lenses an corneal integrity.

Corneal Topography

Topography with the EYESYS computerized photokeratoscope will be done on subject exam. Evaluation and comparisons will be noted with attention give to sphericalization.

SUBJECTIVE RESPONSES

Development of a questionnaire log to be completed by the subjects to included:

1. Duration of unaided visual acuity daily.
2. Any task that proves to increase in difficulty without corrective lenses or unaided vision tolerances
3. Not Any particular problems with the lens comfort or eye irritation.
4. Note the ease of compliance of the retainer schedule.
5. Overall opinion of the orthokeratology therapy and the retainer schedule.

COMPARISON

This will allow for comparison and determination of night retainer lenses as it relates to the traditional orthokeratology therapy.

This is not an attempt to quantify results of the usefulness of orthokeratology as a whole. By looking at usable unaided vision duration, acuities, and corneal changes a more structured system of therapy may be instituted in the future.

REFERENCES

1. Kerns William. Orthokeratology Literature Review. *JAOA* 1978 ; 14: 234-243.
2. Grant Stuart. Orthokeratology Night Therapy and Night Retention. *Contact Lens Spectrum* 1992; 7; 11: 28-34.
3. Harris Donald, Stoyan Nick. A New Approach to Orthokeratology. *Contact Lens Spectrum* 1992; 7; 4: 37-40

ORTH-K RETAINER LENS STUDY

PATIENT INFORMATION

Date _____

Name _____

Address _____

City _____ State _____ Zip _____

Summer Address _____

City _____ State _____ Zip _____

Phone: local ____ - ____ summer (____) - ____ - ____

Date of Birth ____ - ____ - ____

Occupation _____

Hobbies _____

SECTION

THREE

Informed Consent
Evaluation of Night Retainer Lens Wear
Following Orthokeratology Contact Lens Therapy

Patient: _____ Date: _____

I consent to be in this study which involves nearsighted control through Orthokeratology (Ortho-K) therapy. The therapy consist of fitting a series Rigid Gas Pearmeable (RGP) contact lenses in which the cornea become more round and flat. After the optimum shape reached a retainer lens will be required to maintain the corneal shape. These retainer lens will be a RGP lens which has been FDA approved for extended (overnight) wear. The study is being carried out to compare overnight wearing schedule to a traditional Ortho-K retainer daytime wearing schedule.

No discomfort or adverse reactions are expected with the use of these lenses, other than those normally associated with contact lens wear, if used according to the instructions. The complications that may occur with daily and extended contact lens wear can include mild discomfort, irritation, corneal abrasion, infection and/or temporary blurred vision. There is an increased risk of these problems when the lenses are worn at night.

The fitting of these lenses and the follow-up evaluations will be performed by Dr. Lakin or Dr. Pole who are authorized to use the services of other qualified personnel in the performance of the study.

I understand that at least 16 visits will be required over the course of the first year of the study period. I also agree to follow the lens wearing and care instructions given me and to report any problems to the investigators immediately.

The above items have been orally explained to me by _____ and I understand them. I understand any further inquiries I may make concerning the procedures will be answered. I understand I am free to withdrawal my consent and discontinue participation in the study at any time after notifying the project director and without prejudicing my future care. No guarantee has been given me concerning the clinical safety or effectiveness of this procedure.

If I am a student or employee at Ferris, I understand participating or withdrawing from the study will not effect my status as a student or employee.

If any problems occur or any other questions please call:
FSU Clinic: 592-2222
Dr. Lakin: 592-2189 Res. 775-1872
In case of no answers or emergency:
Pager 339-0087, leave a display number.

Signed: _____ Witness: _____
(subject)

The following is a list of instructions for completion of the retainer lens study. Please read the following instructions carefully and ask any questions.

Thank you for participating in this study, now the work is up to you.

In completing the Ortho-k program you must progress with the retainer lens wear schedule.

In addition to your normal lens care it is required you complete a patient log and measure your acuity with the chart provided. The time of insertion and removal of lenses must also be recorded. Please record the Acuities at these times if possible.

You may wear your lenses as much or as little as you feel necessary however please record the times.

To measure Acuities place the chart in a well lighted area in which you can stand 10 feet away from the chart. Measure one eye at a time then both eyes together. Record the number which coincides with smallest line of letters you can see. Record the right eye, then the left on the space provided.

Night Schedule _____

Night Schedule instructions: Prior to sleeping.

1. Measure Acuity as instructed above, and record on log.
2. Place your lens in your eyes before retiring to bed, record time on log.
3. When you awake you must leave your lenses in your eyes for ONE HOUR. At this time you are to use eye lubricants as needed for comfort. (you may remove lens briefly to clean if you feel it is necessary but reinsert as soon as possible)
4. Remove lenses, record time on log, and follow normal lens care regimen.
5. Measure Acuity after lens removal and record on log.
6. Record on log the time and acuities before you reinsert lenses during the day if necessary.
7. Record on progress notes any problems you experience with your vision or related items with the time and date included.

Day Wear Schedule _____

Day Schedule Instructions: Upon waking

Day wear of lenses is based on your personal needs. You are the best judge of the amount of time you need to wear the lenses. Attempt to wear the lenses as long as you can continue to perform your necessary visual tasks. Please record these times as instructed below.

1. Measure Acuities as instructed above prior to inserting lenses. Record Acuities and time on log.
2. Upon removing lenses record Acuities and time on the log.
3. Record on the log Acuities and time prior to reinsertion of the lenses during the day as necessary.
4. Record on the log the final removal time and Acuities prior to retiring to sleep.
5. Follow normal lens care instructions.
6. Record on the progress notes any problems you experience with your vision or related items including the time and date.

=====
For all Participants fill out the questionnaire inclosed at the end of your monthly log.

Bring logs with you when you return for follow up exams.
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If any problems occur or any other questions please call:

FSU Clinic: 592-2222
Dr. Lakin: 592-2189
In case of no answer at FSU Dr. Lakin: residence 775-1872

Thank you for your help and assistance with this project.

PATIENT LOG

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NAME _____

QUESTIONNAIRE

What is the name of your lens care products? _____

Rating: poor average excellent
 1 2 3 4 5

1. How is your distance vision? _____ 1 2 3 4 5

Comments _____

2. How is your near vision? _____ 1 2 3 4 5

Comments _____

3. How well do you perform your visual tasks without wearing any
corrective lenses, compared to your performance with corrective
lenses in place? _____ 1 2 3 4 5

Comments _____

4. How do you rate the wearing schedule. _____ 1 2 3 4 5

Comments _____

5 Rate your overall experience with the Ortho-k Retainer lens
program. _____ 1 2 3 4 5

Comments _____

Any suggestions or comments not already made please express them
on the back of this form. Your input is very important.

O-K CHART

Z S H C 10 $\frac{20}{125}$

H S K R N 9 $\frac{20}{100}$

C H K R V D 8 $\frac{20}{80}$

H O N S D C V 7 $\frac{20}{60}$

O K H D N R C S 6 $\frac{20}{50}$

V H D N K U O S R C 5 $\frac{20}{40}$

B D C L K Z V H S R O A 4 $\frac{20}{30}$

H K G B C A N O M P V E S R 3 $\frac{20}{25}$

P K U E O B T V X R M J H C A Z D I 2 $\frac{20}{20}$

D K N T W U L J S P X V M R A H C F O Y Z G 1 $\frac{20}{16}$

SECTION

FOUR

**SUBJECTIVE RESPONSE
STUDY of PATIENT
WEARING RETAINER
LENSES**

Paul Ware
March 19, 1994

INTRODUCTION

It has long been realized rigid contact lenses can cause corneal warpage. Now with the use of computer aided corneal topography corneal flattening was found to last up to 5 month after the removal of lens wear.¹ Orthokeratology therapy is a technique which controlled flattening of the cornea is attempted to improve unaided vision of the myopic patient with rigid contact lenses. Many anecdotal reports and clinical cases have been reported.² The recognized end point of the therapy is the best possible acuity without correction and the continued use of retainer lenses. Very little information is available on the use of retainer lenses compared to the information provided by the anecdotal reports. This study attempts to elicit patient subjective responses to retainer therapy after the procedure to improve acuity is successful.

After successful therapy is achieved the retainer lens must be worn at intervals to maintain the optimal unaided acuity. With the availability of extended wear RGP lenses it is possible use the retainer lenses a night.³ The more traditional method of limited day wear is also employed.⁴ At the present time no nomograms exist to aid in proper intervals and the proper schedule is made on clinical judgment. This decision relies on close interaction of the patient and clinician. Clinical decisions must rely on a patient's subjective response to the therapy.

This study attempts to determine trends in the patient responses as they relate retainer lens wear. The retainer schedule is individualized and a study in conjunction with this present study is ongoing to determine trends in wearing time as it relates to visual acuity and other factors.

INITIAL THERAPY

The initial orthokeratology therapy is not the scope of this report. However, the therapy was aided by the use of corneal topography. This allowed closer monitoring of the therapy and added to decision making on lens fitting. The progress of the corneal flattening could be quantified and demonstrated with the EyeSys system. The end point of the therapy was reached as acuity was optimally reached. Though functional acuity is the vision stressed in orthokeratology all subject in the study had reach unaided acuity of Snellen 20/30 or better.

SUBJECT SELECTION

A total of 23 subjects consisting of college students initially began therapy with RGP lenses 17 patient remained throughout orthokeratology therapy and 10 patient participated in the subjective questionnaire. Of the six initial subjects to drop out 2 did not tolerate any RGP fit, 3 expressed problems with the studies time frame an elected not to participate, and 1 subject moved from the study area. Of the 17 patient only 10 responded to the questionnaire at the time of this writing. The subject data is listed. ^(table 1)

LENSES

The lenses used as the retainer lenses were the last lenses used in the initial therapy in all but two of the subjects. The lenses used were the OK-3 lens by Contex or the prism weighted OK-5. The other two subject were switched into a standard tricurve design . The base curve of all the lenses were the final base curve used to provide the optimal visual acuity. The final base curves are listed. ^(table 1)

Table 1

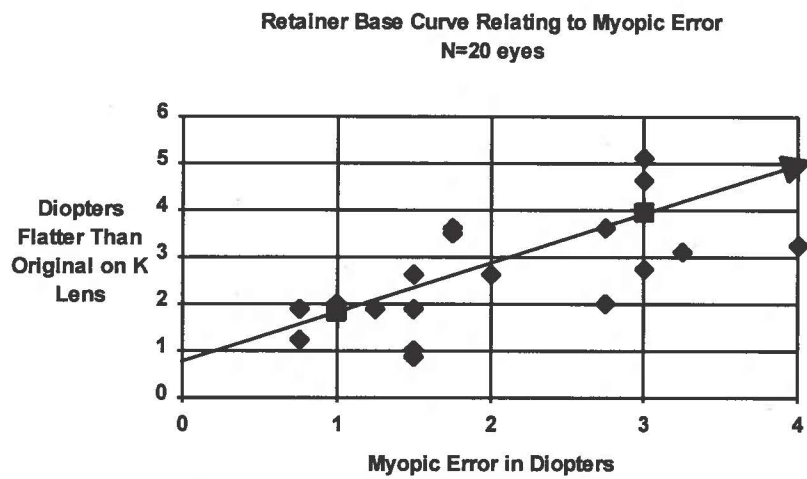
SUBJECT DATA

Number of Subject	Base Curve of Retainer	Keratometry Data	Refractive Error
1.	8.40 8.40	45.25 @ 180, 45.25 @ 090 45.00 @ 180, 45.00 @ 090	-3.00 -0.50 x 060 -3.00 -0.75 x 105
2.	7.90* 7.80	43.50 @ 175, 44.00 @ 085 43.62 @ 180, 44.00 @ 090	-1.50 -0.25 x 083 -1.50 -0.25 x 090
3.	7.70* 7.70	46.87 @ 175, 48.00 @ 085 47.37 @ 013, 47.75 @ 103	-3.25 -2.75
4.	8.20 8.40	43.00 @ 180, 44.00 @ 090 42.75 @ 180, 43.75 @ 090	-1.25 -0.50 x 180 -2.00 -0.25 x 180
5.	8.50 8.50	43.25 @ 005, 43.62 @ 095 43.12 @ 020, 43.87 @ 110	-1.75 -0.50 x 012 -1.75 -0.50 x 180
6.	8.70 8.70	42.00 @ 180, 43.00 @ 090 42.00 @ 180, 43.25 @ 090	-4.00 -0.50 x 005 -4.00 -0.50 x 180
7.	7.90 7.80	44.00 @ 010, 45.75 @ 100 44.00 @ 180, 45.75 @ 090	-0.75 -0.25 x 160 -0.75 -0.50 x 020
8.	8.50 8.50	41.50 @ 167, 42.12 @ 077 41.50 @ 163, 42.87 @ 073	-1.50 -1.00 x 170 -1.50 -1.50 x 165
9.	8.50 8.50	42.37 @ 180, 42.50 @ 090 41.75 @ 006, 43.12 @ 096	-3.00 -2.75 -0.75 x 005
10.	8.60 8.50	42.00 @ 020, 41.75 @ 110 42.00 @ 175, 41.62 @ 085	-1.50 -0.50 x 100 -1.00 -0.50 x 087

* Tricurve Design

The fitting of the retainer lenses is based on the individual fitting characteristics and the visual result. Graph 1 shows a relationship between the patient sphere refractive error and the dioptric value of the base curve to the flatter initial keratometric reading. An attempt to identify trends may establish numerical relationships in the use of retainer lenses.

Graph 1



The slope of the line is 1.06, the y-intercept 0.77, and the correlation value (r) is +.65 using linear regression.

WEARING SCHEDULE

The schedule of the lenses wear was discussed with patient and determined on individual basis. A concurrent study of wearing time with the same patient base is continuing. Of the 10 subjects responding 3 were on a night retainer schedule. The subjects removed the lenses after waking and inserted lenses before sleep.

QUESTIONNAIRE

A copy is provided. The patient were asked to rate five separate questions on a 1 to 5 scale. (5 being optimum). Also any anecdotal information was encouraged from the patients. The five areas related to:

1. distance vision
2. near vision

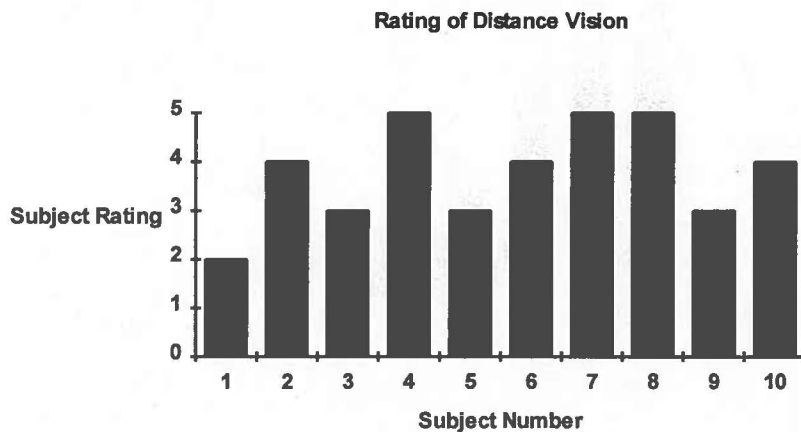
3. visual tasks
4. wearing schedule
5. overall experience

The subjects were asked to concurrently take their own acuities and document wearing time for a concurrent study.

RESULTS

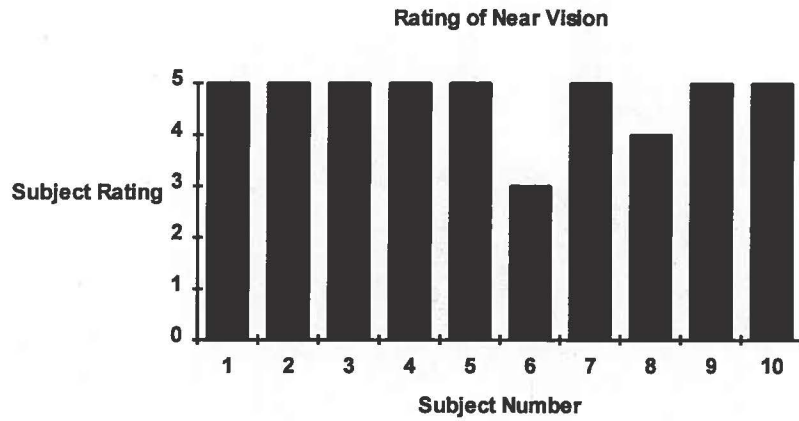
The following is the graphic presentation of the results as well as anecdotal reports from the subjects.

Distance Vision



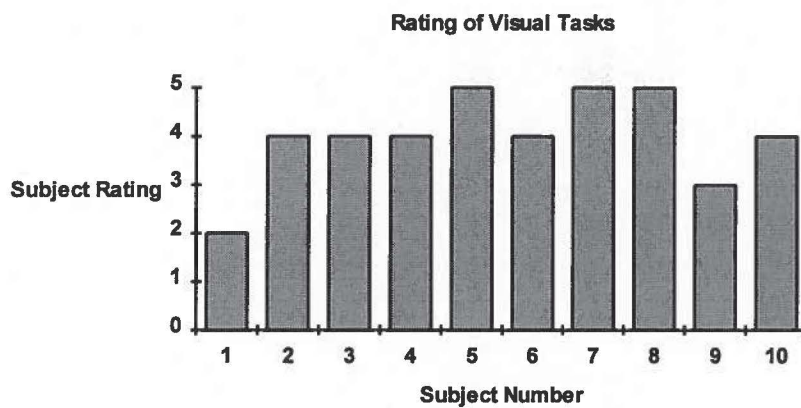
Subjects reported 2 cases of mild diplopia immediately after lens removal which resolved shortly and good vision followed. One reported case of halo around lights when driving at night. This was not present with lenses on. This subject also reported night driving was not impaired without his lenses. One case of disparity of vision between the two eyes was also reported.

Near Vision



The subjects noted very little problems with near vision. One case of diplopia, and slight clouding of vision was initially reported, however these problems resolved after the first week of the retainer lens wear.

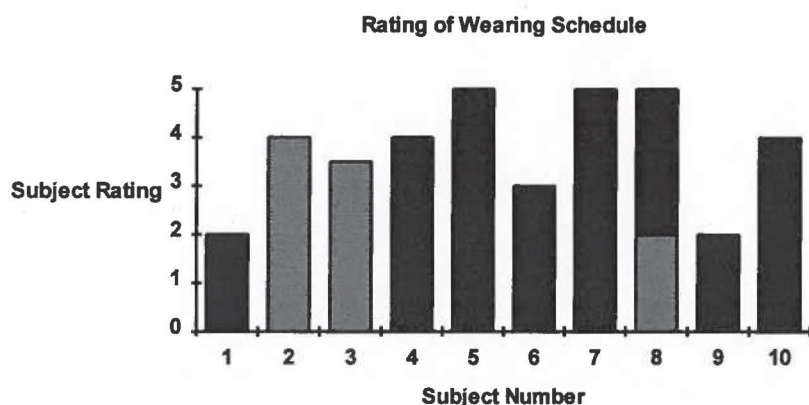
Visual Tasks



All but one of the subjects noted any significant impairment. The one subject felt the distortion he experienced was distracting. One subject felt

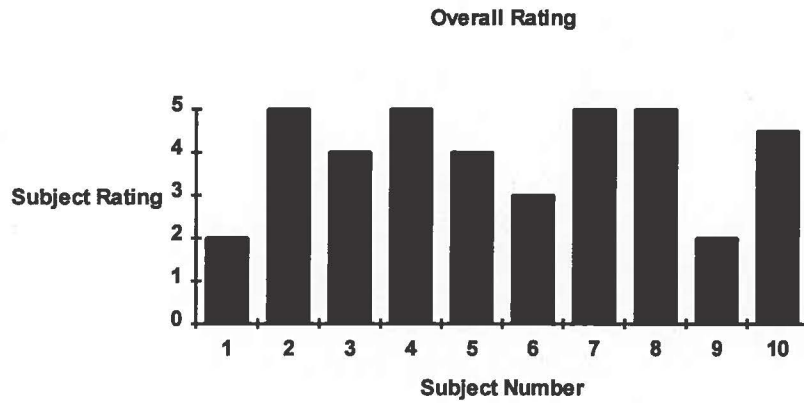
though her vision was more than adequate, she would prefer slight correction for night driving.

Wearing Schedule



Of all of the question this provided the most anecdotal information. Three of the subjects were wearing the lenses at night.(gray on the chart). Subject 8 had problems with complying to the night schedule due to his line of work as a firefighter paramedic. When subject 8 used a more traditional orthokeratology retainer schedule he was very pleased with his unaided vision and vision while wearing the lenses. The subjects enjoyed the freedom to choose when to wear the lens. All but one subject settled into some type of wearing regimen. Two of the subjects felt it would be easier with a traditional corrective lens. The remaining subjects reported positively concerning the length of time with good unaided vision.

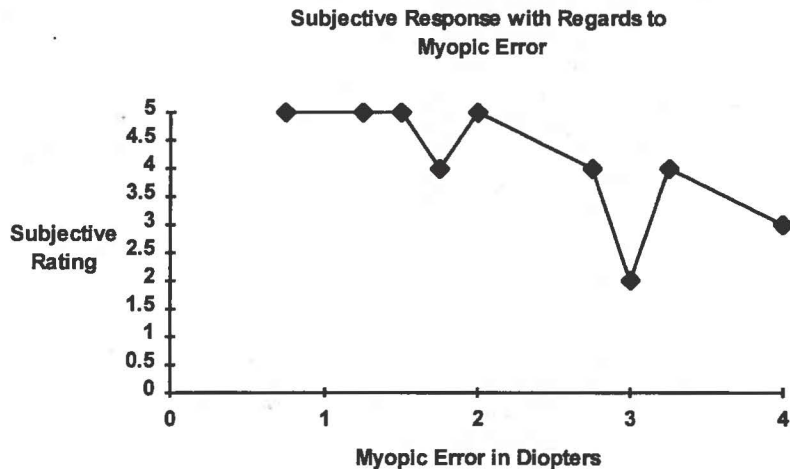
Overall Experience



Again most of the subjects responded favorably. Two subjects reported overall comfort of the hard lens was very difficult to adjust too. These two subjects also reported distortions were distracting and vision was not as well as they had anticipated. The positive remarks were in the regards to the length of time in which no correction was necessary and the activities performed without corrective lenses. Examples of swimming and contact sports were used. One subject felt his vision had improve beyond the correction that any spectacles or contact lenses had previously provided.

Overall Rating Compared to Myopic Error

The following is the graphical representation comparing the overall rating of the therapy as it relates to the myopic error.



DISCUSSION

The analysis of the information in graph 1 is an attempt to find more correlative data to base lens selection then clinical trial and error. The $r = +.65$ shows a relation to the slope of the line that identifies the possible predictable retainer lens base curve. The sample size remains very small and further investigation is necessary. The information suggests for every diopter of myopia the successful base curve of the retainer lens is that amount flatter plus another 0.75 diopters flatter than the original keratometric data.

Previous attempts at predicting success of orthokeratology by using temporal keratometry have been reported.⁵ Predictions of the results and defining lens parameters that correlate with clinical findings will help establish treatment monograms. An effort must be made to statistically correlate findings such as these. Only then can repeatable and more reliable therapy result.

In examining the subjects' responses refractive error determined much of the patient overall satisfaction. The subjects' expectation influences the

responses. The less myopic individual expectations were generally exceeded. The larger myopic patient found no real advantage to therapy than spectacles or standard contact lenses.

As with any discussion of orthokeratology it is very easy to get caught in an anecdotal evidence debate. This project was not an attempt to provide more anecdotal information regarding the orthokeratology. Further statistical, clinical information and study are necessary for orthokeratology to become more accepted as a treatment methodology. In the limited number of the subjects significant statistical data would not be credible for critical analysis. When receiving subjective responses from individuals, variations arise from expectations and individual preference again, making statistical interpretation difficult.

Subjective responses do greatly influence the therapy concerning compliance and success. *Consumers Reports* recent article on Radial Keratometry will have a profound effect on the public.⁶ By paying attention to the responses it will be easier to provide for patients. The results of the questionnaire show some individuals are successful with orthokeratology therapy. In the comparison the individuals with 2.00 diopters or less of myopia and 1.50 diopters or less of cylinder gave more positive responses to the therapy. Judging the patient motivations and expectations as well as clinical information, orthokeratology may provide another option for the provider to present to the patient.

NAME _____

QUESTIONNAIRE

What is the name of your lens care products? _____

Rating: poor average excellent
 1 2 3 4 5

1. How is your distance vision? _____ 1 2 3 4 5

Comments _____

2. How is your near vision? _____ 1 2 3 4 5

Comments _____

3. How well do you perform your visual tasks without wearing any
corrective lenses, compared to your performance with corrective
lenses in place? _____ 1 2 3 4 5

Comments _____

4. How do you rate the wearing schedule. _____ 1 2 3 4 5

Comments _____

5 Rate your overall experience with the Ortho-k Retainer lens
program. _____ 1 2 3 4 5

Comments _____

6. Any suggestions or comments not already made please express them
on the back of this form. Your input is very important.

REFERENCES

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