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# The effects of myopic orthokeratology on intraocular pressure

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## Abstract

Twelve orthokeratology patients were studied to determine whether myopic orthokeratology treatments had an effect on intraocular pressure. It was our hypothesis that myopic orthokeratology would have no significant effect on intraocular pressure. The patients were fit in the OK-3 design lens and re-evaluated each week for changes in intraocular pressure using a Goldmann applanation tonometer. The results of this study indicated that the null hypothesis was accepted. Although it was indicated that there was a statistically significant difference between pre- and post-treatment IOP measurements, we feel that this variation is well within the normal range for Goldmann applanation. The literature suggests that the following factors can cause variation in Goldmann IOP measurements: measurement technique, physiological and anatomical status of the eye and diurnal variation.



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Neil Hodur

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Optometry

# THE EFFECTS OF MYOPIC ORTHOKERATOLOGY ON INTRAOCULAR PRESSURE

By

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Advisor:

Dr. Neil Hodur

Signature Page

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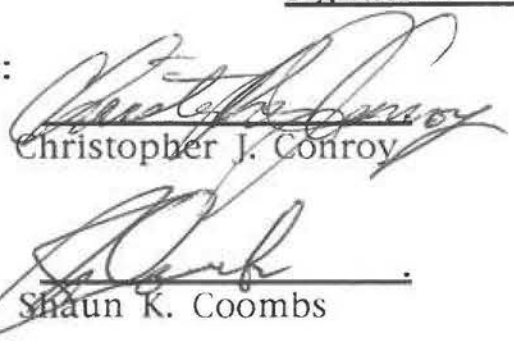

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Advisor:

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## Biography Page

**Chris Conroy:**
Chris Conroy graduated from Moorhead State University with a B.S. in Biology prior to entering the Pacific University College of Optometry. Chris hopes to enter a partnership or private practice where he can provide the highest level of vision care possible.

**Shaun Coombs:**
Shaun Coombs graduated from the College of Arts and Science at Pacific University with a B.S. in Biology prior to entering the College of Optometry. Shaun hopes to make enough money to pay off his school loans so that he does not have to share a cramped cell in Leavenworth Pen for loan evasion.

## Abstract

Twelve orthokeratology patients were studied to determine whether myopic orthokeratology treatments had an effect on intraocular pressure. It was our hypothesis that myopic orthokeratology would have no significant effect on intraocular pressure. The patients were fit in the OK-3 design lens and re-evaluated each week for changes in intraocular pressure using a Goldmann applanation tonometer. The results of this study indicated that the null hypothesis was accepted. Although it was indicated that there was a statistically significant difference between pre- and post-treatment IOP measurements, we feel that this variation is well within the normal range for Goldmann applanation. The literature suggests that the following factors can cause variation in Goldmann IOP measurements: measurement technique, physiological and anatomical status of the eye and diurnal variation.

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# THE EFFECTS OF MYOPIC ORTHOKERATOLOGY ON INTRAOCULAR PRESSURE

## Introduction

Orthokeratology is defined as the "programmed application of contact lenses to correct refractive errors."(1) According to the AOA, orthokeratology is the reduction, modification, or elimination of refractive anomalies by the programmed application of contact lenses or other related procedures.(2)

Currently there is a limited understanding of the effects of orthokeratology on the structures and physiology of the eye. In order to understand the effects of orthokeratology, and make its practice a widely acceptable and clinically prudent treatment for myopia, many controlled scientific studies need to be completed. The results of these studies are vital for the understanding of the process and mode of myopia reduction with contact lenses.

It is in this vein of thought that we initiated our study of the effects of myopic orthokeratology on intraocular pressure. It is our hypothesis that myopic orthokeratology does not significantly affect intraocular pressure. In the course of the background discussion we will present the history of orthokeratology, a review of the current literature on intraocular pressure, and a brief discussion regarding the specifics of this study.

## Background

Kerns reported that the origin of orthokeratology "...may be traced to the early Chinese who applied small bags of sand to their eyelids overnight in an attempt to alter the refractive status of the eye. (3) Modern orthokeratology began in the early 50's and 60's when eye care practitioners found that their keratometric readings and refractions changed after several years of contact lens wear. Furthermore, many eye care practitioners found that their myopic patients did not continue to progress in myopia after wearing contact lenses, but other practitioners felt that the evidence for the retardation of myopia was not conclusive. (4)

Due the controversy regarding the use of contact lenses for the treatment of myopic progression, the members of the Seventh Congress of the International Society of Contact Lens Specialists (1962) began formal investigation of this area. It was also in 1962 that Jessen and others founded the Society of Orthokeratology.

It was originally believed that all refractive errors could be reduced by steepening or flattening the cornea. Jessen stated that for orthokeratology to work, the contact lens should "act as a pressure bandage" to change corneal shape. Jessen's original orthokeratology lens for the reduction of myopia was designed with a base curve such that the lacrimal lens compensated for the refractive error. Jessen reported that these lenses were uncomfortable due to their flatness, but they did flatten the cornea and reduce myopia. (5)

Ziff found that, for best results with myopes, the base curve design should be determined by referencing the original keratometry measurements. (6) In effect, his final lens design was intimately tied to the original keratometric reading such that a flat cornea was fit on K, and steep cornea was fit 0.50D to 1.00D flatter than K.

Unlike their predecessors, May, Neilson and Grant felt that excessively flat lenses may induce edema, and that a mildly flat lens may promote flattening of the cornea. In addition, these practitioners utilized photo-electronic keratoscopy (an early predecessor to corneal topography) to aid in the fitting process. (7)

Other practitioners, such as Jenkin and Tabb, routinely fit slightly steep lenses to induce orthokeratology effects, while minimizing adverse physiological effects such as corneal edema, induced astigmatism and punctate staining. (8, 4) It is Tabb's assertion that these steep fitting contact lenses induce orthokeratology effects by introducing hydraulic forces on the central cornea while maintaining optimal corneal physiology.

Although other lens designs are utilized by contemporary orthokeratology practitioners, "reverse geometry" lens designs are becoming increasingly popular. One such "reverse geometry" design is the OK-3 from Contex, INC. The lenses that were used in this study were the OK-3 design lenses (Contex, INC.). The OK-3 lens is manufactured in a fluoro-silicone acrylate material with a Dk of 88. The design of these orthokeratology specific lenses is based on a reverse geometry with aspheric peripheral curves. These lenses have a flat central zone 6.0 mm in diameter with a secondary zone of steeping, and an aspheric peripheral fitting curve. In the case of the

OK-3 lens design, the central zone is 3 diopters flatter than the intermediate zone. The standard OK-3 lens is 9.6 mm in overall diameter, although we utilized lenses of varying diameters in order to better fit each individual patient.

Figure#1(10):


**The OK-3 lens is a reverse-geometry design from Contex. The Menicon Plateau lens is well-suited for accelerated ortho-K as well.**

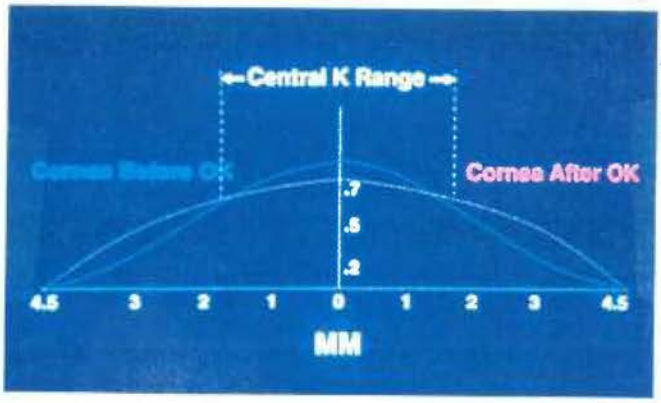
The mechanism of action of the OK-3 lens relies on altering the normal asphericity of the cornea, thus displacing corneal tissue from the steeper central zone to the mid periphery of the cornea. The steeper secondary zone in the OK-3 lens design facilitates this process by providing a displacement zone, or tear reservoir, into which the central corneal tissue migrates.

The maximal effect of the OK-3 lens is achieved when there is minimal fluorescein pooling in the secondary curve zone, and the lens appears to fit in alignment with the cornea. It is at this point, where there is minimal pooling in the secondary curve zone, that the orthokeratology lens has reached its maximal effectivity, and a flatter lens must be utilized. In effect, the endpoint in orthokeratology is achieved when the corneal topography underneath the lens approximates a sphere. As the cornea begins to

sphericalize under the treatment zone, the lens begins to demonstrate the instability evident in any flat fitting RGP lens. Due to the importance of maintaining the treatment zone directly over the corneal apex, it is important to change the lens when this classical flat fit is achieved.

When myopia reduction has plateaued, retainer lenses are utilized which maintain stable uncorrected vision, and adequate tear exchange. The wearing schedule must be customized for each individual patient in order to achieve expected levels of unaided acuity. One of the most common and effective schedules with the OK-3 lens design is to employ a split wearing schedule where the lenses are worn two to three hours in the morning, and one to two hours before bedtime, three to seven days per week, depending on the patient. An alternative is to wear the lenses during sleep and to remove it in the morning three to six nights per week.(9) Retainer lens wear must be tapered off slowly in order to prevent treatment regression.

Figure #2 (10):




**Ortho–K creates central corneal flattening and paracentral steepening, which yeilds a more spherical cornea and reduces myopia.**

## Subjects

Sixteen subjects were selected from the classes of 1999 and 2000 at the Pacific University College of Optometry. Both male and female subjects were used, although there was no attempt to match their numbers equally. Eligible candidates were given group, or individual counseling related to the nature of the study, the procedures, and alternative treatments available. The subjects were required to sign an informed consent form prior to participating in the study. The subjects were selected based on having a refractive error of less than 3 diopters of myopia with less than 1 diopter of corneal astigmatism. In addition, any subjects that had any pre-existing ocular pathology contraindicating contact lens wear were excluded from the study.

Due to the importance for the subjects to adhere to the prescribed treatment protocol, all patients were told to contact the researchers immediately if they felt that they could not successfully follow the treatment regiment. In addition, we made ourselves available in the event that any contact lens related problems arose which would prevent successful continuation in the study. At the conclusion of this study, twelve subjects remained active participants and continued onto the second phase of the research project. The data from the four subjects who discontinued their participation in the study was not utilized in our final data analysis. The subjects that discontinued the study either never achieved an optimal lens fit despite all efforts, and/or had difficulty adhering to the treatment regiment.

## Methods

### Fitting

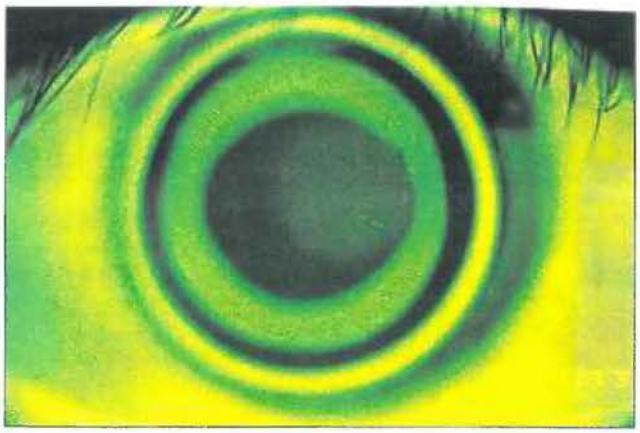
Once we had selected and fit the subjects based on our inclusion criteria of less than 3 diopters of myopia with less than 1 diopter of corneal astigmatism, and the absence of any pre-existing ocular pathology contraindicating contact lens wear, we began the fitting process. The OK-3 contact lenses were fit based on keratometric readings, corneal topography, and fluorescein slit lamp observations of the lenses.

The fitting protocol that was utilized in the course of fitting the lenses was to order the lenses 0.50 to1 diopter flatter than the flattest K readings as determined by standard keratometry. In a few cases, in which the patient had 3 diopters or more of refractive error, the lenses were fit 1.5 diopters flatter than the flattest K. In addition, the overall diameter was selected in order to insure optimal lens dynamics. Corneal topography was utilized in order to aid the fitting of lenses that did not respond to more conservative fitting approaches already mentioned. The contact lenses were fit in a daily wear approach instead of the night retainer modality. The patients were instructed to wear the lenses at least two hours per day, and to increase their wearing time to at least six hours per day over the course of the first week.

In the course of fitting the OK-3 lenses, the following three fitting criteria were utilized as presented by Rodger Kame (10):

1. Optimal Lens Centration: Lenses must be centered over the corneal apex in order to avoid corneal warpage and undesirable outcomes.
2. Optimal Lens Movement: Lenses must demonstrate 1 mm to 2 mm of movement with each blink in order to maintain adequate tear flow under the lens.
3. Optimal NAFL Pattern: Lens to Cornea relationship must demonstrate an apical bearing zone of 3 mm to 4 mm, a circular area of pooling in the intermediate zone of the lens, a narrow mid-peripheral band of touch, and a peripheral edge lift.

Figure #3 (10):



**After four hours of wear, this OK-3 lens reduced 1D of myopia. The mid-peripheral bearing is now too heavy, indicating corneal flattening and lens tightening. Thus a flatter lens is needed at this point.**

All of the aforementioned criteria were re-evaluated at each follow-up visit in order to insure a safe and successful treatment. If it was determined that any of the above criteria were not met at the follow-up visits, we either performed in-office modification, and/or ordered new lenses from the laboratory.

Data Collection

The subjects were initially followed one day post treatment, one week post treatment, and weekly for three months. At each follow-up visit, the following steps were completed in the following order:

1. Case History: To ascertain compliance with the the treatment regiment, and to determine any contact lens related complaints that arose since the last visit. The patients were also required to self-monitor aided and unaided visual acuities.
2. Slit Lamp Evaluation: The fit of the lenses was evaluated with fluorescein.
3. Visual Acuities: The acuities were taken with the lenses on and off. If the patient reported that aided and unaided acuities were below expected, and we found substandard acuities at follow-up, an over-refraction was performed.
4. Pachymetry: The corneal thickness was measured with an optical, slit lamp mounted pachymeter. The corneal thickness data was analyzed by another research team.
5. Corneal Topography: The corneal topography data was taken with a Humphrey corneal topographer, and an ORB-SCAN corneal topographer. This data was taken in order to follow the progression of the orthokeratology treatment, and for the purpose of future data analysis.
6. Intraocular Pressure: The intraocular pressures were taken with a standard Haag-Streit Goldmann applanation tonometer mounted to a standard Haag- Streit slitlamp. This step was left for last in order to prevent

contamination of the pachymetry and corneal topography data.

Since our research objective was to study the effects of myopic orthokeratology on intraocular pressure, we will limit our discussion of methodology to our determination of intraocular pressure. As stated before, intraocular pressures were determined with the use of a Haag Streit Goldmann applanation tonometer. The IOP measurements were taken as the last step in our data collection protocol in order to prevent contamination of the other ocular measurements. Two readings were taken per eye at each visit. The same researcher took the intraocular pressure measurements at each visit in order to prevent inter-observer variablity.

Once the IOPs were determined, the patients were instructed to return to the preliminary data collection room in order to re-insert their contact lenses. If modifications were required in order to improve the fit and/or comfort of the lenses, it was completed before they were dismissed.

For the purpose of our research project, we statistically compared the pre-treatment IOPs to the following post-treatment intervals: one day, two week, one month, and two month.

## Results

The null hypothesis for this thesis is that myopic orthokeratology affects intraocular pressure. In order to test this hypothesis, we compared the pre-treatment IOP to the one day, two week, one month and two month post treatment IOPs. This statistical comparison was made with the t-Test comparing pre-treatment measurements with each post-treatment measurement individually. The following table presents the raw data, and the mean IOP after each measurement interval.

The first comparison of the pre-treatment IOPs versus the one day post-treatment IOPs indicates that the null hypothesis is accepted at the P= 0.437 level (t=-0.160). In other words, there is a 43.7% chance that the orthokeratology treatments caused a change in IOP at this measurement interval.

The second comparison of the pre-treatment IOPs versus the two-week post-treatment IOPs indicates that the null hypothesis is accepted at the P=0.074 level (t=-1.472). In other words, there is a 7.4% chance that the orthokeratology treatments caused a change in IOP at this measurement interval.

The third comparison of the pre-treatment IOP versus the two week post-treatment IOPs indicates that the null hypothesis is accepted at the P= 0.242 level (t=0.705). In other words, there is a 24.2% chance

that the orthokeratology treatment caused a change in IOP at this measurement interval.

The fourth comparison of the pre-treatment IOP versus the two week post-treatment IOPs indicates that the null hypothesis is accepted at the P=0.069 level (t=1.514). In other words, there is a 6.9% chance that the orthokeratology treatment caused a change in IOP at this measurement interval.

## Discussion

The results indicate that we must reject our hypothesis that myopic orthokeratology has no statistically significant effect on intraocular pressure. It was initially felt that the central corneal flattening that occurs as a result of orthokeratology may alter the volume of the anterior chamber angle, and thus exert an influence on intraocular pressure. In the course of our research, we did not make efforts to analyze the volume of the anterior chamber. Despite possible changes to the anterior chamber, a statistically significant change in IOP was found as a result of orthokeratology treatment, or some other factor which will be presented in this discussion.

It is our assertion that any possible changes in the anterior chamber resulting from orthokeratology do not affect aqueous outflow in a manner that would lead to an increase in intraocular pressure. In theory, if the central cornea is flattened, and the mid-peripheral cornea is steepened, the anterior chamber angle may widen slightly thus facilitating aqueous outflow. However, increased aqueous outflow and the corresponding decreased IOP was not observed at a

statistically significant level in this study. We believe that either the anterior chamber is not significantly altered to induce a change in IOP, or the changes in the anterior chamber angle are not significant enough to affect the aqueous production-outflow equilibrium.

It is our belief that the statistically significant difference between the pre-treatment and post-treatment IOP is most likely unrelated to the orthokeratology treatment, and is most likely due to other factors such as diurnal variation, measurement error, patient compliance, and a relatively small patient population and short research time interval.

The possible sources of error associated with this study are as follows: measurement error, anatomical and physiological changes of the cornea, treatment compliance, and diurnal variation of intraocular pressure. The primary measurement error associated with Goldmann applanation tonometry is inter-observer variability. We minimized this variable by having the same researcher take the IOP measurements at each visit.

The main sources of technique error, and their respective error range in mmHg, are as follows: concentration of NaFl (-1.5 to -9.5), contact with ocular adnexa i.e. lids, lashes, facial hair (overestimation), duration of tonometer-eye contact (-2.0 to -3.8), applanation with paracentral applanation (overestimation). (11) As demonstrated in clinical practice, it is common to obtain IOP measurements that are 1 to 2 mmHg apart despite taking the readings in rapid succession.

Whitacre and Stein indicate that differences of 1.5-2.5 mmHg are within the limits of acceptable variation when measuring sequential IOPs. For a more complete listing of source of error associated with Goldmann applanation, see Table1 in the appendix.

The main sources of error associated with corneal anatomy and physiology and their respective error range in mmHg are as follows: shape of the anterior cornea (-2.5 to +2.5), corneal epithelial edema (-10 to -30), corneal stromal thickness (-6.2 to +24). (11) For a more complete listing refer to Table1 in the appendix. As can be seen from the short listing above, corneal edema can lead to a large variability in intraocular pressure measurements. Although great efforts were made to insure that the fit of the orthokeratology lenses did not lead to physiological compromise, it is possible that sub-clinical corneal edema could have effected our post-treatment IOP measurements.

Whitacre and Stein indicate that several studies have shown that changes of 2 to 3 mmHg can be found in readings taken several minutes apart. We minimized this effect by taking the IOP measurements in rapid succession, and as stated before, we maintained the same researcher in the role of the official tonometrist.

In order to draw a correlation between changes in intraocular pressure secondary to the implementation of orthokeratology treatment, it was important that the subjects adhered to the

treatment regiment. Compliance to the treatment regiment was assessed during each visit, but the subject's reflection on compliance may be somewhat less than accurate. Subject's were encouraged to contact us immediately if they felt that they could not adhere to the treatment regiment, and were terminated from the study if poor compliance was evident.

The final source of error that we will discuss is the presence of normal diurnal variation of intraocular pressure. We attempted to minimize the effects of diurnal variation by taking the measurements at approximately the same time of day to maintain measurement consistency. Like all biological parameters, IOP exhibits a circadian rhythm. Normal individuals show a daily IOP fluctuation of 3 to 6 mmHg. IOP has been reported to be highest in the morning and lowest in afternoon. Diurnal variation that exceed 10 mmHg are considered to be pathological.(12) For this reason, we took our measurements at approximately the same time each day.

Another research team at the Pacific University College of Optometry will be continuing with the orthokeratology study to determine if there are any changes in intraocular pressure over a longer research time interval. We will be looking forward to the final results of this study to determine if the changes in IOP are indeed statistically significant over a longer research interval.

Further research is required to study the effects of orthokeratology on many other variables such as corneal thickness, corneal warpage,

corneal physiology, duration of orthokeratology effectivity, and a comparison of different orthokeratology treatment methodologies. Further research is needed to compare a control population versus an orthokeratology population for IOP changes. If orthokeratology is to ever become a part of mainstream optometric practice, it is vital that strong scientific evidence is collected to support its practice.

## Conclusions

Although our analysis indicates that orthokeratology does affect intraocular pressure at a statistically significant level, we feel that it is too soon to sound the alarm against orthokeratology. It is important to note that our mean pre-treatment IOP varied less than 1 mmHg from all the post-treatment IOPs. As we discussed earlier, there are many factors that affect the measurement of IOP, such as physiological and anatomical variation, and standard measurement errors. We feel that the most significant factors affecting our statistical analysis are diurnal variation and measurement variability. In examination of the means of the pre-and post-treatment IOPs at every measurement interval, it is evident that they were always well within normal variation for Goldmann applanation tonometry measurement.

In final assessment, we feel that despite the statistical significance of orthokeratology's effect on IOP, that there are other confounding factors which contributed to the IOP variability found in our study. We feel that orthokeratology should still be pursued as a viable alternative to spectacle, contact lens, and refractive surgery correction for a well selected patient population. Despite this vote of

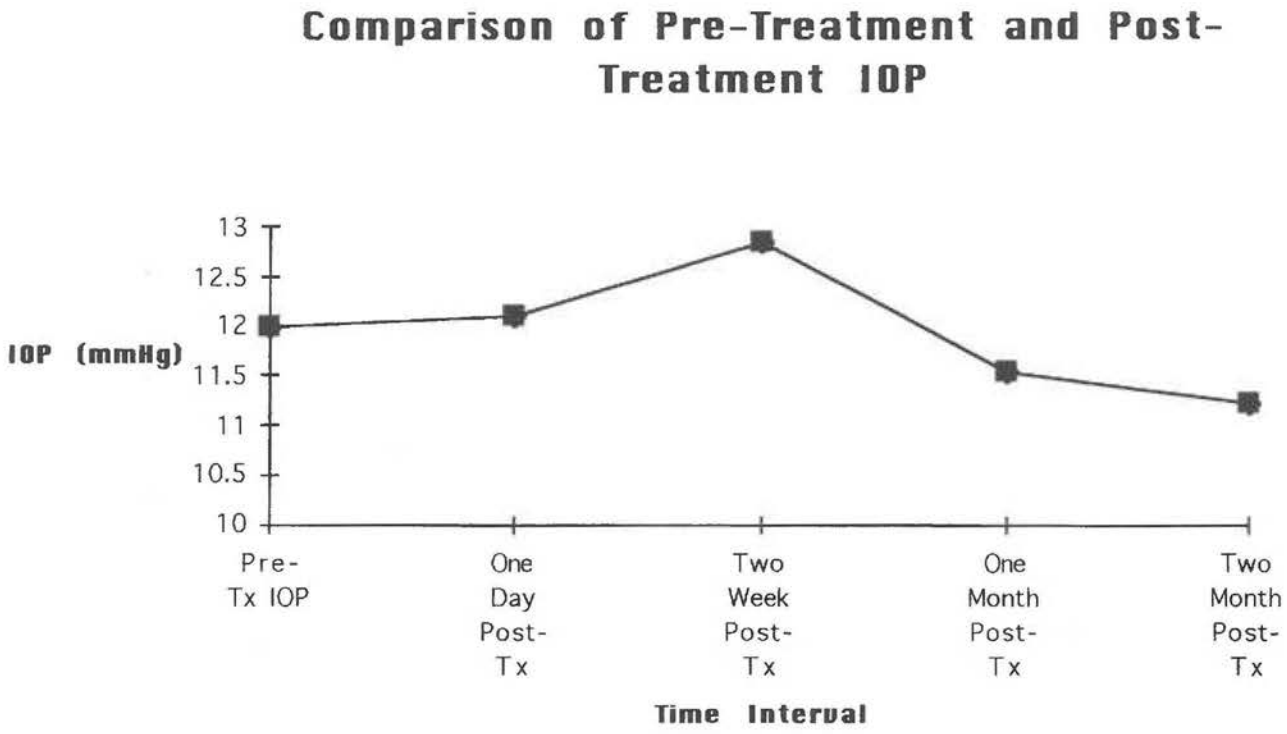
confidence, we would like to encourage further research into the effects of orthokeratology on all ocular variables.

# Appendix

Appendix 1

| Eyes | Pretreatment | One Day Post-Tx | Two-Week Post-Tx | One Month Post-Tx | Two Month Post-Tx |
|---|---|---|---|---|---|
| 1 | 12.5 | 16 | 16 | 16 | 11 |
| 2 | 12 | 16 | 16 | 16 | 11 |
| 3 | 12 | 12 | 12 | 12 | 10 |
| 4 | 12 | 13 | 12 | 12 | 12 |
| 5 | 8 | 9 | 10 | 8 | 9 |
| 6 | 10 | 10 | 10 | 8 | 9 |
| 7 | 11 | 12 | 15 | 10 | 13 |
| 8 | 11 | 12 | 15 | 11 | 12 |
| 9 | 12 | 9 | 9 | 7 | 10 |
| 10 | 12 | 9 | 10 | 7 | 9 |
| 11 | 12 | 12 | 13 | 10 | 8 |
| 12 | 12 | 12 | 13 | 10 | 10 |
| 13 | 12 | 12 | 14 | 14 | 13 |
| 14 | 12 | 12 | 14 | 15 | 13 |
| 15 | 13 | 10 | 14 | 12 | 13 |
| 16 | 13 | 11 | 14 | 12 | 12 |
| 17 | 14 | 16 | 16 | 14 | 14 |
| 18 | 16 | 16 | 16 | 14 | 15 |
| 19 | 11.5 | 11 | 10 | 11 | 9 |
| 20 | 11 | 12 | 10 | 11 | 10 |
| 21 | 12 | 12 | 12 | 12 | 12 |
| 22 | 13 | 12 | 12 | 12 | 12 |
| Mean | 12.00 | 12.09 | 12.86 | 11.55 | 11.23 |

Appendix 2


Comparison of Pre-Treatment and Post-Treatment IOP
IOP (mmHg)
13
12.5
12
11.5
11
10.5
10
Pre-Tx IOP
One Day Post-Tx
Two Week Post-Tx
One Month Post-Tx
Two Month Post-Tx
Time Interval

# Appendix 3

**Pre-Tx vs. One Day Post-Tx**
t-Test: Two-Sample Assuming Equal Variances

| | *Variable 1* | *Variable 2* |
|---|---|---|
| Mean | 12 | 12.09090909 |
| Variance | 2.214285714 | 4.848484848 |
| Observations | 22 | 22 |
| Pooled Variance | 3.531385281 | |
| Hypothesized Mean Difference | 0 | |
| df | 42 | |
| t | -0.160446817 | |
| P(T<=t) one-tail | 0.43664917 | |
| t Critical one-tail | 1.681951289 | |
| P(T<=t) two-tail | 0.87329834 | |
| t Critical two-tail | 2.018082341 | |

**Pre-Tx vs. One Month Post-Tx**
t-Test: Two-Sample Assuming Equal Variances

| | *Variable 1* | *Variable 2* |
|---|---|---|
| Mean | 12 | 11.54545455 |
| Variance | 2.214285714 | 6.926406926 |
| Observations | 22 | 22 |
| Pooled Variance | 4.57034632 | |
| Hypothesized Mean Difference | 0 | |
| df | 42 | |
| t | 0.705178571 | |
| P(T<=t) one-tail | 0.242295907 | |
| t Critical one-tail | 1.681951289 | |
| P(T<=t) two-tail | 0.484591814 | |
| t Critical two-tail | 2.018082341 | |

**Pre-Tx vs. Two Week Post-Tx**

t-Test: Two-Sample Assuming Equal Variances

| | *Variable 1* | *Variable 2* |
|---|---|---|
| Mean | 12 | 12.86363636 |
| Variance | 2.214285714 | 5.361471861 |
| Observations | 22 | 22 |
| Pooled Variance | 3.787878788 | |
| Hypothesized Mean Difference | 0 | |
| df | 42 | |
| t | -1.471733672 | |
| P(T<=t) one-tail | 0.074273376 | |
| t Critical one-tail | 1.681951289 | |
| P(T<=t) two-tail | 0.148546753 | |
| t Critical two-tail | 2.018082341 | |

**Pre-Tx vs. Two-Month Post-Tx**
t-Test: Two-Sample Assuming Equal Variances

| | *Variable 1* | *Variable 2* |
|---|---|---|
| Mean | 12 | 11.22727273 |
| Variance | 2.214285714 | 3.517316017 |
| Observations | 22 | 22 |
| Pooled Variance | 2.865800866 | |
| Hypothesized Mean Difference | 0 | |
| df | 42 | |
| t | 1.513908329 | |
| P(T<=t) one-tail | 0.068769413 | |
| t Critical one-tail | 1.681951289 | |
| P(T<=t) two-tail | 0.137538825 | |
| t Critical two-tail | 2.018082341 | |

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