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The effects of night wear orthokeratology lenses on central corneal thickness

Abstract

Purpose: This study was performed to determine the effectiveness and safety of Night Move™ orthokeratology lenses and to examine their effects on central corneal thickness.

Methods: Ten subjects (20 eyes) with myopia less than 5D and with the rule astigmatism less than 1.50D were fitted with the Night Move™ orthokeratology lenses. The lenses were worn at night for a period of 30 days. Subjects were examined prior to the study, at 1 day, 7 days and 30 days. Unaided visual acuity, refractive error, keratometric readings, intraocular pressure and central pachymetry measurements were determined at each visit.

Results: All eyes reached unaided visual acuities of at least 20/40 with 90% reaching 20/20 or better. Mean refractive error demonstrated a decrease in myopia from -2.26D to -0.04D at 30 days. The mean steep K was reduced 1.46D at 30 days. The mean decrease in central corneal thickness was 0.022mm after 30 nights of lens wear. Mild cases of epithelial staining were seen in 2 eyes at 1 day and 7 days. No staining was seen after 7 days. All other ocular health was unremarkable throughout the study.

Conclusions: Changes in mean keratometric readings and mean refractive error do not explain the acuities achieved by the subjects in the study. A decrease in central corneal thickness provides the additional power to allow subjects to achieve optimum visual acuity. The change in corneal thickness is small compared to photorefractive surgeries and provides a safer alternative maintaining greater corneal integrity.

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Roger L. Tabb

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**THE EFFECTS OF NIGHT WEAR ORTHOKERATOLOGY LENSES ON
CENTRAL CORNELA THICKNESS**

BY

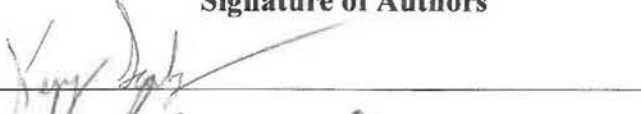
**KERRY SANCHEZ
JON PEDERSON**

**A thesis submitted to the faculty of the
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Pacific University
Forest Grove, Oregon
For the degree of
Doctor of Optometry
December, 2002**

**Advisors:
Roger L. Tabb, O.D., FA.A.O, F.I.O.S
Scott Pike, O.D.**

Signature of Authors

Kerry Sanchez



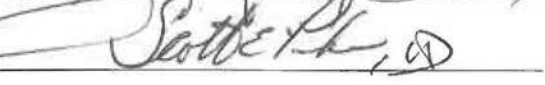
Jon Pederson



Roger L. Tabb, O.D., Advisor



Scott Pike, O.D., Advisor



Biographies

Kerry Sanchez: Kerry grew up in Billings, Montana, the son of an optometrist and Pacific graduate. Kerry received his B.S. in Biology from the University of Montana in 1998. He plans to move back to Billings and practice in his father's practice.

Jon Pederson: Jon grew up in Denver, Colorado, also the son of an optometrist. He received his B.S. in Zoology from Washington State University in 1998. He plans to practice in Denver, Colorado.

Abstract

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Conclusions: Changes in mean keratometric readings and mean refractive error do not explain the acuities achieved by the subjects in the study. A decrease in central corneal thickness provides the additional power to allow subjects to achieve optimum visual acuity. The change in corneal thickness is small compared to photorefractive surgeries and provides a safer alternative maintaining greater corneal integrity.

INTRODUCTION:

The idea behind orthokeratology, using a rigid contact lens to change the shape of the cornea to reduce or eliminate refractive error, has been around since the early 1960's. Orthokeratology is defined as the temporary reduction or complete elimination of myopia, astigmatism or hyperopia with the application of specifically designed rigid gas permeable lenses. It can be accomplished with a single contact lens or may require a series of lenses, which flatten the central anterior radius of the cornea. Often it will achieve the desired result of reducing refractive error and improving unaided visual acuity.² Many earlier designs failed to produce these desired results. However, the most recent designs called reverse geometry curve lenses have achieved greater success. These designs have the advantage of increased stability as the cornea flattens, along with producing a desired result in less time.⁶

The reverse geometry curve lenses used in this study are advanced orthokeratology lenses designed by Dr. Roger Tabb, called Nightmove™ refractive lens™ Nightwear End Result Orthokeratology (NERO). The lenses are constructed with 4 to 9 curves, depending on power, keratometric readings and desired refractive change. The major back curves of this design are the power zone template (base curve), relief curve (reverse curve), control curves, and the peripheral curve. Dr. Tabb has also designed a unique program which can vary one set of fitting parameters with an automatic mathematical rematching of other parameters to design the most safe and effective lens for each individual.

With all the different fitting parameters and curves of the Nightmove™ lens, it is believed that proper determination of the reverse curve is one of the most essential for a

successful fit. The reverse curve moves the contact lens back to meet the cornea, creating a hydraulic holding system, thus producing hydraulic and mechanical pressures acting together to produce a true corneal mold.⁶

The overall change in the shape of the cornea (corneal mold) determines the amount of refractive change produced by the lenses. Nightmove™ refractive lens™ are specifically designed to be worn at night while sleeping allowing less effect on the corneal mold by large eye movements and eyelid interaction from blinking. Additionally, small eye movements while sleeping (REM) are believed to aid in the pumping action for adequate tear exchange⁶ allowing the orthokeratology process to be safer, more effective, and healthier for the eye. Upon awakening the patient remove the lenses and allow the corneal mold produced by the visco-elastic properties of the cornea to maintain the desired refractive change for clear and comfortable vision.

Another major part in successful orthokeratology fittings is proper selection of candidates. For our study, we selected patients with 5.00 D of myopia or less and 1.50 D of astigmatism or less. In selecting candidates for orthokeratology the following are also desirable characteristics:

- Spherical myopia between -0.75 D to -4.00 D.
- With-The-Rule astigmatism up to -1.50 D.
- Patients with a strong passion for improvement of unaided visual acuity.
- A full understanding of realistic visual outcomes.

Some less than ideal candidates are patients with a larger refractive error than previously described, recurrent or active ocular surface disease, and keratoconus patients.¹ Though there was no bias to age in this study, there are two age groups that make particularly

good candidates, presbyopic patients and children/young adults between the ages of 8 to 20 years old.

Presbyopic patients are usually interested in non-surgical procedures to change their refractive status. Unlike refractive surgery, with orthokeratology, monovision can be offered with the understanding that if the patient not comfortable with the initial results their refractive status can be fine tuned or even fully reversed if necessary. Kids and young adults, who are not good candidates for refractive surgery because their refractive error is not stable, make wonderful candidates for orthokeratology. The parents of these patients often have an interest in investigating myopia control as well. In these situations, orthokeratology lenses can be very useful.¹

Once a patient is made aware of the parameters involved with being a candidate, they must also be made aware of all the advantages and disadvantages of orthokeratology. Specifically when compared to more invasive techniques which attempt to alter a patient's refractive status, such as Laser Assisted In situ Keratomileusis (LASIK). One major advantage is that orthokeratology is a noninvasive procedure with a high safety record and is almost always completely reversible.⁸ Unlike LASIK which is an invasive surgical procedure that is not reversible and can sometimes compromise the ocular health of a patient. Some other general advantages which may or may not be similar to LASIK are occupational and recreational freedom to not have to rely on corrective eyewear. Nightwear End Result Orthokeratology (NERO) enables a person to function throughout the day without the aid of optical devices. According to an unpublished study done by Neil, Neil, and Tabb, from Pacific University, the NERO have an average holding time of 16.6 hours per day.⁶

Even though orthokeratology has a superior track record in regards to safety and efficacy, the procedure is not completely without risk. In some cases, miscalculations of various fitting factors or physiological structural differences with patients may result in decentration of a lens, which may cause glare and ghosting. Another seldom adverse reaction is the occurrence of a corneal compression abrasion because of a flat fitting lens. This condition is easily treated with lubricants and discontinuation of lens wear until the abrasion has healed. Again, the risks involved with this procedure are far less than more invasive ones, such as LASIK where there can be dramatic corneal compromise.

It is well documented in the optometric literature that orthokeratology is a safe alternative to LASIK. It's also well documented what happens to the corneal shape, specifically the anterior corneal curvature and corneal thickness during wear of orthokeratology lenses. In the case of orthokeratology, these corneal thickness changes could predictably take the form of central thinning and mid-peripheral thickening in turn giving rise to a change in anterior corneal sagittal height.⁷ In this study, a Haig-Streit optical pachymeter was used to measure the changes in central corneal thickness as a component of change in refractive error and the results were compared to other studies that have well documented changes.

Methods and Materials

Subjects

10 myopic subjects were selected to participate in the study. The protocol and risks and benefits of orthokeratology lens wear were explained to each of the subjects before they were enrolled. The age range of the subjects was from 21 to 49 years of age

and 6 out of the 10 participants were female. Five of the ten patients were participating in another study for FDA approval of the NightMove Lenses.

Refractive error varied from -0.75 to -5.00 in the subjects and none had refractive astigmatism greater than -0.75. None of the subjects had large amounts (>0.50D) of lenticular astigmatism. Refractive error was determined through binocular subjective refractions.

Baseline exams were performed on all subjects verifying the absence of ocular pathology or contact lens contraindications. Baseline exams consisted of a complete ocular history, binocular subjective refraction, keratometry, pachymetry, tonometry, biomicroscopy and corneal topography.

Nine of the ten subjects were previous soft contact lens wearers. The tenth subject had previously been corrected only with spectacles.

All participants wore orthokeratology lenses in both eyes making a total of twenty eyes used for the study.

Lenses

The orthokeratology lenses used for this study were the NightMove™ refractive lens designed by Dr. Roger Tabb. The lenses are constructed with 4 to 9 curves on each lens depending on refractive error and corneal curvature characteristics. The properties of each curve are described in greater detail in the introduction to this paper.

Equipment

Equipment used for the study and baseline exam are as follows: Greens phoropter, EyeSys topographer, Haag-Streit pachymeter, B&L manual keratometer, and an AO non-contact tonometer.

Protocol

All patients were given their orthokeratology lenses within 2 weeks of the baseline exam. Each lens was manually verified for accurate parameters. Each lens was then evaluated on the eye to determine centration, movement in primary gaze and upgaze, fluorescein pattern with apical touch or alignment, edge alignment, and mid-peripheral pooling. An over-refraction was performed subjectively of the subjects at this time.

Insertion and removal techniques were taught in office and a Boston Original care system was dispensed to each subject. Lens care with this care system was also taught at this time. Subjects were asked to begin overnight wear on the night following the dispensing visit. Subjects were instructed to wear the lenses for a minimum of 10 hours on the first night. Subjects reported the morning after the first night of lens wear for a one day evaluation.

Subjects were examined at one day, 7 days and one month after orthokeratology lens wear began. Each follow up examination consisted of the following procedures: subjective history regarding wearing time, comfort and efficacy of the lenses, unaided visual acuities, binocular subjective refraction, biomicroscopy, tonometry, pachymetry and topography.

At one month subjects were given the choice of remaining with the orthokeratology lenses or returning to previous refractive error correction modalities.

Results:

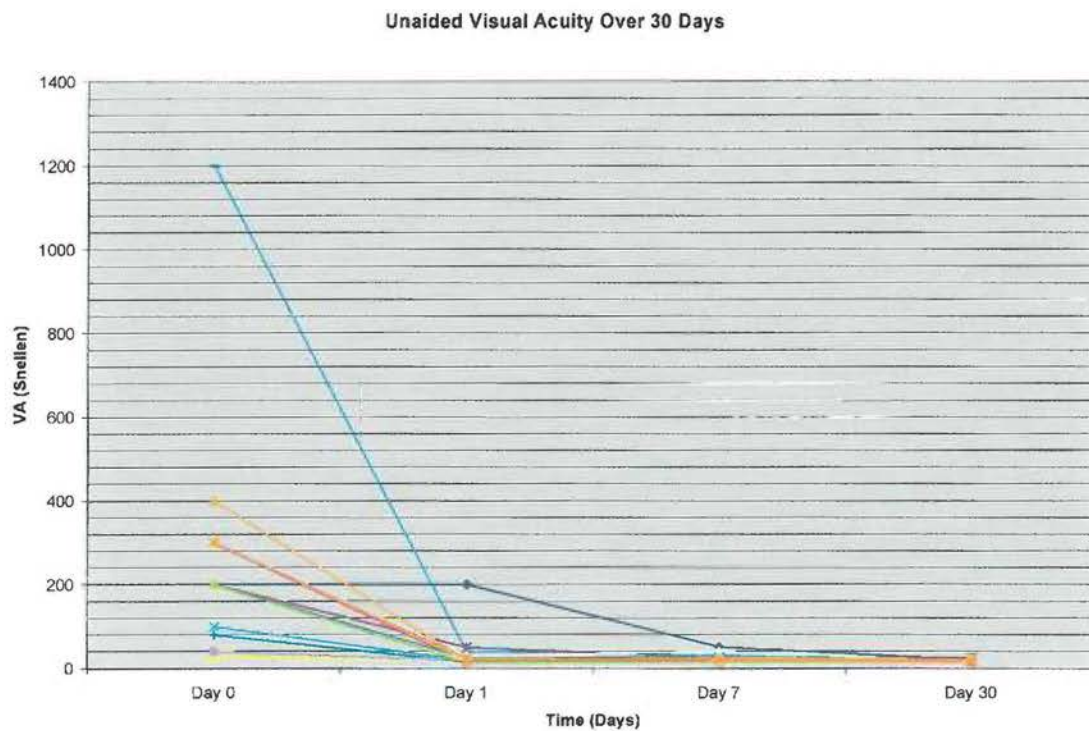
There were 14 subjects that originally began the study. Of these subjects, 4 discontinued wear in a period of less than 30 days and their results were not used in the data analysis. Of the 4 subjects that discontinued wear, 2 complained of unsatisfactory

visual acuity and were not motivated to continue without quicker improvements. The other 2 subjects discontinued due to inability to wear the lenses with satisfactory comfort. Both of these subjects were previous soft contact lens wearers.

Unaided Visual Acuities:

Unaided visual acuities were taken in each eye at the onset of every visit. A standard Snellen chart was used to determine the acuities. Chart 1 demonstrates the progression of unaided visual acuities in every eye. The chart represents the acuities starting before lens wear (day 0) until the completion of the study (day 30). Best uncorrected visual acuity level reached by subjects is expressed in percentages in Table 1.

Chart 1



In a paired t-test, a mean difference of 243.00 decrease in the Snellen denominator value ($p < 0.001$) between the initial unaided visual acuity and final unaided visual acuities. After 1 day, the mean difference was determined to be a decrease of

229.25 in the Snellen denominator ($p < 0.001$). There was not a statistically significant change in Snellen denominators between the left and right eyes.

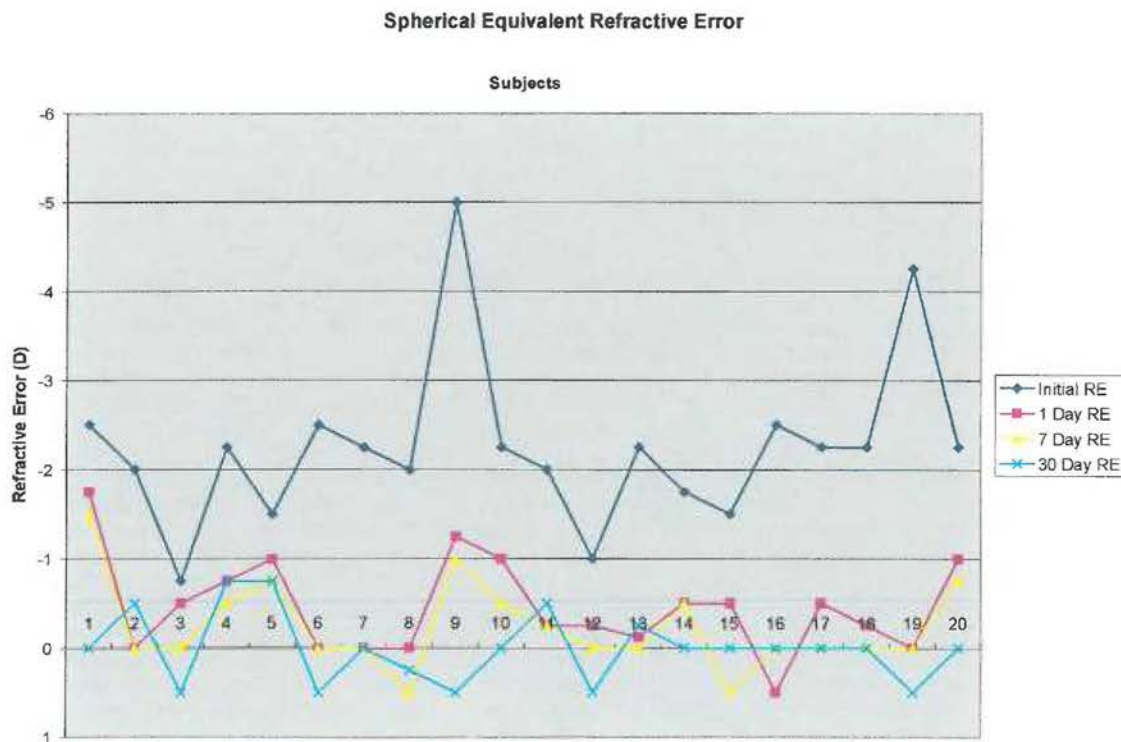
Table 1

Visual Acuity					
	20/40	20/30	20/25	20/20	20/15
Number of Eyes at Acuity Level or Better	20	19	19	18	7
Percentage of Eyes at Acuity Level	100	95	95	90	35

Refraction:

A sphero-cylinder refraction was performed on each eye at every visit. A spherical equivalent calculated from the refraction was used for data analysis. Chart 2 shows the change in refraction over the course of the study for each eye. Table 2 demonstrates the mean refraction changes through the study.

Chart 2



A paired t-test shows a mean change in spherical equivalent refractive error of 1.78D (less minus) ($p < 0.0001$) after one night of lens wear. After 30 nights of lens wear a mean difference was determined to be 2.23D (less minus) ($p < 0.0001$). There was not a statistically significant difference between the changes in spherical equivalent refractive error between right and left eyes.

Table 2

Mean Refractive Error (D)				
Initial RE	1 Day RE	7 Day RE	30 Day RE	Mean Change
-2.26	-0.48	-0.24	-0.04	2.23

Keratometry:

Using a B&L manual keratometer, measurements of each eye were taken at each visit. Keratometry measurements using the Eyesys topographer were not taken at each visit and therefore were not included in data analysis. Table 3 shows the changes in mean steep K throughout the study.

Table 3

Mean Steep K Values (D)				
Initial K	1 Day K	7 Day K	30 Day K	Mean Change
44.29	43.54	43.54	42.83	1.46

A paired t-test was again performed to calculate means. After 1 night of lens wear the mean change (flattening) in steep K was 0.757D ($p < 0.0001$). After 30 nights of lens wear the mean change (flattening) in steep K was 1.463D ($p < 0.0001$).

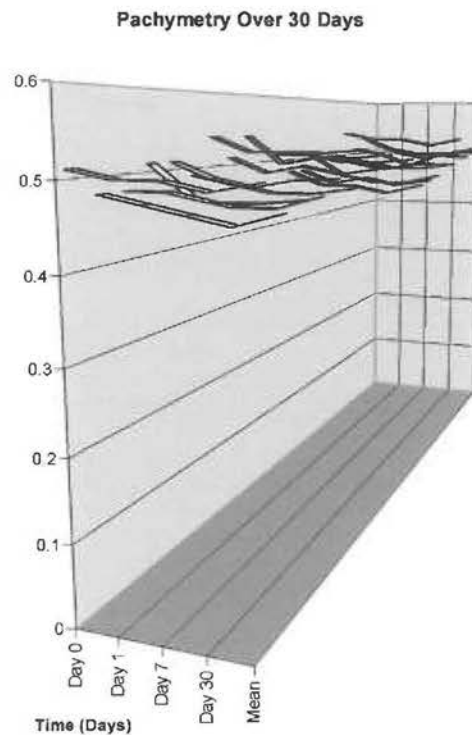
IOP:

Intraocular pressures were measured at each visit using an AO non-contact tonometer. There was a small, but not statistically significant decrease in intraocular pressure throughout the study.

Pachymetry:

Pachymetry readings for each eye were taken at each visit using a Haag-Streit pachymeter. The results demonstrating the change in pachymetry in each eye are shown in Chart 3. The change in mean central thickness readings from the beginning to the end of the study are shown in Table 4.

Chart 3



Using a paired t-test, the mean change in central corneal thickness after 1 night of lens wear was 0.017 mm ($p < 0.0001$). After 30 nights of lens wear the mean change in

corneal thickness was 0.022 mm ($p < 0.0001$). Both of these means reflect a central thinning of the cornea.

Table 4

Mean Central Thickness (mm)				
Initial	1 Day	7 Day	30 Day	Mean Change
0.508	0.491	0.486	0.486	0.022

Ocular Health:

Biomicroscopy was performed on each eye at every visit. Each examine included a thorough anterior segment evaluation with the primary focus being corneal changes. Of the eyes that wore lenses for the duration of the study 2 showed mild (1+) staining of the corneal epithelium after 1 night of wear. There were 2 other instances of mild staining at 7 days. No additional epithelial staining was found at the remaining visits. Two of the subjects that did not complete the study demonstrated staining after the first night of wear.

There were no instances of visible endothelial or stromal changes observed on biomicroscopic examination for any of the eyes in this study. Additionally, no cases of corneal ulcers wear found in any eye throughout the study.

Four patients (8 eyes) reported lens adhesions upon removal of lenses in the morning after 1 night of wear. After additional insertion and removal training was performed and artificial tears was given to these patients only 1 additional report of lens adhesion was noted at 7 days.

Discussion:

It has been shown in many studies that orthokeratology is a safe and effective alternative to LASIK for correction of refractive error. This study produced similar results when considering the minimal risk for any compromise to ocular health. The 10 subjects in our study were fit with the NightMove™ N.E.R.O. orthokeratology lenses for a period of thirty nights of continuous overnight wear. Of the 20 eyes that were followed up at one day, one week, and one month; not one episode of microbial keratitis was found. Half of the subjects experienced halos around lights and slight ghosting in the evenings. Objectively, there was no evidence of corneal edema or epithelial compromise. There was no statistically significant decrease in intraocular pressure during this study in any of the eyes, though it has been reported that IOP readings can read falsely low after corneal thinning with LASIK. Though this sample size is very small, the lack of complications is very clear. Other studies with much larger sample sizes experienced similar results as were found in this study. More importantly, when compared to invasive procedures such as LASIK, orthokeratology has far less complications.

The results from this study demonstrate a significant change in unaided visual acuity with the Night Move Lenses. The mean unaided visual acuity decreased from 20/263 to 20/33 after only 1 night of wear and to 20/20 after 1 month of wear. Subjective complaints of halos and glare at night were common with patients, but with continued wear the complaints decreased. Halos and glare are due to the pupil dilating to a diameter greater than the zone of flattening, similar to complaints with LASIK. After 1 day of lens wear there may be a noticeable change in daytime acuity, but the central zone of

flattening is smaller than the zone noted at 30 days. With increased use of the lenses the zone expands and subjective complaints decreased. One patient with 8mm pupils reported halos and glare at 30 days.

Refractive error changes with orthokeratology lenses have been reported to represent changes in corneal curvature and anterior corneal thickness⁷. In this study, the mean refractive error changed from -2.26D to -0.04D after 30 days. The mean change in corneal curvature determined by keratometer readings 1.46D. These results show a difference of over 0.75D that should be accounted for in a subjective refraction. Subjects would also be unlikely to present with 20/20 unaided visual acuities with 0.75 D of myopia. These results would suggest that an additional factor, such as anterior corneal thickness changes must account for the discrepancies between the keratometric readings and refractive errors. In a study by Swarbick, et al. pachymetry readings were taken at various locations on corneas after orthokeratology lenses were worn. It was determined that central corneal thinning occurred after lens wear as well as peripheral thickening. It was suggested by the authors of the study that central thinning occurred primarily in the epithelium while peripheral thickening occurred in the stroma. The technology used to make these measurements was not available for this study, but a statistically significant change in central corneal thickness was determined through pachymeter readings. Several studies have demonstrated that using Munnerlyn's formula can demonstrate how central thinning can contribute to additional reduction in refractive error^{1,7}. This formula has been used to determine parameters with surgical photorefractive procedures⁹. The formula can be summarized as:

$$T = -S^2 \times D / 8(n-1)$$

Where t is the ablation depth, S is the ablation diameter and D is the desired refractive change⁷. Refractive index of the cornea is assumed to be 1.377. Due to lack of resources to accurately measure the diameter on the flattened zone, it was not practical to apply this formula to patients in this study. This formula does, however, demonstrate that changes in corneal thickness can correspond to significant changes in refractive error.

Pachymetry results from this study yielded a mean change in central thickness of 0.022mm. While the results from this are statistically significant, it seems like a small change when compared to the amount of corneal thinning that occurs with photorefractive procedures. The difference here is that this change is in addition to a change in corneal curvature. Together these factors provide patients with optimal unaided visual acuity. The major advantage with orthokeratology lenses is that they are able to provide this acuity without thinning the cornea to the extent that photorefractive procedures do. This allows patients to maintain a thicker, stronger and safer cornea while enjoying the benefits of good unaided visual acuity.

A benefit even more specific to the Nightmove™ lens used in this study was the speed at which the desired results occurred. Typically that being one night of wear for most of our subjects. For example, one very successful case in this study was a subject with an initial spectacle prescription of -2.00 D OU, with unaided visual acuities of 20/300 OU. At the one day follow up visit, after having removed the lenses one hour and five minutes before being examined. Our subject had unaided visual acuities of 20/15 OU, and her refraction was plano OD and -0.25 OS. The one week follow up produced results exactly the same as her one day follow up. The subject reported to us that she had been wearing her lenses about an average of eight to ten hours per night and that she

really hadn't noticed any decrease in vision at any point during the day. At the one month follow up visit, her unaided acuities were still 20/15 OU. However, the refraction changed slightly to -0.50 OU. She also reported to us that she was only wearing her lenses about every third night and that her vision was remaining stable during that time frame. The patient's only complaint for this study was the slight halos around lights that she was experiencing at night. However, she felt that her new and improved vision was well worth a little distraction at night.

While the sample size for this study is small, the results demonstrate the effectiveness of the NightMove™ orthokeratology lenses as well as their safety. It is clear that with a proper fit, these lenses are able to quickly improve unaided visual acuity and maintain this vision. In a previous study performed with these lenses, patients reported clear vision for an average of 16.6 hours after removing the lenses⁶. These results were found after the subjects had worn the lenses for only 3 weeks.

Bibliography

1. Bauman, Optometric Management, "Ortho-K." Pgs. 87-90, May 2001.
2. Caroline, Patrick, "Contemporary Orthokeratology/ CLAE Commentary." Contact Lens & Anterior Eye, Pgs. 41-46, 2001.
3. Johnson, A.M., Lakin, D.H., "Axial Length Changes Associated with Orthokeratology Treatment Procedures." Contacto 1995 Nov: 14-16
4. Kame, RT, Kennedy, JR, "Corneal Contour Change with 3M Fluoropolymer Lenses." Contact Lens Spectrum 1987;2(5):53-9
5. Medford, J, Caroline, P, Contact Lens Spectrum, "Corneal Topography and Orthokeratology: Pre-fitting Evaluation." Pgs. 38-44, April 2002.
6. Neil, Abigail, Neil, Robert, Tabb, Roger, "Nightwear Orthokeratology as a Fast, Safe, and Effective Correction for Myopia." Thesis document at Pacific University, Feb 1998.
7. Swarbrick, etal., "Corneal Response to Orthokeratology." Optometry and Vision Science, Vol 75, No. 11, Nov. 1998
8. Tabb, Roger, "Surgical and Non-surgical Techniques to Correct Refractive Errors." Optometry Today, Pgs. 34-38, June 1, 2001.