Night wear orthokeratology as a fast, safe, and effective correction for myopia

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Night wear orthokeratology as a fast, safe, and effective correction for myopia

Abstract
Background: Orthokeratology has been a topic of increasing interest and has seen increasing success over time. The following paper is a study done to determine the effectiveness and safety of a new lens design worn at night only.

Methods: Twenty-six subjects (50 eyes) with myopia between 0.500 and 4.000 with astigmatism no greater than 2.000 were fitted with the Dreimlens™ orthokeratology lens. The lenses were worn at night only, every night for six weeks. Visual acuities, refraction, slit lamp exam, keratometry, tonometry, pachymetry, and refraction were performed at one day, one week, three weeks, and six weeks into lens wear. Subjects then discontinued lens wear and were seen again in one week to determine reversibility.

Results: All eyes reached 20/30 unaided VA, 44 eyes reached 20/20 or better lasting all day for 21 of the 26 subjects (10 hrs or more). No serious health complications arose with overnight wear of the lenses and the lenses were thought to be comfortable with sleep. Within one week after discontinuing, all but one eye had returned to their original refractive error.

Conclusions: The DreimlensTM proved in this study to be a safe and effective method of reducing or eliminating low to moderate amounts of myopia.

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NIGHT WEAR ORTHOKERATOLOGY AS A FAST, SAFE, AND EFFECTIVE CORRECTION FOR MYOPIA.

BY

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ROBERT K. NEAL

A thesis submitted to the faculty of the
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-Abstract-

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Methods: Twenty-six subjects (50 eyes) with myopia between 0.50D and 4.00D with astigmatism no greater than 2.00D were fitted with the Dreimlens™ orthokeratology lens. The lenses were worn at night only, every night for six weeks. Visual acuities, refraction, slit lamp exam, keratometry, tonometry, pachymetry, and refraction were performed at one day, one week, three weeks, and six weeks into lens wear. Subjects then discontinued lens wear and were seen again in one week to determine reversibility.

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Conclusions: The Dreimlens™ proved in this study to be a safe and effective method of reducing or eliminating low to moderate amounts of myopia.

Key Words: Orthokeratology, myopia reduction, Dreimlens™, refractive error change, corneal power change.
-Acknowledgements-

We would like to thank Euclid Systems Laboratories, located at 2810 Towerview Rd., Herndon, VA. 20171, for providing all of the lenses used in this study free of charge. We would also like to thank Ortho-K Vision, Inc., located at 981 E. Eaugallie Blvd., Melbourne, FL 32900, for designing and calculating the curves of the Dreimlens™ for each individual subject in this study.
Introduction:

Orthokeratology has been a controversial topic since it was originally introduced at the first meeting of the National Eye Research Foundation (N.E.R.F.) in 1962 by Dr. George N. Jesson. An idea that stemmed from practitioners’ observations of corneal changes instigated by rigid contact lens wear, orthokeratology is defined by the International Orthokeratology Section of the N.E.R.F. as, “the reduction, modification, or elimination of refractive anomalies by the programmed application of contact lenses or other related procedures.” Practitioners decided to educate themselves on the reasons behind the adverse effects, and use the concept to their advantage. However, the results were extremely variable, and it was difficult to organize specific research projects. Anecdotal successes reported by doctors were difficult to substantiate in research, and were not aided by the fact that each practitioner used a slightly different fitting protocol to effect orthokeratology. However, the procedure has improved greatly and now, thanks to the research of many practitioners over the years, we are poised on the edge of the ability to make orthokeratology a reliable, viable option for any practitioner that wishes to incorporate myopia reduction into his/her practice.

The first efforts to modify the shape of the cornea in hopes of reducing myopia involved using the central pressure of a flat base curve created by fitting rigid contact lenses up to 1.00 to 2.50 diopters flatter than flattest K. This method was lengthy (18 months or more) and often unpredictable, with decentration of the lens and instigation of against-the-rule astigmatism as the cornea flattened.

The next step in orthokeratology introduced a whole new fitting philosophy. A lens was designed in which the base curve was steeper than the flattest K. It was called the Hydraulic method. The theory was to use the paracentral cornea to cause central shape change, thus effecting improved unaided visual acuity.

The next innovation occurred in 1975 when back surface aspheric base curves were tried. They worked but unfortunately, the results did not last.

The next generation of designs introduced were called reverse geometry lenses, in which the intermediate curves are steeper than the base curves. This design had the advantage of increased stability as the cornea flattened as well as effecting orthokeratology much more quickly. As a result, this philosophy was termed “accelerated orthokeratology”. Accelerated ortho-k had good results up to −2.00 diopters, with variable results in greater amounts of myopia. The time to
reach endpoint was reduced to 2-6 months, but again, many lenses were needed to reach that point. This fitting philosophy followed the concept described by Charles May in which Bowman’s membrane cannot alter its shape in response to ortho-k. Based on this theorem it is believed that you cannot add to or take away from the total surface area, and the chord length from limbus to limbus and the surface length of the fiber must remain constant. What this means is that as the cornea flattens centrally, the displaced epithelium must have somewhere to move to. The reverse geometry lens allows that movement into the steeper areas of the fit curve.

May’s concept is incorporated into the third and most recent philosophy of orthokeratology, using a custom lens design based on individual corneal shape as measured by a corneal topographer. This method has been termed advanced orthokeratology and has a primary difference when compared to prior philosophies. This difference is that the total amount of myopia reduction no longer has to be based on the eccentricity of the cornea. Past methods used a ratio of approximately .2 units of corneal eccentricity for each diopter of myopia that can be eliminated as the cornea sphericalizes. Trying to flatten the cornea beyond this point was thought to be futile, because it was believed that it was impossible to mold the cornea to a shape that was flatter than a perfectly round sphere. However, the technology in the past wasn't equipped to identify an oblate cornea. Now, with more sophisticated technology, an oblate cornea can both be identified, and created. Advanced orthokeratology can take a prolate cornea, bring it to sphericalization, and beyond. Drs. Pat McGonagill and Thomas Reim, et al. summarized these changes: “advanced orthokeratology is designed not to sphericalize the cornea, but to form an oblate shape. Previous methods were designed to stop when the cornea was spherical.”

The lenses used in this study are advanced orthokeratology lenses designed by Dr. Thomas Reim, called the Dreimlens™ N.E.R.O. The magic of the Dreimlens™ N.E.R.O., we believe, is the relationship of the entire back surface of the contact lens with the accurate elevation data of the cornea. The most critical portion of the lens is the fit curve and the alignment curve relationship. This is a specific mathematical relationship and must be calculated for each cornea. We are finding now that micron changes can create large changes in outcome of the orthokeratology results.

Our belief is that the reverse geometry base curve area provides an end result template for the optical part of the cornea. The reverse curve or fit curve moves the contact lens back to meet the cornea, creating a hydraulic containment system. This gives the best of both worlds:
mechanical and hydraulic pressures acting together, creating true molding of a visco-elastic structure—the cornea. These lenses are specifically designed to be worn only at night which gives a wearing schedule which has many advantages, the most important being that the eye movement while sleeping is REM, which encompasses a much smaller excursion than with daytime blinking. This movement is thought by the authors to be beneficial to the ortho-k process and corneal health, providing a pumping action for tear exchange and a "massaging" effect, helping the visco-elastic molding process to occur.

We believe that advanced orthokeratology is a fast (effective within the first week to reach the desired end results), effective (working with myopes up to −4.00 diopters), safe (causing no harm to the cornea, and actually safer than daytime RGP wear), and fully reversible process, providing an alternative to glasses, contact lenses, and refractive surgery for those low to moderate myopes who wish to be able to function without a prescription.

Methods:

31 subjects enrolled in the study. All subjects were chosen from a pool of Optometry students. Two of the subjects participated with only one eye due to anisometropic refractions. (The second eye was virtually plano in both cases.) Requirements for acceptance into the study included myopia no greater than −4.00, astigmatism no greater than −2.00 in any meridian; no history of any corneal trauma, disease, or surgery; a healthy slit lamp exam revealing no corneal compromise, edema, or infection; and regular keratometry mires. Each subject was informed that he/she could withdraw at any time from the study with no penalty.

The initial evaluation of each subject consisted of a complete ocular history, a basic refraction, keratometry, pachymetry using a Haig-Streit optical pachymeter, Goldman applanation tonometry, and corneal topography using both the Eyesys and Euclid corneal topography systems. The Euclid information is taken by Fourier profilometry, measuring direct elevation data. The Eyesys system uses a placido disc system and a mathematical algorithm to calculate the corneal shape. Lenses were ordered based on each subject's refraction and keratometry readings.

The orthokeratology lenses used were the Dreimlens™ N.E.R.O. design. This specific design was chosen because it was designed for end results utilizing night wear only. The lenses were designed and calculated by Ortho-K Vision, Inc. located at 981 E. Eaugallie Blvd., Melbourne,
FL. 32900. Lenses were manufactured and provided by Euclid Systems Laboratories located at 2810 Towerview Rd., Herndon, VA. 20171.

Construction of the standard Dreimlens™N.E.R.O. design is a reverse geometry lens with a 10.0-mm diameter. The lens has a 6.0-mm central zone, which is designed as an end result template for the final central shape of the cornea. The fit curve is paracentral and is 0.6 mm wide with a calculated curve from elevation data. The alignment curve is 1.0 mm wide and is calculated to correlate with the base curve and fit curve to achieve chord length consistency while still accommodating shape change. The peripheral curve is 0.4/10.50 mm. Thickness was a standard 0.22-mm. The material was Equalens II, which is manufactured by Polymer Technology.

Lenses were dispensed approximately two weeks after the initial exam. Each lens was evaluated for good centration, slight movement in primary gaze with increased movement on upgaze, a fluorescein pattern with apical alignment or slight apical touch, mid-peripheral pooling, and proper edge alignment. This created a bullseye pattern appearance typical of reverse geometry designs. An example of this is shown in figure 1. An over-refraction was performed on each subject.

The subjects were instructed on proper insertion and removal techniques, as well as how to handle and care for their lenses. Boston Original formula was given to each subject to care for his/her lenses. Each subject left wearing his/her lenses, was instructed to wear the lenses overnight for a minimum of 10 hours, remove the lenses in the morning, and return to the clinic for the one-day evaluation.

All subjects were evaluated one day, one week, three weeks, and six weeks post-OK wear. At each evaluation the following tests were performed: subjective questioning as to the efficacy of the lenses, unaided visual acuities, subjective refraction, slit lamp exam, keratometry, and topography on both the Eyesys and Euclid systems. Goldman tonometry and pachymetry were performed at the initial, one day, and six-week evaluations.

At six weeks, all subjects discontinued ortho-K lens wear and were fit into standard daily-wear RGPs, with the fit based on pre-ortho-K measurements. The subjects returned in one week for a final evaluation. The final evaluation included unaided visual acuities, refraction, slit lamp exam, keratometry, eccentricity and topography on the Eyesys and Euclid systems. Each subject was asked to assess the time it took for he or she to return to their original refraction. This subjective response was compared to our refraction.
Results:

31 subjects began the study. Of these, 5 subjects did not participate in the study for longer than a week. Their results are not included in the following data as a result of not completing the study, and will be addressed later in the paper.

Unaided Visual Acuities:

Unaided visual acuities (UVAs) were taken at each visit. The mean visual acuities after one night of wear, one week of wear, and at the final visit are shown in Table 1. Individual subject VAs over the course of the study are shown in graphs 1 and 2. The following table shows a summary of the results of the uncorrected visual acuity.

In the 26 subjects completing the study: 50 eyes = 100% (two subjects had only one eye done)

- All eyes reached 20/40 UVA or better (100%)
- All eyes reached 20/30 UVA or better (100%)
- 48 eyes reached 20/25 UVA or better (96%) OD: 96% OS: 96%
- 44 eyes reached 20/20 UVA or better (88%) OD: 92% OS: 84%
- 29 eyes reached 20/15 UVA or better (58%) OD: 52% OS: 64%

In a paired t-test, there was a mean difference of 116.154 decrease in the Snellen denominator value \((p<.0001)\) between OD initial and OD one-day unaided visual acuities. The mean difference between OD initial and OD six-week was 132.0 \((p<.0001)\). OS findings had a mean difference of 105.192 \((p<.0001)\) Snellen value between OS initial and OS one-day UVAs. OS initial and OS six-week UVAs had a mean difference of 119.250 \((p<.0001)\).

UVA had an average holding time of 11.0 hours after the first week of lens wear, 15 hours after 3 weeks of lens wear, and 16.7 hours after six weeks of lens wear, as determined by subjective questioning. Individual holding times are shown in Table 2.

Refraction:

A refraction was performed at each visit. Individual refraction changes over the course of this study are shown in graphs 3-6. Graph 3 and 5 show the OD and OS sphere changes, respectively. Graphs 4 and 6 show the OD and OS cylinder changes, respectively. Mean refractive changes in sphere and cylinder in each eye are shown in Table 3.
A paired t-test was performed, showing a mean decrease in OD spherical refraction from initial to day one of 0.875 D (of minus power), with a p-value of <.0001. Comparing initial OD spherical refraction to the final OD spherical refraction showed a decrease of 1.375 D (p=<.0001). The mean decrease in the cylinder component of the OD refraction from initial to day one was 0.106D (p= 0.1631). Initial versus final values of the OD cylinder component showed an increase in cylinder power of 0.269D (p= 0.0147). The OS spherical refraction values showed a mean decrease of 0.952D (p= <.0001). The decrease of OS spherical refraction from the initial measurement to the final measurement was 1.471D (p= <.0001). Comparing the initial cylinder component of refraction OS to the day one value showed an increase of 0.010D (p=0.8958). The difference between the initial OS cylinder component and the final OS cylinder component showed an increase of 0.183D (p= 0.0076).

**Keratometry:**

Keratometry measurements were taken at each visit using three techniques; a B&L manual keratometer, Eyesys corneal topographer sim-K values, and the Euclid corneal topographer calculated K values. Mean keratometry findings for all three methods are shown in Table 4.

The manual keratometry measurements showed a mean flattening of the OD flat K of 0.711D when comparing initial and day one findings, and a mean flattening of 1.289D when comparing initial and final measurements (both with a p-value of <.0001). The OD steep K showed a flattening of 0.578D when comparing initial and day one findings, and a mean flattening of 1.182D when comparing initial and final measurements (both with p=<.0001). The OS flat K measurements showed a mean flattening of 0.763D (p=.0001) when comparing initial and day one findings, and a mean flattening of 1.405D (p=<.0001) when comparing initial and final measurements. The OS steep K showed a mean flattening of 0.730D (p=.0001) when comparing initial and day one findings, and a mean flattening of 1.239D (p=.0001) when comparing initial and final measurements.

The Eyesys sim K values showed a mean flattening of the OD flat K of .009D (p=.9276) when comparing initial and day one findings, and a mean flattening of 0.847D (p=0.3298) when comparing initial and final measurements. The OD steep K showed a steepening of 0.076D (p=0.6463) when comparing initial and day one findings, and a mean steepening of 0.036D
(p=0.8462) when comparing initial and final measurements. The OS flat K measurements showed a mean flattening of 0.193D (p=0.4782) when comparing initial and day one findings, and a mean flattening of 0.701D (p=0.0897) when comparing initial and final measurements. The OS steep K showed a mean steepening of 0.171D (p=0.3933) when comparing initial and day one findings, and a mean steepening of 0.048D (p=0.8170) when comparing initial and final measurements. All of these values did not seem to show statistically significant changes in either direction.

The Euclid keratometry values showed a mean flattening of the OD flat K of 0.322 D (p=.0471) when comparing initial and day one findings, and a mean flattening of .715D (p=.0006) when comparing initial and final measurements. The OD steep K showed a mean flattening of .302D (p=.0148) when comparing initial and day one findings, and a mean flattening of .718D (p<.0001) when comparing initial and final measurements. The OS flat K measurements showed a mean flattening of .372 (p=.0239) when comparing initial and one day findings, and a mean flattening of .664 (p=.0015) when comparing initial and final measurements. The OS steep K showed a mean flattening of .248 (p=.0148) when comparing initial and one day findings, and a mean flattening of .539 (p<.0001) when comparing initial and final measurements.

**Eccentricity:**

Eccentricity values were measured on both the Euclid and Eyesys systems. The Euclid gave an eccentricity value in both the flat and steep meridians, while the Eyesys gave an overall eccentricity value with no specification as to what meridian. It would be assumed to be the horizontal meridian.

Euclid eccentricity showed a mean flat OD reading of −0.029 initially, −0.057 after one day, and −0.222 at the final measurement. Steep eccentricity values showed a mean OD reading of 0.108 initially, 0.072 after one day, and −0.155 at the final measurement. On the left eye, there was a mean flat reading of −0.036 initially, −0.061 after one day, and −0.233 at the final measurement. The mean steep reading of the left eye was 0.107 initially, 0.089 after one day, and −0.154 at the final measurement.

A paired t-test of this data showed a mean change toward the oblate in the flat OD meridian of 0.031 (p=.0882) when comparing initial and one day findings, and a mean change toward the oblate in the flat meridian of 0.195 (p<.0001) when comparing initial and final measurements. There was a mean change toward the oblate in the steep OD meridian of 0.035
(p=.0655) when comparing initial and one day findings, and a mean change toward the oblate in the steep meridian of 0.262 (p<.0001) when comparing initial and final measurements. On the left eye the findings showed a mean change toward the oblate in the flat meridian of 0.027 (p=.0178) when comparing initial and one day findings, and a mean change toward the oblate in the flat meridian of 0.200 (p<.0001) when comparing initial and final measurements. There was a mean change toward the oblate in the steep meridian of 0.258 (p<.0001) when comparing initial and one day findings, and a mean change toward the oblate in the steep meridian of 0.258 (p<.0001) when comparing initial and final measurements.

**Pachymetry:**

Pachymetry was performed at the initial, one day, and six-week evaluations. The mean initial OD corneal thickness was .524 mm, at the one-day evaluation the mean thickness was .506 mm, and at the final evaluation the mean thickness was .523 mm. The mean initial OS corneal thickness was .531 mm, at the one-day evaluation the mean thickness was .508, and at the final evaluation the mean thickness was .522 mm.

A paired t-test showed a mean difference of 0.018 (p=.0659) when comparing initial OD and one day findings, and a mean difference of −0.016 (p=.0411) when comparing initial and final findings. On the left eye, the t-test showed a mean difference of 0.024 (p=.0152) when comparing initial and one day findings, and a mean difference of −0.006 (p=.3417) when comparing initial and final findings. Given this information, there was no statistically significant change in corneal thickness throughout the six weeks.

**Tonometry:**

There was mild decrease, but no statistically significant increase in ocular pressure during the six-week study.

**Ocular Health:**

1. **Corneal Staining**

   Day 1: 3 of 66 eyes showed 1+ staining, one of which was slight foreign body tracking. All staining resolved within 24 hours and did not reoccur.
Week 1: None noted.

Week 4: None noted.

Week 6: 1 of 34 eyes showed 1+ staining, and 1 of 34 eyes showed 1+ inverse staining. All staining resolved within 24 hours and did not reoccur.

2. Induced Conjunctival Injection

Day 1: 2 of 66 eyes showed 1+ induced injection nasally, 1 of 66 eyes showed 2+ induced injection inferiorly, and 1 of 66 eyes showed 4+ induced injection nasally caused by a lens which had decentered. All injection resolved within 24 hours and did not reoccur. No other injection was noted throughout the remainder of the study.

3. Endothelium

There was a small, .5mm round white spot noted on the endothelium of one eye during the week 1 visit, which resolved and was not noted again. No other endothelial changes were noted during the study.

4. Corneal Ulcers/Infections

There were no corneal ulcers or eye infections of any kind throughout the study.

5. Lens Adhesions

There were no episodes of lens adhesion, however 10% of the patients commented that the lenses were difficult to remove immediately upon waking, but were removed easily after a couple of minutes of blinking.

6. Summary:

Over a 6-week period, 196 eyes were evaluated, and 10 of these showed minor complications, all of which resolved within 24 hours.

Discussion:

The uncorrected visual acuities and the refraction showed the largest changes of the parameters checked. Keratometric findings did change, but do not necessarily correlate with the refractive changes.
Eccentricities did changes toward greater oblation. Since the Eyesys only shows positive eccentricities, once the e value reached 0 it could not give further information. The Euclid topographer did show the increases in negative eccentricities.

We are aware that there are researchers who report a thinning of the cornea. Our study did not in fact show this. It may very well be related to the type of lenses used. For instance, in the corneaplasty research a corneal softening agent is injected which breaks down the protoglycon bonds. It is reasonable to expect the corneal thickness could be altered in corneaplasty because the very nature of that procedure is to soften the cornea to make it easy to change the shape.

Helen Swarbrick of Australia reported on a study in which 11 subjects wore ortho-k lenses with 6-hour daytime wear schedule for 28 days. The protocol included fitting guidelines of the OK-74 lens by Contex Laboratories. She reported epithelial thinning and suggested that further research might be done using a nightwear lens. She also suggested in the article that, “the epithelial thinning, although it’s quite dramatic, may have only minimal clinical consequences.”

Tonometry and ocular health was not found to be an issue. From the information gathered in this study we would conclude there are no more and possibly less problems which occur with this procedure than we see with normal RGP contact lens wear.

We were able to effect corneal change safely on all corneas, and were also able to reverse these changes after six weeks of lens wear. All but one of the eyes in the study had returned to their original refraction within one week of discontinuing ortho-k. The one eye that had not yet returned fully was -2.50 before ortho-k and still had 0.75D to go to return fully, and had done so within 2 more days. The majority of the patients reported that they were back to their eyeglass prescription within 48 to 60 hours.

Of the five patients who dropped out of the study, one achieved 20/15 UVA OU, but had ghosting and this bothered her when she played basketball competitively so she chose to cease at one week. Three other patients withdrew because of ghosting and/or undesirable VA within the first few days and withdrew after one week. The final patient who withdrew had one eye that worked well, but the vision in the other eye was undesirable and he discontinued lens wear after two nights. Another attempt to fit that eye was unsuccessful, possibly due to the patient’s very flat K’s before the procedure making the peripheral fitting relationship difficult.

The newest form of orthokeratology, visco-elastic molding lens, Dreimlens™ N.E.R.O., has brought a much more personalized and effective means of myopia reduction and control. This
specific form of therapy works well on children as well as adults and is proving to be extremely safe and effective regardless of age, race or sex.\textsuperscript{5,9} The lack of complications is clear, even though this sample size is not large. We have been made aware of much larger sample sizes involving several hundred subjects with very similar results as were found in this study. With all of the new literature on the subject, ortho-k is proving to be a beneficial and versatile procedure. The following is a list of the benefits and versatility points we have experienced with orthokeratology:

- Unlike refractive surgeries, it can be performed on children with little fear of problems beyond normal contact lens wear.
- It can be reversed if there is something the patient doesn't like about it.
- The possibility of injury appears to be very low.
- The process causes a very rapid but safe response.
- The question of permanency becomes a moot point. All that is required to maintain this system is nightwear of the lenses, which is simple and comfortable.
- For presbyopia, one eye can be done for near and one for distance with no fear of the patient not being able to tolerate it. If they don't like it, the near eye can be switched to distance and the other for near, or both for distance. Both eyes can be corrected for near with high myopes, and distance correction can be worn.
- If for any reason the patient is not happy or if there is undue ghosting, the patient can stop wearing the lenses and the cornea will go back to what it was before.
- The patient can see at night with the lenses on if needed and can see in the daytime without them, giving near 24-hour functional vision.
- The risk is extremely low in comparison to refractive surgery.
- The possibility for as good or better unaided VA as with glasses or contact lenses is high with Dreimlens\textsuperscript{TM} N.E.R.O.
- The speed with which Dreimlens\textsuperscript{TM} N.E.R.O. can be done is overnight for most.
- The patients have been enthusiastic about the results and the freedom they acquire in doing this therapy.

An example of one successful case in this study is that of a subject with an initial spectacle refraction of $-3.00$ D OU. At the one day visit, the subject was seen at 8:40am, one hour and forty minutes after lens removal and had uncorrected visual acuities of 20/40\textsuperscript{1} OD and 20/40\textsuperscript{1} OS. Her refraction at this time was $-1.50$ sph OU. At the one week visit, the subject was seen at 4:30pm and had taken the lenses off at 6:00am that morning. Her unaided visual acuity at this time was 20/15 OD and 20/15 OS with a refraction of $-0.50-0.25\times180$ in each eye. Subjectively, this subject did not notice a decrease in vision at any point during the day. Figure 2 shows this subject's topography before orthokeratology and after one week of lens wear, which shows the classic pattern seen in a successful patient with acuities which hold for a long period of time. At the three-
week visit, the subject was still doing well and had noticed consistently clear vision all day every
day. Her unaided visual acuity at this visit was 20/20+2 OD and 20/20+3 OS with a refraction of
plano-0.50x116 OD and -0.50sph OS. This subject also did well for the final three weeks of the
study and at the final visit had unaided acuities of 20/15 OU with a refraction of -0.50-0.25x180 in
each eye. Subjectively, this subject answered that her unaided acuity at near and far, and aided
acuity and near and far were excellent at every visit (with choices of excellent, good, OK, below
average, unacceptable). The subjects were also asked to rate night vision and ghosting (with
choices of excellent, slight, very noticeable, distracting). This subject reported slight ghosting at
the one day visit, and excellent (no ghosting) at the remaining visits. At the one-week visit, she
reported her night vision as having “very noticeable” halos. At both the three and six week visits,
the subject reported her night vision improving with only “slight” halos around lights.

With the subjective questioning, the above mentioned seemed to be a consistent pattern.
The subjects’ main negative responses to questioning (if any) were some degree of halos around
lights at night, and to a lesser extent, ghosting. Both of these factors improved and the problem
was often absent by the end of the study. We consider this to be due to a combination of the lens
settling more over time, which increases the corneal optic zone, and the subject learning to adapt
and less distracted by these factors. The subjective responses to questioning at each visit for
all patients is summarized in table 5.

The purpose of this study was to determine the safety and efficacy of overnight orthokeratology
as a method of myopia reduction. We found in specific, the Dreimlens™ N.E.R.O. is a safe,
reliable, consistently repeatable, relatively trouble free method of improving uncorrected visual
acuity to good functional levels for long periods during the day. We believe that most practitioners
who have knowledge of fitting RGP lenses can adapt rapidly to offering this therapy to their
patients. We also believe this therapy will prove over the next few years to be the method of
choice for refractive change method and for refractive correction in certain ranges over regular
contact lenses or glasses.
References:

Table 1

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## Table 3

### Mean Refraction Changes

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<td>-1.00</td>
<td>-0.50</td>
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<td>-0.15</td>
<td>-0.53</td>
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<td>OS sphere</td>
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<td>-0.89</td>
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### Table 4

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### Table 5

#### Unaided Distance VA

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<th></th>
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<th>OK</th>
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<td>47.8%</td>
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<td>73.8%</td>
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<td>7.1%</td>
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<td>79.4%</td>
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#### Night Vision

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<tr>
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<th>Slight</th>
<th>Very Noticeable</th>
<th>Distracting</th>
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<tr>
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<td>50.0%</td>
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<td>17.4%</td>
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<tr>
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<td>26.3%</td>
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<td>21.1%</td>
<td>5.2%</td>
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<td>Week 6</td>
<td>20.6%</td>
<td>67.6%</td>
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#### Ghosting

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<tr>
<td>Week 1</td>
<td>45.7%</td>
<td>37.0%</td>
<td>17.3%</td>
<td>0.0%</td>
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<tr>
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<td>51.2%</td>
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<td>76.5%</td>
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Percentages given are based upon the total number of eyes, since subjects responded differently between their two eyes in some cases.
Graph 1

Unaided Visual Acuities - OD

Subject Number

Snellen Denominator

Initial OD
1-day OD
Final OD
Graph 2

Unaided Visual Acuities - OS

Subject Number

Graph showing changes in unaided visual acuities over time for different subjects.
Graph 3

Refraction - OD Sphere Changes

Subject Number

Sphere Refraction Component

OD Initial Sphere
OD 1-day Sphere
OD Final Sphere
Graph 4

Refraction - OD cylinder changes

Subject Number

Cylinder Refraction Component

- OD Initial Cylinder
- OD 1-day cyl
- OD Final Cylinder

Initial Cylinder

1-day cyl

Final Cylinder

0.75
0.5
0.25

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
Graph 5

Refraction - OS Sphere Changes

Subject Number

Sphere Refraction Component
Graph 6

Refraction - OS Cylinder Changes

Cylinder Refraction Component

Subject Number

OS Initial Cylinder
OS 1-day cyl
OS Final Cylinder
Figure 1
Figure 2

EyeSys