The effect of increasing the treatment zone diameter through a larger optical zone lens in orthokeratology

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**Recommended Citation**  
Johnson, Christopher; Kelly, Christopher; and Kim, Denis, "The effect of increasing the treatment zone diameter through a larger optical zone lens in orthokeratology" (2006). *College of Optometry*. 1531.  
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The effect of increasing the treatment zone diameter through a larger optical zone lens in orthokeratology

Abstract

Purpose: To evaluate the effect of increasing the treatment zone diameter through a larger optical zone (OZ) lens in orthokeratology.

Methods: This study involved the evaluation of 12 eyes of 6 patients with low to moderate myopia and/or astigmatism. Subjects wore BE Retainer lenses (6.0 mm optic zone) overnight and were evaluated the following morning. Successful subjects then wore these lenses consecutively for 1 week and 1 month from the time of the initial dispensing. The second phase of the study involved switching the subjects from initial phase to larger B zone lens (6.7 mm optic zone). Again, 1 day, 1 week, and 1 month evaluations were conducted. On each follow up visit, subjective questionnaires, case histories, visual acuities, refractions, biomicroscopy, and corneal topographies were performed.

Results: Most subjects reached an uncorrected visual acuity (UCVA) of either 20/20 or 20/16 with both optical zone lenses. No significant improvements or deteriorations in visual acuity were noted with the different optical zone treatment diameters. Refractive error changes also showed similar results between the right and left eyes for each optical zone lens diameter with a mean change of 2.26 D (R) and 1.94 D (L) with the 6.0 mm OZ lens and 1.92 D (R) and 1.81 D (L) with the 6.7 mm OZ lens. The final average spherical equivalent refractive error was +0.63 OS (R) and +0.60 OS (L) for the 6.0 mm OZ and +0.29 OS (R) and +0.60 OS (L) for the 6.7 mm OZ lens. The subjects did not have significant changes in the treatment zone diameters between the 6.0 mm OZ and 6.7 mm OZ lenses with a mean average increase of 0.195 mm OS and 0.162 mm OS. Most subjects had a slightly progressive decrease in nighttime glare from pretreatment to post-treatment with both optical zone lenses.

Conclusion: An increase in optical zone diameter lens did not significantly increase the treatment zone diameter and did not adversely affect uncorrected visual acuity. There was a small decrease in the effects of nighttime glare with the larger optical zone lens.

Degree Type
Thesis

Degree Name
Master of Science in Vision Science

Committee Chair
Patrick Caroline

Subject Categories
Optometry

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THE EFFECT OF INCREASING THE TREATMENT ZONE DIAMETER THROUGH A LARGER OPTICAL ZONE LENS IN ORTHOKERATOLOGY

BY

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CHRISTOPHER KELLY
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A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
May 2006

Advisor:
Patrick Caroline, C.O.T., F.A.A.O.
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BIOGRAPHY

Christopher Johnson
Christopher Johnson was born and raised in Edmonton, Alberta. He received his Bachelor of Science degree from the University of Alberta. Upon graduation and licensure, he plans on practicing in Calgary, Alberta.

Christopher Kelly
Chris Kelly was born in Fargo, North Dakota. He spent most of his younger years between Minnesota and Alaska, but moved to Oregon in high school. He received his Bachelor of Science degree from the University of Oregon. Upon completion of the Doctor of Optometry program from Pacific University he will be commissioned as a Captain in the U.S. Army, where he will serve as an Army Optometrist for his fellow soldiers for a minimum of three years. After completion of his tour in the Army he plans on practicing in Oregon or Minnesota, where most of his family resides.

Denis Kim
Denis Kim was born in Grande Cache, Alberta Canada but spent most of his life in Edmonton, Alberta. He completed undergraduate work at the University of Alberta and upon graduation and licensure, he plans on practicing in the Pacific Northwest or in British Columbia.
ABSTRACT

Purpose: To evaluate the effect of increasing the treatment zone diameter through a larger optical zone (OZ) lens in orthokeratology.

Methods: This study involved the evaluation of 12 eyes of 6 patients with low to moderate myopia and/or astigmatism. Subjects wore BE Retainer lenses (6.0 mm optic zone) overnight and were evaluated the following morning. Successful subjects then wore these lenses consecutively for 1 week and 1 month from the time of the initial dispensing. The second phase of the study involved switching the subjects from initial phase to larger B zone lens (6.7 mm optic zone). Again, 1 day, 1 week, and 1 month evaluations were conducted. On each follow up visit, subjective questionnaires, case histories, visual acuities, refractions, biomicroscopy, and corneal topographies were performed.

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Conclusion: An increase in optical zone diameter lens did not significantly increase the treatment zone diameter and did not adversely affect uncorrected visual acuity. There was a small decrease in the effects of nighttime glare with the larger optical zone lens.
ACKNOWLEDGEMENTS

Patrick Caroline, C.O.T, F.A.A.O., for his extensive assistance in contact lens fitting, professional insight, and advocacy for the completion of this study.

Randy Kojima, director of technical affairs for BE Enterprises in Vancouver, British Columbia, for supplying materials for the study, professional insight, and willingness to help.
INTRODUCTION

Orthokeratology (ortho-k) is a non-invasive, reversible procedure that allows for a temporary correction of myopia with moderate amounts of astigmatism. This procedure involves wearing gas-permeable lenses overnight that flatten the central cornea during sleep, resulting in clear uncorrected visual acuity (UCVA) when the lenses are removed upon waking. Vision is considerably improved after just one night of wear and most patients can go through the day wearing no correction. However, the effects of ortho-k are temporary and usually last up to one to two days. Therefore, patients must wear a retainer lens to maintain the desired correction and a minimal wear time is established to maintain the ideal corneal shape and visual function.

Orthokeratology is viable, non-invasive, reversible alternative to refractive surgery, such as LASIK, and offers freedom from glasses and the inconvenience of wearing contact lenses during the day. It can be performed on virtually anyone as long as there are no ocular or systemic contraindications to contact lenses. Ortho-k holds particular appeal for athletes, those who work in dusty, dirty environments, and/or occupations, such as pilots, police officers, or fire fighters, where regular contact lens wear may be contraindicated. Because this procedure offers similar benefits to LASIK, it is also a viable option to adolescents and teens that are not eligible for refractive eye surgery. Furthermore, it eliminates any apprehension towards the complications and permanency of surgery. It can also be a good option for patients suffering from dry eye, which is commonly exacerbated by refractive laser surgery, and irritation associated with contact lens wear from dust and pollutants.

In the late 1950's and early 1960's, optometrists noticed that patients, who were fitted with contact lenses flatter than k, were less myopic after lens removal. Consequently, orthokeratology techniques were developed using flat lenses with large optical zones. The choice of material then was polymethyl-methacrylate (PMMA) and thus required long adjustment periods. Moreover, these plastic
lenses did not allow passage of oxygen to the cornea. The subsequent
development of rigid gas permeable (RGP) lens materials markedly improved the
safety of lens wear as these materials allow oxygen to pass through to the
cornea. The RGP lenses also increase the performance of orthokeratology as the
ability to use larger overall diameters allow for a greater centration.

Our understanding and knowledge of orthokeratology has significantly
increased, resulting in the development of modern corneal refractive therapy
(CRT) and vision shaping treatment (VST). The Paragon CRT, and recently FDA
approved VST by Bausch & Lomb, are the result of ongoing research and
technological advancements in corneal reshaping and lens materials. According
to Patrick Caroline, FCLSA, FAAO, five technological advances have enabled
orthokeratology to achieve a greater success rate:

1) Advances in multicurve GP lenses specifically designed to facilitate the
   safe redistribution of corneal tissue while sleeping.
2) Advances in computer-controlled lathing technology, allowing complex
   lens designs to be consistently fabricated and with seamless polished
   surfaces and on a tolerance level measured in microns.
3) The development of stable wettable, high Dk materials that can be
   safely worn overnight.
4) Advances in computerized corneal mapping techniques providing more
   precise fitting and follow-up of patients.
5) A greater understanding of how corneal reshaping works and the
   tissues involved in the process.

The Food and Drug Administration granted overnight wear approval to a
CRT is already widely available and according to www.allaboutvision.com, about
2000 practitioners are expected to be fitting VST by the end of 2005.

Many patients that undergo orthokeratology complain of nighttime glare.
Most of this can be attributed to the fact that with standard ortho-k lenses, the
 treatment zone (area of corneal flattening) is 5.0mm in diameter. If the pupil
dilates to more than 5.0mm at night for example, the result is glare. Currently, standard ortho-k lenses have an optical zone of 6.0mm, leading to a 5.0mm treatment zone. The main objective of this study was to determine whether an increase in the treatment zone from a 5.0mm to 5.7mm with a 6.0mm and 6.7mm optical zone lens respectively, would decrease glare. We hypothesize that increasing the treatment zone will not only significantly reduce complaints of nighttime glare and not adversely affect UCVA, but it will decrease the gap with corrective laser surgery, which has a 6.0mm treatment zone. This will ultimately make orthokeratology a more viable option to a larger segment of the population.
METHODS

In this study, we used the BE Retainer lens design which is one of the designs utilized with Bausch & Lomb's Vision Shaping Treatment. This gas-permeable lens has a unique back surface geometry but is not a true reverse geometry or four-curve retainer design. According to Dr. John Mountford and Dr. Don Noack, the developers of the BE Retainer lens, it is a platform that produces the required tear layer profile for an individual corneal shape that produces squeeze film forces that effectively control epithelial redistribution causing the desired refractive change. It is custom fit to the patient’s specific corneal shape, which is determined utilizing topographical information. They have termed this therapy Optimal Orthokeratology (OOK). This therapy allows the practitioner to be in total control of the fitting process through the use of BE software, which allows for trial retainer determination, problem solving, custom retainer construction, predictions of the amount of refractive change possible, and potential treatment zone size. A patient's potential for OOK is determined from four topographical components:

1) Sagittal height: the height in microns of the cornea over a specific cord diameter so that a fit to a desired apical clearance in order to achieve the correct squeeze film pressure.
2) Eccentricity Value (E-value): the “rate of flattening” of the cornea from the apex to the periphery; indicates a patient’s potential for OOK; the lower the e-value, the lower the potential for OOK and vice versa.
3) Apical radius (Ro): the calculation of the radius at the apex of the cornea.
4) Required refractive change.

The program also determines the potential success of OOK for the patient by comparing the refractive potential of the cornea from the apical radius and sagittal height with the required refractive change. Once the patient's data is entered into the BE program and the desired refractive change is determined, the patient's required custom ordered BE Retainer and diagnostic trial retainer in the
standard BE Retainer set are calculated. This trial retainer is then worn overnight and follow-up examinations are performed the next morning. This involves an evaluation of the retainer lens positioning and any notable physiological response to the therapy. Upon removal of the retainer lens, a subjective over-refraction is performed and topographical maps are taken. These maps are evaluated (as axial, tangential, and subtractive/difference maps) and the measured responses to the therapy are determined. The three main responses are:

1) Bulls-eye: The ideal corneal shape change for accurate refractive response.
2) Smiley Face: The negative corneal response to a flat fitting BE Retainer OOK.
3) Central Island: The negative corneal response to a steep fitting BE Retainer OOK.

Depending on the response, final retainer parameters are determined and ordered or retrials are performed after the cornea returns to its normal curvature.

This study involved the evaluation of 12 subjects from the class of 2007 at Pacific University College of Optometry, approximately 18 to 30 years of age. All subjects were required to be low to moderate myopes and/or astigmats (approximately 0.75 to 4.00 diopters spherical correction of myopia and 1.50 diopters or less correction of astigmatism). Subjects were screened for ocular health based on systemic health history, anterior segment evaluation, Goldman applanation tonometry, corneal topographical mapping, habitual visual acuities, and baseline manifest dry refractions. Those whose ocular health were compromised and/or did not meet the refractive error criteria were excluded from the study. Informed consent was obtained from all participants outlining the nature of the study, procedures, and proper lens care regimen. Moreover, subjects were asked to complete a subjective questionnaire on glare. From the initial twelve applicants, six did not achieve an optimal lens fit and/or had difficulty
with gas-permeable lens wear hindering participation in the study. Therefore, six subjects completed the study.

Prior to dispensing the trial lenses for overnight wear, subjects were supplied with an adequate amount of Advanced Medical Optics (AMO) cleaning and conditioning gas-permeable lens solutions and educated on proper lens care and insertion/removal techniques. They were also instructed to wear the lenses for a minimum of six hours at night. Following an evaluation of overnight trial lenses the following morning, standard custom BE retainer lenses (6.0 mm optic zone) were ordered from Precision Technologies in Vancouver, British Columbia. Subjects were again asked to wear the lenses overnight and to return to clinic the next morning for an evaluation. If these subjects were successful, they were asked to wear the lenses consecutively for 1 week and 1 month from the dispensed time of the custom lenses. The second phase of the study involved switching successful subjects from initial phase to larger B zone lens (6.7 mm optic zone) after allowing the corneas to normalize for 1 week. Again, 1 day, 1 week, and 1 month evaluations were conducted once these new lenses were dispensed.

Follow up visits consisted of the following procedures:

1) Subjective questionnaire: to assess glare with questions about visual disturbances during night driving and with bright lights.

2) Case history: to determine the compliance of the lens wear regimen and to determine any symptoms of lens wear.

3) Visual Acuity: distance monocular uncorrected visual acuities were tested.

4) Refraction: a manifest dry refraction was performed upon removal of the lens after visual acuity assessment.

5) Biomicroscopy: the ocular health was evaluated for fluorescein staining of the cornea and any other complications related to contact lens wear.

6) Topography: the topographical maps were taken with the Medmont E300 topographer to monitor the treatment zones. Analysis with
subtractive/difference display maps was also performed to compare the base line maps to the 1 day, 1 week, and 1-month topographical maps with both optical zone lenses.
RESULTS

From the data collected, we analyzed four criteria from the different optical zone treatment lenses: uncorrected visual acuity, refractive error change, treatment zone diameter, and glare responses.

Most subjects achieved similar final visual acuities in both eyes with the 6.0 mm OZ and 6.7 mm OZ lenses after 1 month of lens wear reaching an UCVA of either 20/20 or 20/16. No significant improvements or deteriorations in visual acuity were noted with the different optical zone treatment diameters. However, one subject did not achieve a 20/20 or 20/16 UCVA, achieving a UCVA of 20/25 OU with the 6.0 mm OZ lens that deteriorated to a 20/40 visual acuity OU with the 6.7 mm OZ lens. This subject also had complaints of headaches, visual distortion, and glare with both lenses. The remaining subjects did not have any of the previously mentioned vision concerns during the study (Table I, Figure 1).

The refractive error changes showed similar results between the right and left eyes for each optical zone lens. An average refractive error change was 2.26 D (R) and 1.94 D (L) with the 6.0 mm OZ lens and 1.92 D (R) and 1.81 D (L) with the 6.7 mm OZ lens. Moreover, the final average spherical equivalent refractive error was +0.63 DS (R) and +0.60 DS (L) for the 6.0 mm OZ and +0.29 DS (R) and +0.60 DS (L) for the 6.7 mm OZ lens. Five subjects were mild to moderately overcorrected while one subject was moderately under-corrected (Table II). In general, there was a larger change in refractive error with the 6.0 mm OZ lens versus the 6.7 mm OZ lens (Figure 2).

Overall, the subjects did not have significant changes in treatment zone diameters between the 6.0 mm OZ and 6.7 mm OZ lenses despite the increase in optical zone (Table III, Figure 3). Of the 12 eyes that were treated, 7 eyes had an increase in the treatment zone diameter, while unpredictably 5 eyes had a decrease in the treatment diameter. Overall, there was a 0.195 mm increase in treatment zone diameter OD and a 0.162 mm increase OS. We also noted that the largest change observed from a 6.0 mm OZ treatment lens to a 6.7 mm OZ treatment lens was 0.93 mm while the largest decrease was 0.43 mm.
All of our subjects were asked about glare and halos during night driving and with bright lights pre-treatment and 1 month post-treatment with the 6.0 mm OZ and 6.7 mm OZ lenses. Glare assessment was based on a subjective questionnaire with numeric values assigned to the degree of perceived visual disturbance (0 = no glare, 2 = occasionally, 3 = half of the time, 4 = most of the time, 5 = all of the time). Most subjects had a slightly progressive decrease in glare and halos effects from pre-treatment to post-treatment with the 6.0 mm OZ and 6.7 mm OZ lens (Table IV, Figure 4). One subject however, noticed a slight increase in visual disturbance while the final results for two of the subjects were inconclusive.
DISCUSSION

This purpose of this study was to observe the effects of nighttime glare and vision with an increase in the treatment zone diameter. We hypothesized that an increase in the treatment zone from a 6.0mm to 6.7mm optical zone lens would decrease glare and not adversely affect uncorrected visual acuity, allowing orthokeratology to be a viable, non-invasive, alternative option for refractive surgery and for those with glare problems.

Most subjects achieved clear UCVA with both the standard 6.0 mm OZ and the larger 6.7 mm OZ lens without significant differences between the final uncorrected visual acuities. This increase in optical zone did not seem to adversely affect the UCVA, and treatment zone diameters with both lenses developed good bull’s-eye pattern topographical maps for each subject. This indicates that both optical zone lenses may be good options for orthokeratology patients. Most of the subjects in this study however, had mild amounts of myopia and astigmatism and subsequently developed good final visual acuities with minimal overcorrected refractive errors after treatment with both lenses. On the other hand, one subject had a moderate amount of myopia and notably, did not achieve 20/20 vision with the larger OZ lens resulting in even worse UCVA. This subject was also moderately under corrected and had the most complaints of glare and halo effects from the treatment. With larger refractive errors, it may be more challenging to achieve clear UCVA and treatment results can be more variable. This may account for this subject not being able to achieve 20/20 UCVA and visual disturbances with glare and halos. Further investigations are needed with a larger patient population of moderate to moderately high myopes to fully assess the effects of glare and UCVA with an increase in treatment zone diameter.

We predicted that increasing the treatment zone diameter would decrease the effects of nighttime glare. Unexpectedly, there was not a significant increase in the treatment zone diameters from the 6.0 mm OZ to the 6.7 mm OZ lens, with some eyes even showing a decrease in the treatment zone diameter with the larger OZ. It was therefore difficult to assess the effects of glare and halos
subjectively, without a significant change between the treatment zone diameters. The majority of the subjects did however show a small decrease in visual disturbance despite this small change. Patient compliance may account for this small increase as any variability in wearing schedules of the participants can result in unreliable data between the two treatment zone diameters. Moreover, pupillary diameter in photopic and scotopic conditions was not considered in this study. According to Macsai et al., pupil size is arguably the most important predictor of night-vision disturbances and future quantification may provide for a more accurate assessment of glare. Those subjects with small pupillary diameters may not appreciate glare effects when moving from a smaller to larger optical zone diameter lens while those individuals with larger pupillary diameters may experience glare effects in scotopic conditions when the pupillary diameter exceeds the treatment zone diameter. An objective measurement of glare should also be considered in future studies for a more comprehensive investigation of the effects of glare with a larger treatment zone diameter. Another consideration may include a larger optical zone (>6.7 mm OZ) to better discriminate the effects of glare with different OZ lenses.

Similar studies on the effects of increased treatment zone diameter and glare in refractive laser surgery have been studied in the past and are currently ongoing. Macsai et al. evaluated the effect of expanding the treatment zone of the Nidek EC-5000 laser on postoperative visual acuity as well as night glare and halos after laser in situ keratomileusis (LASIK) using 4 ablation zone diameters. They used a 6.5 mm optical zone with a transition zone 1.0 mm larger than the pupil under scotopic conditions (7.5, 8.0, 8.5, or 9.0 mm) and queried about glare and halos preoperatively and 3 months postoperatively using a subjective questionnaire. They found that the use of a peripheral transition zone 1.0 mm larger than the pupil under scotopic conditions resulted in a low incidence of glare and halos postoperatively and did not adversely affect visual acuity.

Our investigation demonstrated that an increase in treatment zone diameter did not significantly decrease glare and that it did not adversely affect uncorrected visual acuity. Other studies with refractive surgery, such as the study
mentioned previously, have shown a lower incidence of visual disturbance with larger treatment zones. However, with a patient population of 6 subjects, the data obtained in this study may be questionable and larger patient populations would allow us to determine whether a decrease in glare is statistically significant. Furthermore, time constraints in this study allowed only one month wear times for each lens and may not have been an optimal treatment duration. Future experiments may consider longer treatment periods, which would allow for more reliability and observations to determine whether any symptoms of glare resolve over time.

These considerations for future studies should be investigated in order to explore the full effect of optic zone on visual acuity and glare. Promising results have been produced from refractive surgery and similar studies in orthokeratology can give patients a more viable, non-surgical option to laser eye surgery.
REFERENCES

4. All About Ortho-k. The Ortho-K.NETwork. Available at: http://www.ortho-k.net/orthok.htm
9. Hadrill M. Contact Lenses Shape Eye's Surface. Available at: http://vision.about.com/od/contactlenses/a/visionshaping.htm
**TABLE I. FINAL UNCORRECTED VISUAL ACUITY ACHIEVED**

(SNELLEN FRACTION)

<table>
<thead>
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<th>Subject</th>
<th>6.0 mm OZ (R)</th>
<th>6.0 mm OZ (L)</th>
<th>6.7 mm OZ (R)</th>
<th>6.7 mm OZ (L)</th>
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<td>20/16</td>
<td>20/20</td>
<td>20/16</td>
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<tr>
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<td>20/16</td>
<td>20/20</td>
<td>20/16</td>
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(SNELLEN DECIMALS)

<table>
<thead>
<tr>
<th>Subject</th>
<th>6.0 mm OZ (R)</th>
<th>6.0 mm OZ (L)</th>
<th>6.7 mm OZ (R)</th>
<th>6.7 mm OZ (L)</th>
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Table II. Refractive error change

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<th>Subject</th>
<th>Baseline (R)</th>
<th>Baseline (L)</th>
<th>6.0 mm OZ (R)</th>
<th>Δ SE</th>
<th>6.0 mm OZ (L)</th>
<th>Δ SE</th>
<th>6.7 mm OZ (R)</th>
<th>Δ SE</th>
<th>6.7 mm OZ (L)</th>
<th>Δ SE</th>
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<td>-2.75 DS</td>
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TABLE IV. SUBJECTIVE GLARE ASSESSMENT

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Figure 1. Final Uncorrected Visual Acuity Achieved
Figure 3. Average Treatment Zone Diameter
Figure 4. Subjective Glare Assessment