Increasing the treatment zone in orthokeratology through a larger optical zone diameter

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Increasing the treatment zone in orthokeratology through a larger optical zone diameter

Abstract
Standard ortho-k lenses have a treatment zone (area of corneal flattening) of 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. In our experiment, we attempted to increase the treatment zone to 6.0m by using ortho-k lenses with a 7.0mm optical zone. Increasing the treatment zone would not only significantly reduce complaints of night-time glare, but it would put us on par with corrective laser surgery, which also has a 6.0mm treatment zone. This would ultimately make orthokeratology a more viable option to a larger segment of the population. Originally 16 subjects were used for the experiment. The 1 half of the experiment consisted of fitting the students with standard 5.0m treatment zone ortho-k lenses. This trial period allows for lens parameter changes to achieve the optimum fit. The second trial consisting of the larger treatment zone has not been reached as of right now. The initial standard fits are being refined to custom fits for many patients. There have also been significant complications in terms of allergic reactions, undercorrection/overcorrection, non-compliance and high patient discomfort. The study has yet to be completed and therefore any results regarding the treatment zone expansion are inconclusive. The study will be completed within 1 year of this paper’s release date and definitive conclusions will be made at that time.

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Increasing the treatment zone in Orthokeratology through a larger optical zone diameter.

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A thesis submitted to the faculty of the
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Biography

Denny Birring attended the University of British Columbia and graduated with degrees in Science (BSc.) and Education (BEd.). After a year of teaching high school science in the Vancouver area, Denny enrolled in the College of Optometry at Pacific University to work towards his Doctorate of Optometry. Currently in his fourth year of the program Denny is looking forward to embarking upon practicing optometry and perhaps, in the near future, look towards teaching opportunities in the field of optometry.

TJ Khanghura attended the Simon Fraser University located in Burnaby, B.C., Canada and obtained a Bachelor’s Science majoring in Biology and minorin in kinesiology. TJ enrolled in College of Optometry at Pacific University to attain his Doctorate of Optometry. Future plans include moving back to the great province of British Columbia and pursuing a career in private care and hopefully own a private practice one day.
Abstract

Standard ortho-k lenses have a treatment zone (area of corneal flattening) of 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. In our experiment, we attempted to increase the treatment zone to 6.0mm by using ortho-k lenses with a 7.0mm optical zone. Increasing the treatment zone would not only significantly reduce complaints of night-time glare, but it would put us on par with corrective laser surgery, which also has a 6.0mm treatment zone. This would ultimately make orthokeratology a more viable option to a larger segment of the population. Originally 16 subjects were used for the experiment. The 1st half of the experiment consisted of fitting the students with standard 5.0mm treatment zone ortho-k lenses. This trial period allows for lens parameter changes to achieve the optimum fit. The second trial consisting of the larger treatment zone has not been reached as of right now. The initial standard fits are being refined to custom fits for many patients. There have also been significant complications in terms of allergic reactions, undercorrection/overcorrection, non-compliance and high patient discomfort. The study has yet to be completed and therefore any results regarding the treatment zone expansion are inconclusive. The study will be completed within 1 year of this paper's release date and definitive conclusions will be made at that time.
Acknowledgements

We would like to thank both Pat Caroline and Randy Kojima for all their efforts in putting together this great opportunity to perform this study of orthokeratology. We would also like to thank our partners Denis Kim, Chris Johnson and Chris Kelly for continuing on with the study and seeing it through.
Introduction

Orthokeratology has been a very viable option for many patients who are cautious with their eyes and do not want to have lasik preformed for vision correction. The orthokeratology procedure has been around for many decades and recently has undergone vast improvements in the lens design to significantly increase the success rate of the lenses. Modern ortho-k lenses are healthier in that they allow for more gas exchange. The lenses have also changed in shape. The lenses have multiple curvatures to allow for maximal centration of fit and maximum efficiency of vision correction. In relation to lasik the advantage of ortho-k lies in the fact that it isn’t an invasive procedure. Ortho-k involves gas permeable lenses that sit on your eye while you sleep. These lenses reshape the cornea resulting in a desirable change in refractive error. The results of these lenses are also reversible and therefore any undesired changes in prescriptions can be compensated for.

Over the many years both ortho-k and lasik have been performed there have been significant number of cases of unwanted vision changes. The most notable side effects have been night vision concerns with patients displaying symptoms of halos and glare. These symptoms seem to rise due to a direct result of pupil expansion from lack of light causing peripheral light rays that are normally blocked to enter the eye. These peripheral beams of light are passing through untreated corneal area therefore focused at a different retinal point than the central rays that pass through the treated corneal area. In attempt to decrease the amount of halos and glare lasik has used a large treatment zone which is Imrn larger than the standard ortho-k lens design. Also in order to further decrease patient symptoms a new technology has been introduced for lasik. Wavefront technology
which allows for a more accurate custom removal of sections of the stroma provides even a better spherical surface on the cornea resulting in fewer symptoms of glare or halos.

The goal of this study is to attempt to keep ortho-k at par with lasik by increasing the original corneal treatment zone of 5mm to 6mm (equivalent to lasik treatment zones). The lens changes will not eliminate all symptoms of halos/glare but will decrease some of issues that subjects with larger pupils present.

Methods

The study initially began with 25 possible candidates for the study with age ranges from 20-40. Subjects were initially recruited through the use of a sign up sheet. Subjects had to meet a certain criteria entailing; myopic range of -0.75 D to -4.00 D and/or up to 1.00 D of astigmatism. Potential subjects were put through a comprehensive visual examination. The examination allowed for us to selectively remove candidates that did not meet the above criteria and provided a more accurate distance prescription. The Case History screened for any systemic/ocular conditions that could complicate the candidate’s vision. Ocular health exam portion determined if any candidate displayed any ongoing infection or had any corneal complication that could inhibit the candidate from wearing the ortho-k lenses. The exams gave us a final number of 16 subjects. These subjects were asked to fill out a consent form informing the subjects of common potential risks associated with any and all contact lenses, trial outline consisting of wear schedule. Subjects were informed the study consisted of two trials of a month each with
2 different lenses but were given no information regarding lens names or of the change of treatment zone size increase from 5mm in the 1st trial to 6mm in the 2nd trial.

Each subject was required to fill out a questionnaire at three points of the study: 1st exam before any lens is inserted, end of the 1st trial and end of 2nd trial. The questionnaire gave the subjective feedback regarding halos around light. Subjects were asked about halos around light in different settings and also the difference in halos when wearing corrective spectacles vs. contact lenses.

BE ortho-k lenses were used for the study. The selection of lens parameters was determined by the HVID, topography from the Medmont and manifest refraction. This data is inserted into the BE computer program and the program calculates an initial trial lens for the subject. The trial lenses were dispensed and each subject received patient education on removal and insertion. Each subject received Optimum Care system and was educated regarding cleaning procedures. One day morning follow up was scheduled with specific instructions of wearing the lenses to visit. The follow up consisted of visual acuities, topography, over refraction and slit lamp evaluation to assess the position and fit of lenses. The BE computer program compares the topographies and evaluates the prescription change to give the final lenses for the trial. The final lenses are the same pair or another more accurate lens pair is calculated out. In the later case a 1 day follow up is again rescheduled to reassess the new pair of lenses. After the final fit is determined and the 1 day follow up is successful a 1 week follow up, and 4 week follow up is performed. At the end of the 4 weeks the lens is changed to the larger 6mm treatment zone lens. This marks the end of the 1" trial and the beginning of the 2nd trial. The same protocol is used for this trial as the last. Subjects at the end of the trial return the lenses and receive no
compensation other than a retainer lens which maintains corrective efforts of the BE ortho-k lenses.

**Results**

Currently the 1st trial is underway and not completed. The BE system required multiple custom fits for the subjects and therefore time delays occurred. Also the BE company is based in Canada the lenses have to pass through U.S. Customs. The FDA has to approve lenses in order for them to enter the country. These delays took away the window of opportunity to do a complete consecutive 2 month trial study. Complications of the study resulted in the loss or dismissal of 4 subjects. One subject relocated and could not reach the clinic for the trials and therefore discontinued. Two subjects had too much lens discomfort on the 1st follow up with one subject showing significant signs of punctate keratitis. These subjects removed themselves from the study. One subject was removed from study due to papules forming on the lid conjunctiva indicating an allergic reaction. Other complications of the study include non-compliance by patients in terms of wearing schedule. Multiple patients have lost or damaged a lens therefore requiring the shipping of new ones. The remaining subjects have shown significant improvements in VA’s and final custom lenses have been ordered for many these subjects. Subjective responses from patients are positive in terms of lifestyle changes however the trial is in the preliminary stages therefore no feedback in terms of night vision and halos has been collected.
Discussion

Complications of this study have resulted in delays that were unexpected. The patients that remain with the study have shown great motivation and patience. The study is being continued by our fellow colleagues and will be completed in the near future. The final analysis of this study has yet to be completed therefore any conclusions at this time would be invalid.