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Seven orthokeratology patients were studied to determine whether the myopic orthokeratology treatments of 7.0, 6.0, 5.0 mm optical zones would make a significant difference in the outcome of visual acuity, apical radius, and treatment area. It was our hypothesis that the 7.0 mm optical zone would give the best outcome in visual acuity, the biggest change in apical radius and treatment area. Our hypothesis was supported in the two areas above. The 7.0 mm optical zone has the biggest change in the apical radius and treatment area. However, the best visual acuity outcome was seen with the 6.0 mm optical zone orthokeratology lenses.

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THE EFFECTS OF OPTIC ZONE DIAMETER

IN ORTHOKERATOLOGY

ΒY

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A thesis presented to the faculty of the College of Optometry Pacific University Forest Grove, Oregon for the degree of Doctor of Optometry May, 2001

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Biography

Connie Chi Linh Vuong

Connie was born in Saigon, Vietnam. She received her Bachelor of Art degree in Biology from the California State University, San Bernardino. Upon graduation and licensure she plans to practice in Southern California in a commercial or private practice setting.

Constance Mullinax

Constance Mullinax was born in Crookston, Minnesota and spent most of her life in northeastern Minnesota. She graduated with a Bachelor of Science degree from the College of St. Scholastica in Duluth, Minnesota prior to entering Pacific University College of Optometry in Forest Grove, Oregon. Constance plans on staying in the pacific northwest to join a commercial or private practice.

Cang Bui

Cang was born in Saigon, Vietnam. He received his Bachelor of Science degree in Biochemistry from the California University of Berkeley. Upon graduation and licensure he plans to join the Air Force for a few years.

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Metro Optics located at 11034 Shady Trail, Suite 106, Dallas, Texas 75229, for providing all of the free lenses used in this study.

Abstract

Seven orthokeratology patients were studied to determine whether the myopic orthokeratology treatments of 7.0, 6.0, 5.0 mm optical zones would make a significant difference in the outcome of visual acuity, apical radius, and treatment area. It was our hypothesis that the 7.0 mm optical zone would give the best outcome in visual acuity, the biggest change in apical radius and treatment area. Our hypothesis was supported in the two areas above. The 7.0 mm optical zone has the biggest change in the apical radius and treatment area. However, the best visual acuity outcome was seen with the 6.0 mm optical zone orthokeratology lenses.

THE EFFECTS OF OPTIC ZONE DIAMETER IN ORTHOKERATOLOGY

Introduction:

Orthokeratology (aka Ortho-K) is a non-surgical procedure to correct low amounts of myopia and astigmatism, using rigid gas permeable contact lenses (RGPs). The procedure requires patients to wear RGPs for a short part of a day or most often over night. During this time, the center portion of the cornea is reshaped or molded into the matching correction for the patient's myopia or astigmatism. When the RGPs are taken out, the patients are able to see 20/20 vision or better for the rest of the day. Unlike laser eye surgery, this kind of correction is reversible. After taking the RGPs off, the cornea will slowly start to reform to its natural shape. For this reason, patients treated with Ortho-K must periodically wear a "retainer" lens to re-establish and maintain the desired corneal shape and correction.

Orthokeratology started over 39 years ago, in 1962 when doctors noticed that some of their contact lens patients showed improved visual acuity after wearing their lenses for a period of time. The technique started out using hard plastic contact lens material (PMMA). Patients had to wear a series of plastic lenses, which slowly flattens out small amounts of the cornea until the desired correction was attained. This procedure along with the complications of the PMMA materials usually takes up to 2 years before any results were noted. Today orthokeratology (aka AOK for Accelerated orthokeratology) has changed tremendously and has seen many successes. With safer and better contact lens materials, computer-assisted lathes to precisely reproduce contact lenses and technological advancement in the procedure, it is possible to achieve reduction of myopia in a matter of days or weeks. The procedure is safe, fast and effective. The contact lens materials used today are very safe. Oxygen permeability is high and there are no greater risks with orthokeratology than with wearing regular contact lenses for correction. So why choose orthokeratology over the conventional spectacles, contact lenses and laser eye surgery? There are many benefits to orthokeratology. Orthokeratology is not a surgical procedure and therefore there are no additional risks from cutting or burning of tissue. And unlike laser eye surgery (e.g. LASIK), the correction from orthorkeratology is not permanent. The reversibility of this procedure makes it safe for both adults and children. Laser surgery cannot be performed on anyone under the age of 21. Orthokeratology can be started on children as young as 10 years of age. In addition, it has be theorized to stop the progression of myopia in young children. Orthokeratology is advantageous for occupations where glasses and contact lenses are a hindrance, such as athletes and firemen. Dusts can build in contact lenses and the constraints of glasses can inhibit many of these people. Orthokeratology is simply another option for people who do not desire permanent eye surgery or wearing glasses everyday.

Purpose of the Study:

The main objective of the study was to determine, in a clinical setting, if enlarging or decreasing the size of the optic zone in a reverse geometry lens makes a difference in the amount of flattening or modification of the cornea which occurs during orthokeratology. Although other lens designs have been used by contemporary orthokeratology practitioners, reverse geometry lenses are becoming recognized as highly effective. Contrary to the conventional contact lens design, in which the secondary and peripheral curves are flatter than the base curve, a reverse geometry lens has a secondary curve which is steeper than the base curve. These lenses accelerate the orthokeratology treatment program when compared to conventional lenses. The developers of reverse geometry lenses experimented with various parameters to design a lens that would produce the best results, that is, rapid improvement in uncorrected visual acuity, comfort and physiological compatibility. The final result of their clinical trials was a lens that incorporated a 6.0 mm. optic zone diameter and a secondary curve 3 diopters steeper than the base curve. We wanted to investigate larger, 7.0 mm., and smaller, 5.0 mm. optic zones to compare the treatment area, apical radius and the efficacy of correction with the standard 6.0 mm. optic zone lens.

The lenses that were used in this study were FluoroPerm rigid gas permeable lenses from Paragon Vision Sciences. These lenses have a central zone that was 3 to 5 diopters flatter than the peripheral alignment zone fitting curve. The diameter of the lens was 10.6 mm. overall, although we utilized lenses of varying diameters in order to better fit some patients. The lenses were individually designed for each patient using OrthoTool 2000 Lens Design by EyeDeal Software Design. The mechanism of action of the FluoroPerm lens relies on altering the normal asphericity of the cornea by displacing corneal tissue from the steeper central zone to the mid-periphery of the cornea. The steeper secondary zone in the FluoroPerm lens design facilitates this process by providing a displacement zone, or tear reservoir into which the central corneal tissue migrates. The endpoint in orthokeratology is achieved when the corneal

topography underneath the lens approximates a sphere. When myopia reduction has plateaued, in normal practice, the same lenses are worn overnight to maintain stable uncorrected vision.

Methods:

The study involved the evaluation of 20 subjects from the class of 2002 at Pacific University College of Optometry. Both male and female subjects were used with no specific gender proportions targeted. All subjects were required to be low to moderate myopes, with 2.00- 6.00 diopters spherical correction and 1.50 diopters or less astigmatism. There was no exclusion based on the subjects history of previous contact lens wear. However, subjects with compromised ocular health based on ocular and systemic health histories, anterior segment evaluation and topographical mapping, were excluded. The subjects were counseled regarding the nature of the study and the procedures, including proper lens care. Lenses were custom designed using the OrthoTool 2000 program based on dividual parameters including flat K readings from the topographical map and refractive error. A tear profile was calculated for each lens based on topographical K readings and shape factor/eccentricity data entered into the fit design worksheet. From the initial 20 applicants, we chose 12 subjects who we determined to be good orthokeratology subjects based on their physical ocular parameters, design data and their willingness to follow the treatment regiment. Five of these subjects either achieved an optimal lens fit late in the study or had difficulty as first time RGP wearers in adhering to the treatment program. Thus, only seven subjects completed the study.

Following ordering and receiving the lenses from Metro Optics in Dallas, Texas, the lenses were dispensed to the subjects along with an adequate supply of Boston cleaning and conditioning solutions. Subjects were educated on proper lens care at the dispensing visit. The lenses were evaluated for fit based on optimal lens centration and movement. Lenses had to be centered over the corneal apex in order to avoid corneal warpage and undesirable outcomes. Lenses needed to demonstrate 1mm. to 2mm. of movement with each blink in

order to maintain adequate tear flow under the lens. The lens to cornea relationship had to demonstrate an apical bearing zone of 3mm. to 4mm., a circular area of pooling in the intermediate zone of the lens, a narrow mid-peripheral band of touch and a peripheral edge lift. All of these criteria were evaluated at each visit in order to insure a safe and successful treatment. Inclinic modification was done on some lenses.

The subjects were instructed to wear the lenses for two weeks, 8 hours a night, then discontinue wear for one week before starting the next regiment. The subjects were initially followed one day post treatment, one week post treatment, two weeks post treatment, and 24 hours after discontinuing wear of the lens. At each follow-up visit, the following steps were completed:

- Case History: To ascertain compliance with the regiment of lens wear and to determine subjective symptoms since the last visit, subjects were asked to report on the number of hours the lens was worn, discomfort or awareness of the lens, itching or burning, blurred or variable vision, dryness, photophobia and halos.
- 2. Visual Acuities: Distance acuities were tested with the lenses off and following refraction.
- Refraction: A manifest dry refraction was performed with monocular best subjective visual acuity, JCC, ocular balance, and binocular best subjective visual acuity.
- 4. Slit Lamp Examination: The fit of the contact lenses was evaluated with fluorescein. The ocular health was evaluated for edema, neovascularization, fluorescein staining of the cornea, injection of the conjunctiva and tarsal abnormalities of the lid.
- 5. Corneal Topography: The topography map was made with the Humphrey corneal topographer to monitor the progression of the orthokeratology treatment and for future analysis with difference display comparing initial topography to 2 week topographical maps.

Results:

The hypothesis for this thesis is that the 7.0 mm optical zone will lead to the best outcome in visual acuity, the biggest change in apical radius and treatment area. We hypothesized that the next best lens in these areas would be the 6.0 mm optical zone. And the least desirable outcome would be the 5.0 mm optical zone.

From the data collected, we looked at these three criteria in comparison between the three different optical zone lenses. The treatment area is the amount of area that flatten as the result of the overnight wear of the orthokeratology lenses. It is measured in millimeter. The apical radius is the difference between the amount of steepness at the beginning of the study as compared to how flat the central cornea become as the result of the Ortho-K lenses wear. This is measured in dioptic power. The third criteria we looked at is the maximum visual acuity achieved at the end of the two weeks of Ortho-K lenses wear. It is measured in Snellen acuity in fraction or decimals.

The data for the result of the treatment area indicated that the 5.0 mm optical zone lenses have the smallest area of flattening with the average of 3.14 mm for the right eye and 3.43 mm for the left eye. The 6.0 mm optical zone lenses offer the next intermediate area of flattening with an average of 4.29 mm for the right eye and 4.57 mm for the left eye. The largest area of flatten occurs with the 7.0 mm optical zone of 5.41 mm for the right eye and 4.71 mm for the left eye (Table I, Chart Ia, Chart Ib).

The data obtained show that the smallest apical radius change occurs with the 5.0 mm optical zone lenses. The average change for the 5.0 mm optical zone lenses were 0.34 Diopter for the right eye and 0.54 Diopter for the left eye. For the 6.0 mm optical zone the apical radius change was 0.68 Diopter for the right eye and 0.87 Diopter for the left eye. The largest average change in apical radius was seen with the 7.0 mm optical zone of 1.29 Diopter for the right eye and 0.95 Diopter for the left eye (Table II, Chart IIa, Chart IIb).

The most important criteria in determining how well the subjects see after removing their Ortho-K lenses is the subjective visual acuity. We looked at the

maximum or the best visual acuity subjects can achieve. A comparison was made between the lenses to see which lenses have the highest number of eyes with 20/20 or better visual acuity. The 5.0 mm and the 7.0 mm optical zone lenses have only 10 eyes which achieved the visual acuity of 20/20 or better. The 6.0 mm optical lenses have 12 eyes and thus the highest number of eyes with the visual acuity of 20/20 or better (Table IIIa, Table IIIb, Chart IIIa, Chart IIIb).

Discussion:

In term of visual acuity, the 6.0 mm optical zones lenses have the highest number of eyes with 20/20 or better vision. They were also rated by four out of 7 subjects to be the most comfortable lenses with the least subjective symptoms such as lens awareness, burning and itching, variable vision, and halos. Two subjects rated the 7.0 mm optical zone lenses as their " favorite" lenses. No edema, neovascularization, conjunctival injection and tarsal abnormal of the lid were found on any of the 7 subjects. However, mild fluorescein staining was found in one third of the subjects.

This study did not take a few factors into consideration when evaluating the results. The subjects initial refractive error plays an important role in the outcome of visual acuity achieved at the end of two weeks of orthokeratology wear. For instance, one subject refractive error was –5.75 OU. This individual was not able to reach a visual acuity of 20/20 with any of the lenses at the end of the two weeks of ortho-K lenses wear. His best visual acuity at the end of the two weeks was 20/25 with the 6.0mm optical zone lenses.

Although all parameters of the three lenses were exactly the same with the exception of the optical zone differences, two subjects experienced more subjective symptoms such as halos with one optical zone lenses than the other. Thus, the visual acuity was affected as the result. A possible explanation for this is the differences in the pupil sizes of the subjects. Few subjects reported to have more halos with the 5.0 mm optical zone than the other lenses. In fact,

none of the subject reported any halos with the 7.0 mm optical zone. When asked which was their "favorite" lenses, the subjects with the large pupil sizes tend to pick the larger optical zone, the 7.0 mm lenses.

The range of optical zone choosen for this study proves that as one got to one extreme of optical zone, different subjective symptoms are reported by different individuals. The middle of this range, the 6.0 mm optical zone offers the least subject symptoms and the best visual acuity. However, factors have to be considered to fit each individual needs before one can determine the best lenses for each subject.

TABLE I

TREATMENT	AREAS	OD	&	OS
(1	mm)			

SUBJECT	5 OZ:	5 OZ:	6 OZ:	6 OZ:	7 OZ:	7 OZ:
NUMBER	OD	OS	OD	OS	OD	OS
1	3	4	4	4	7	5
2	4	3	4	4	4	3
3	2	4	3	5	3	4
4	2	2	5	5	5	5
5	3	3	4	4	5	4
6	4	4	5	5	6	6
7	4	4	5	5	6	6
AVERAGE	3.14	3.43	4.29	4.57	5.14	4.71

TABLE II

APICAL RADIUS OD & OS (DIOPTIC POWER)

SUBJECT	5 OZ:	5 OZ:	6 OZ:	6 OZ:	7 OZ:	7 OZ:
NUMBER	OD	OS	OD	OS	OD	OS
1	0.63	0.75	2.00	1.50	1.50	1.00
2	0.37	0.75	0.62	0.75	1.50	1.87
3	0.63	0.25	0.12	0.37	0.25	0.52
4	0.25	1.12	0.63	1.25	0.75	0.87
5	0.25	0.12	0.25	0.50	1.00	0.37
6	0.13	0.37	0.12	1.00	2.37	0.75
7	0.12	0.42	1.00	0.75	1.63	1.25
AVERAGE	0.34	0.54	0.68	0.87	1.29	0.95

TABLE III A

SUBJECT	5 OZ:	5 OZ:	6 OZ:	6 OZ:	7 OZ:	7 OZ:
NUMBER	OD	OS	OD	OS	OD	OS
1	20/40	20/40	20/25	20/25	20/60	20/60
2	20/15	20/15	20/15	20/15	20/15	20/15
3	20/70	20/50	20/20	20/20	20/20	20/20
4	20/20	20/20	20/20	20/15	20/20	20/20
5	20/15	20/15	20/15	20/15	20/25	20/30
6	20/20	20/20	20/15	20/15	20/15	20/15
7	20/15	20/15	20/15	20/20	20/15	20/15

MAXIMUM ACUITY ACHIEVED (SNELLEN FRACTION)

TABLE III B

MAXIMUM ACUITY ACHIEVED (SNELLEN DECIMALS)

SUBJECT	5 OZ:	5 OZ:	6 OZ:	6 OZ:	7 OZ:	7 OZ:
NUMBER	OD	OS	OD	OS	OD	OS
1	0.50	0.50	0.80	0.80	0.33	0.33
2	1.33	1.33	1.33	1.33	1.33	1.33
3	0.28	0.50	1.00	1.00	1.00	1.00
4	1.00	1.00	1.00	1.33	1.00	1.00
5	1.33	1.33	1.33	1.33	0.80	0.67
6	1.00	1.00	1.33	1.33	1.33	1.33
7	1.33	1.33	1.33	1.00	1.33	1.33
AVERAGE	0.97	1.00	1.16	1.16	1.02	1.00

CHART Ia: TREATMENT AREAS OD & OS





CHART IIa: APICAL RADIUS OD & OS



CHART IIb: TOTAL APICAL RADIUS CHANGE OD & OS





AVERAGE MAXIMUM ACUITY ACHIEVED (Snellen decimals)



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