Corneal reshaping and myopia progression

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ABSTRACT

Background/aims: Anecdotal evidence indicates that corneal reshaping contact lenses may slow myopia progression in children. The purpose of this investigation is to determine whether corneal reshaping contact lenses slow eye growth.

Methods: Forty subjects were fitted with corneal reshaping contact lenses. All subjects were 8 to 11 years and had between −0.75 D and −4.00 D myopia with less than 1.00 D astigmatism. Subjects were age-matched to a soft contact lens wearer from another myopia control study. A-scan ultrasound was performed at baseline and annually for 2 years.

Results: Twenty-eight of 40 (70%) subjects wore corneal reshaping contact lenses for 2 years. The refractive error and axial length were similar between the two groups at baseline. The corneal reshaping group had an annual rate of change in axial lengths that was significantly less than the soft contact lens wearers (mean difference in annual change = 0.16 mm, p = 0.0004). Vitreous chamber depth experienced similar changes (mean difference in annual change = 0.10 mm, p = 0.006).

Conclusion: Results confirm previous reports of slowed eye growth following corneal reshaping contact lens wear.

Approximately 100 million people in the USA are myopic,[1] and the majority of these patients became short-sighted during childhood.[2] Patients with low myopia are able to wear thinner spectacle lenses that are more comfortable and cosmetically more appealing, they have more predictable refractive surgery results,[3] and they have a lower risk of retinal detachment,[4] glaucoma and chorioretinal degeneration[5] than patients with high myopia. Therefore, slowing the progression of myopia during childhood could have a positive effect on a large number of people.

Orthokeratology contact lenses were originally fitted in the late 1960s and continued through the 1980s. Results with the orthokeratology contact lenses were often incomplete and unpredictable,[6] so orthokeratology was rarely performed until the new millennium. New materials with higher oxygen permeability and reverse geometry contact lens designs allowed short-sighted patients to wear orthokeratology (now commonly called corneal reshaping) contact lenses during sleep to temporarily flatten the cornea and provide consistently clear vision throughout the day without wearing glasses or contact lenses. Several studies have shown that adults[7–9] and children[10 11] can experience clear vision throughout the day if they wear the corneal reshaping contact lenses during sleep. Watt and Swarbrick summarised all of the cases of microbial keratitis related to orthokeratology that have been reported in the literature.[12] They found that approximately half of the cases occurred in children younger than 16 years, and three-quarters of the cases were reported in East Asia. However, the number of people wearing orthokeratology contact lenses is unknown, so the rates of microbial keratitis associated with orthokeratology cannot be calculated for comparison to soft or gas-permeable contact lens wear.

Preliminary data indicate that corneal reshaping contact lenses may slow myopia progression. The first report of corneal reshaping contact lenses slowing myopia progression was published by Reim and colleagues.[13] In a retrospective chart review of 253 eyes examined 1 year after initiating corneal reshaping contact lens wear and 164 eyes examined after 3 years of corneal reshaping contact lens wear, the authors included changes in refractive error and base curve of the contact lens to measure myopia progression. Over a period of 1 year, the refractive error progressed an average of −0.06 D, and the refractive error progressed −0.37 D over 3 years. Both values represent slower myopia progression than has been reported for single vision spectacle wearers, approximately −0.50 D per year,[14 15] but there were no control subjects to provide comparative data.

A case report published by Cheung *et al* measured the axial growth from one child who wore a corneal reshaping contact lens in one eye and no contact lens in the other eye because it was essentially emmetropic.[16] Over a period of 2 years, the uncorrected eye grew 0.34 mm axially, and the eye with a corneal reshaping contact lens grew 0.13 mm. Although this was the first direct measure of slowed eye growth following corneal reshaping contact lens wear, the evidence was anecdotal.

The first controlled trial comparing axial growth of subjects fitted with corneal reshaping contact lenses to a retrospective cohort of single vision spectacle wearers was reported by Cho and colleagues.[17] Over a 2-year period, the corneal reshaping contact lens wearers' eyes grew an average of 0.29 (SD 0.27) mm, and the spectacle wearers' eye grew 0.54 (0.27) mm (p = 0.01). This study provided the first evidence from a controlled trial that indicated corneal reshaping contact lenses slow the growth of the eye, but the subjects were not fitted using a standardised protocol.

All three of these studies indicate that corneal reshaping contact lenses may slow the growth of the eye, but they suffer from limitations that make interpretation of the results difficult, such as lack of an adequate control group,[13 16] indirect measurement of refractive error progression[13] and being fitted by a variety of eye care practitioners from the community.[17] However, confirmation of the study by Cho and colleagues may provide sufficient evidence to

warrant a randomised clinical trial to investigate the effect of corneal reshaping contact lens wear on myopia progression in children. We conducted the Corneal Reshaping and Yearly Observation of Nearsightedness (CRAYON) Pilot Study to investigate the effect of corneal reshaping contact lens wear on eye growth of 8- to 11-year-old myopic children over 2 years.

MATERIALS AND METHODS

The CRAYON Pilot Study followed the tenets of the Declaration of Helsinki and was approved by The Ohio State University Biomedical Institutional Review Board. All parents provided informed consent, and child assent was attained from all subjects.

All subjects were 8 to 11 years old at the baseline visit. They had between −0.75 D and −4.00 D spherical component myopia and less than −1.00 D astigmatism by cycloplegic autorefraction. Cycloplegia was achieved by administering one drop of 0.5% proparacaine, followed by two drops of 1% tropicamide administered 5 min apart. All subjects had 20/20 or better visual acuity in each eye and good ocular and systemic health. They had not previously worn gas-permeable contact lenses, they were not taking medications that might affect contact lens wear, they were not participating in other eye or vision studies, and they had no previous eye surgeries.

Eligible subjects were matched by age category (8 or 9 years vs 10 or 11 years) to a historical control subject who was randomly assigned to wear soft contact lenses during the Contact Lens and Myopia Progression (CLAMP) Study.[18] After participating in a run-in period of gas-permeable contact lens wear for an average of 2 months, CLAMP Study subjects were randomly assigned to wear gas-permeable or soft contact lenses for the remainder of the study. This randomisation visit was considered the basis for determining the timing of all subsequent visits and served as the baseline for measuring changes during the CLAMP Study. Only subjects randomly assigned to wear soft contact lenses were matched to a corneal reshaping contact lens wearer.

The primary outcome of the CRAYON Pilot Study was the difference in the 2-year change in axial length, measured by a-scan ultrasound, between corneal reshaping and soft contact lens wearers. Secondary outcomes included comparisons of anterior chamber depth, lens thickness and vitreous chamber depth between corneal reshaping and soft contact lens wearers. Refractive error and corneal curvature are temporarily altered by orthokeratology, so they are not compared in this investigation.

A-scan ultrasound

The IOLMaster was not available at the beginning of the CLAMP Study, so no baseline measurements were available for comparison with the IOLMaster. Therefore, A-scan ultrasound measurements were performed and edited until five readings with high, equal lens peaks and a distinct, anterior scleral peak were recorded using identical protocols. The measurements were performed while the subject viewed a distant target under cycloplegia using one drop of 0.5% proparacaine, followed by two drops of 1% tropicamide administered 5 min apart. The examiner lightly touched the cornea with a hand-held probe until a reading was automatically recorded in the automatic mode. The vitreous chamber depth was calculated by subtracting the anterior chamber depth and the lens thickness from the axial length. The baseline measurements were performed at the initial visit for the CRAYON Pilot Study subjects and at the randomisation visit for the CLAMP Study subjects.

Contact lenses

Corneal reshaping contact lens wearers were fitted with Corneal Refractive Therapy (Paragon Vision Sciences, Mesa, Arizona) contact lenses, using HDS-100 materials, according to the manufacturer's directions. In summary, the spherical component of the manifest refraction and the flat keratometry meridian were used to determine the initial trial lens, which was placed on the eye and evaluated for a proper fit. Subjects were also provided with Unique-pH Multi-Purpose Solution (Alcon, Ft Worth, Texas) and their contact lenses were occasionally cleaned in-office with Progent (Menicon USA, San Mateo, California). Subjects fitted with soft contact lenses wore Focus 2-week disposable contact lenses, and they were given SOLO Care multi-purpose solutions (CIBA Vision Care, Duluth, Georgia). All subjects received free contact lenses, solutions and eye care throughout both studies.

Statistics

The analyses include only the 28 subjects who completed the entire study and the control subjects to which they were initially matched. Repeated measures over time were collected. For the analysis, data were treated as eyes nested within subjects nested within pairs. A subject with no missing data could have six measures of each outcome, one from each eye in each year. We used multilevel modelling, a generalisation of multiple regression that handles clustered observations, to model each outcome.

For each outcome, a linear growth model was fitted. The model used random effects for pair, subject within pair, and eye within subject which adjusted the mean growth curve intercept and the mean growth curve slope. The effects of treatment, visit and their interaction were then evaluated for each of the ocular components of interest. All analyses were conducted using Statistical Analysis Software (SAS) version 9.1 (SAS Institute, Cary, North Carolina).

Table 1 Baseline demographic and ocular characteristics of subjects who completed (n = 28) and subjects who did not complete (n = 12) the Corneal Reshaping and Yearly Observation of Nearsightedness Pilot Study

Variable	Completed	Not completed	p Value
Age (years)	10.5 (1.1)	10.2 (1.0)	0.44
Female (%)	46.4	58.3	0.49
White (%)	85.7	75.0	0.41
Axial dimensions of average eye (mm)			
Anterior chamber depth	3.84 (0.21)	3.89 (0.29)	0.57
Lens thickness	3.35 (0.13)	3.42 (0.17)	0.13
Vitreous chamber depth	17.11 (0.77)	16.58 (0.83)	0.06
Axial length	24.30 (0.73)	23.83 (0.85)	0.09

Variables are mean (SD) unless otherwise indicated.

Table 2 Baseline demographic and ocular characteristics of corneal reshaping and soft contact lenses wearers participating in the Corneal Reshaping and Yearly Observation of Nearsightedness Pilot Study

Variable	Corneal reshaping	Soft	p Value
Age (years)	10.5 (1.1)	10.5 (1.0)	0.93
Female (%)	46.4	39.3	0.59
White (%)	85.7	89.3	1.0
Axial dimensions of average eye (mm)			
Anterior chamber depth	3.84 (0.21)	3.81 (0.30)	0.74
Lens thickness	3.35 (0.13)	3.38 (0.16)	0.47
Vitreous chamber depth	17.11 (0.77)	17.02 (0.65)	0.61
Axial length	24.30 (0.73)	24.20 (0.63)	0.63

Variables are mean (SD) unless otherwise indicated.

RESULTS

Forty subjects were enrolled in the CRAYON Study between 30 September 2004 and 2 March 2005. Twenty-eight of the 40 (70%) completed the 2-year study. Subjects dropped out of the study before attending the 1-day (n = 4), 10-day (n = 4), 6-month (n = 2), 1-year (n = 1) and 2-year (n = 1) visits. None of the drop-outs were due to complications; the vast majority was due to lack of interest in contact lens wear after the initial experience. The baseline demographic and ocular characteristics are similar between the subjects who completed the study and the subjects who did not complete the study (table 1), and also between the corneal reshaping who remained in the study for 2 years and the age-matched soft contact lens wearers (table 2).

Table 3 shows the mean (SD) ocular components for each treatment group, and table 4 shows the differences between the groups at each visit. The eyes of both treatment groups grew (both p = 0.0001); however, the annual rate of change in axial length was on average 0.16 mm per year less (p = 0.0004) for corneal reshaping contact lens wearers than soft contact lens wearers (fig 1).

Vitreous chamber depth change was similar to that of axial length. There was a statistically significant positive rate of change in vitreous chamber depth in both groups (p<0.0001). Vitreous chamber depth grew 0.10 mm per year faster for soft contact lens wearers than corneal reshaping contact lens wearers (treatment×visit interaction p = 0.006).

The annual rate of change in anterior chamber depth of corneal reshaping contact lens wearers was not statistically significant (mean change = −0.01 mm, p = 0.63), but the rate of change in anterior chamber depth of soft contact lens wearers was statistically significant (mean change = 0.05 mm, p = 0.0005). On average, the anterior chamber depth of the soft contact lens wearers increased 0.06 mm per year more than the anterior chamber depth of the corneal reshaping contact lens wearers (treatment×visit interaction p = 0.004).

Lens thickness did not exhibit any statistically significant annual change for either group (p>0.43); nor was there a statistically significant difference in rate of change between the treatment groups (p = 0.47).

DISCUSSION

Corneal reshaping contact lenses provide short-sighted patients with clear vision without requiring vision correction to be worn during the day.[7–11] Results of this study confirm results from prior investigations that indicated that corneal reshaping contact lenses also slow the progression of myopia in children.[13 16 17] How these contact lenses may control myopic eye growth is still debatable.

Recent animal studies indicate that the peripheral retina is more responsible for regulation of eye growth than previously thought.[19 20] In infant monkeys, form deprivation limited to the peripheral retina produced myopic eye growth, and all monkeys recovered from the induced refractive error, regardless of whether their fovea was ablated with an argon laser.[20] Furthermore, ablation of the fovea at an early age did not prevent emmetropisation typically experienced by infant monkeys; nor did it prevent refractive error development induced by form deprivation.[19]

In humans, myopic eyes experience relative hyperopia in the periphery that hyperopic and emmetropic eyes do not,[21] and children who become myopic have more relative hyperopic peripheral blur than emmetropic children 2 years before the onset of myopia.[22] Patients with peripheral hyperopic defocus are also more likely to develop myopia.[23] Therefore, peripheral hyperopia may act as a signal for increased eye growth.

The focus of light posterior to the peripheral retina may act as a signal for continued myopic eye growth. The current theory of myopia control with corneal reshaping contact lens wear is that the oblate shape of the cornea and the "knee" where the oblate portion of the cornea returns to its original curvature cause peripheral light rays to focus anterior to the peripheral retina. This results in an image shell that provides focused light centrally at the fovea, while the peripheral retina experiences myopic defocus that results in slowed axial growth. There is still

Table 3 Mean (SD) axial dimensions for corneal reshaping and soft contact lens wearers at each visit

Outcome	Treatment	Baseline	Year 1	Year 2
Anterior chamber depth (mm)	Corneal reshaping	3.84 (0.21)	3.86 (0.22)	3.83 (0.22)
	Soft	3.81 (0.30)	3.91 (0.24)	3.91 (0.27)
Lens thickness (mm)	Corneal reshaping	3.35 (0.13)	3.35 (0.11)	3.34 (0.12)
	Soft	3.38 (0.16)	3.37 (0.18)	3.39 (0.18)
Vitreous chamber depth (mm)	Corneal reshaping	17.11 (0.77)	17.24 (0.74)	17.37 (0.79)
	Soft	17.02 (0.65)	17.26 (0.72)	17.48 (0.78)
Axial length (mm)	Corneal reshaping	24.30 (0.73)	24.45 (0.70)	24.55 (0.72)
	Soft	24.20 (0.69)	24.50 (0.69)	24.77 (0.80)

Table 4 Mean (SD) adjusted differences (soft-corneal reshaping) in axial ocular dimensions at each visit

Outcome	Baseline	Year 1	Year 2
Anterior chamber depth (mm)	−0.03 (0.37)	+0.05 (0.35)	+0.08 (0.38)
Lens thickness (mm)	+0.03 (0.21)	+0.02 (0.20)	+0.04 (0.22)
Vitreous chamber depth (mm)	−0.09 (1.02)	−0.01 (1.09)	+0.11 (1.11)
Axial length (mm)	−0.10 (1.05)	+0.05 (1.06)	+0.22 (1.12)

Positive numbers indicate that soft contact lens wearers have longer dimensions.

much to learn about the role of the peripheral optical profile in regulation of eye growth, but peripheral myopic defocus currently is the leading theory to explain the potential myopia control effect of corneal reshaping contact lenses.

The results of our study indicate that eye growth is slowed by 55%, which is similar to the 46% slowed axial elongation reported by Cho and colleagues.[17] Corneal reshaping contact lenses provide clear vision by flattening the cornea, which in theory would shorten the axial length of the eye and could explain the observed treatment effect. In fact, our study found that the anterior chamber depth increased significantly more for soft contact lens wearers than corneal reshaping contact lens wearers. However, when our study and the study by Cho and colleagues eliminated the effects of the anterior chamber by measuring the growth of only the vitreous chamber depth, a significant treatment effect was still present.[17] This indicates that some signal must act to slow the myopic eye growth.

Limitations of the current study

Nearly one-third of the subjects withdrew from the study prior to the conclusion. If poor adaptation to corneal reshaping contact lens wear was related to the treatment response (perhaps flatter corneas make it more difficult to adapt and decrease the treatment response), the results would appear to show significant myopia control when in reality the results were skewed because the treatment effects were only measured for the subjects who benefitted most. However, there were no significant differences in baseline demographic or biometric measures between the subjects who were lost to follow-up and those who remained in the study, decreasing the risk of bias.

The examiners were not masked to the treatment group of the subjects because only the corneal reshaping contact lens wearers were actively enrolled in the study. The control subjects were matched to the corneal reshaping subjects following participation in a different study. Although the examiners were not masked by treatment group, it is unlikely that their knowledge could have influenced the outcome dramatically. The same procedures were used for both studies, and the outcome was change over time. In order to affect the outcome, a difference in procedures would have had to taken place after the baseline visit, but the same procedures were used throughout the study.

Some believe that use of soft contact lens wearers as the control group may artificially inflate the treatment effect experienced by corneal reshaping contact lens wearers due to "myopic creep" that has been reported following initiation of soft contact lens wear. However, studies of adolescents with at least 1 year of follow-up have shown that soft contact lens wear does not increase myopia progression.[24 25] Soft contact lenses do not increase myopia progression or eye growth compared with spectacles, so soft contact lens wearers are an appropriate control group.

Conclusion

Despite the fact that several studies have investigated myopia control over the past few years, an effective treatment with few side effects is still to be discovered. Corneal reshaping contact lens wear holds promise for myopia control. It has now been shown by two separate controlled trials to slow the axial growth of the eye. However, further investigations must apply the gold standard study design, a randomised clinical trial, to definitively determine whether or not corneal reshaping contact lenses slow the growth of the eye. Investigations must also attempt to determine the mechanism of the treatment effect and why the treatment effect may continue beyond the first year.

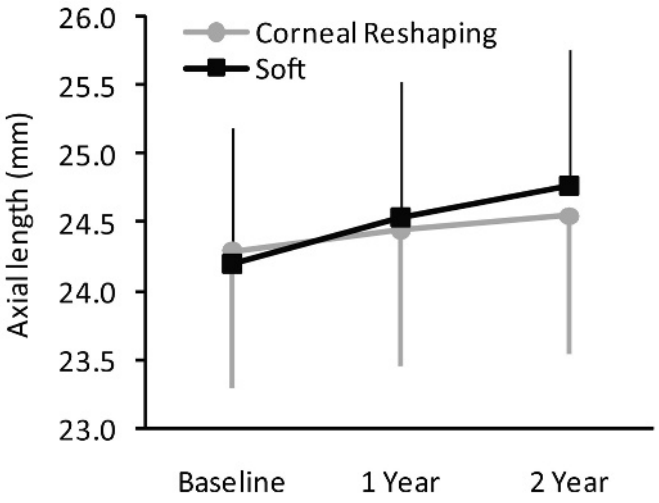

Figure 1 Mean (SD) axial length (mm) during each year of the study.

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Education

ANSWERS

From questions on page 1141

1. Describe the OCT RNFL thickness profile and clock-hour analysis (figs 1C, 2C)

The RNFL thickness profile revealed depressions in the inferotemporal region OU and in the superotemporal region OS. OCT demonstrated borderline thinning compared with the normative database at 7 o'clock and normal thickness in all other clock-hour and quadrants OD. In OS, the clock-hour analysis showed the 1 and 5 o'clock positions and the inferior quadrant to be borderline thin.

2. Describe the cross-sectional scans (figs 1D, 2D)

The cross-sectional scans showed localised thin RNFL within the normally thick superior and inferior areas. The areas of thin RNFL were smoothed out by the software algorithm and were not detected or detected as borderline.

3. How would you interpret OCT results in the future?

The OCT data require careful and critical analysis in order to interpret the information complementary to and in context of the conventional clinical and functional examination. Localised RNFL defects might be missed or underestimated by OCT analysis due to failure of the RNFL defect to thin to such an extent that it falls below the first percentile for the population represented by the device's normative database. It is important to critically analyse the graphic representation and OCT images. The averaging algorithm may "wash out" the data from the defect by averaging them with the data of the adjacent thicker areas. This is most pronounced when the localised defect occurs in an area with thick RNFL such as the superior and inferior regions.

DISCUSSION

The StratusOCT software uses a normative database that allows excellent discrimination between healthy and glaucomatous eyes.[1] There are some patients, however, who may have thinning of the RNFL, yet remain within the normal range. In these patients, RNFL defects and even VF loss may be present, yet the OCT may give readings that do not fall into the borderline or abnormal zones in the clock-hours scheme. It is clear from the RNFL thickness profile that the shape of the RNFL curve is not normal in these patients. That is, instead of having the four elevations ordinarily seen, two superior and two inferior, an area of expected elevation may be flat or even depressed. Because the curve still lies within the boundaries of the normal or borderline range, this RNFL thinning is not flagged or flagged only as borderline. The clinician must identify the abnormal shape of the curve, which indeed deviates from the expected without dropping below the floor of "normal."

StratusOCT uses cross-correlation for alignment of adjacent A-scans and smoothing image processing procedures in order to provide homogenous scans and consistent results. The RNFL is differentiated from other retinal layers using an edge detection algorithm. Using this software, the OCT has been shown to provide reproducible quantitative RNFL data[2] and to enable good discrimination between healthy and glaucomatous eyes.[3] However, this approach, in concert with the limitations of the normative database, is also vulnerable to missing well-established localised RNFL defects as we demonstrated in this study.

When narrow and deep RNFL defects are present, the smoothing algorithm may fail to recognise them and bridge the gaps, thus overestimating thinner RNFL area as seen in our cases. This is most pronounced in places where the RNFL is thickest (superior and inferior regions). Furthermore, the quadrant and clock-hour sectors are arbitrarily defined and do not follow the actual anatomical distribution of the ganglion cell axons which might further affect the analysis output and obscure or underestimate thinning areas.

We therefore recommend that the routine OCT evaluation by the clinician should include careful attention to the thickness profile that might reveal RNFL thinning that is not flagged as borderline or outside normal limits in the quadrant and clock-hour analyses. In cases where there is a discrepancy between the clinical findings and OCT, further insight may also be gained by viewing the actual cross-sectional images, taking into account the limitations of the software as outlined above.

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