

A Randomized Trial of the Effect of Soft Contact Lenses on Myopia Progression in Children

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PURPOSE. Soft contact lenses have been reported to increase the progression of myopia. The purpose of this study was to determine whether soft contact lenses affect the progression of myopia in children.

METHODS. Children between the ages of 8 and 11 years with -1.00 to -6.00 D myopia and less than 1.00 D astigmatism were randomly assigned to wear soft contact lenses ($n = 247$) or spectacles ($n = 237$) for 3 years. Refractive error and corneal curvatures were measured annually by cycloplegic autorefractometry, and axial length was measured annually by A-scan ultrasound. Multilevel modeling was used to compare the rate of change of refractive error, corneal curvature, and axial length between spectacle and contact lens wearers.

RESULTS. There was a statistically significant interaction between time and treatment for myopia progression ($P = 0.002$); the average rate of change was 0.06 D per year greater for contact lens wearers than spectacle wearers. After 3 years, the adjusted difference between contact lens wearers and spectacle wearers was not statistically significant (95% confidence interval [CI] = -0.46 to 0.02). There was no difference between the two treatment groups with respect to change in axial length (ANCOVA, $P = 0.37$) or change in the steepest corneal curvature (ANCOVA, $P = 0.72$).

CONCLUSIONS. These data provide reassurance to eye care practitioners concerned with the phenomenon of “myopic creep.” Soft contact lens wear by children does not cause a clinically relevant increase in axial length, corneal curvature, or myopia relative to spectacle lens wear. (ClinicalTrials.gov, NCT00522288.) (*Invest Ophthalmol Vis Sci.* 2008;49:4702–4706) DOI:10.1167/iovs.08-2067

Myopia typically develops around the age of 8 to 10 years^{1–4} and progresses through the teen years.⁵ Several reports have shown that children in this age group are capable

of wearing gas-permeable,^{6,7} corneal reshaping,^{8,9} or soft contact lenses.^{6,10,11} However, treatment options believed to accelerate myopia’s progression may be met with resistance, whereas those perceived to slow the progression in children may be embraced. Concern over “myopic creep,” an increase in myopia associated with the initiation of soft contact lens wear reported in adults, may contribute to a reluctance of eye care practitioners to prescribe soft contact lenses as a viable treatment option for young myopic individuals.

The reluctance may stem in part from investigations of changes in myopic refractive error after soft contact lens wear that began to appear in the mid-1970s.^{12–14} These initial reports indicated that adult patients adapting to soft contact lens wear may experience an increase in myopia associated with a steepening of the corneal curvature. In investigations of the hypothesis that the increase in myopia was due to relatively hypoxic conditions causing corneal swelling, later studies compared high- and low-Dk (oxygen permeable) contact lens wearers and found that low-Dk contact lenses increase the progression of myopia over short periods more than do high-Dk contact lenses.^{15,16} The results of these studies gave further credence to the hypoxia theory of progression.

The studies noted were conducted on adults, but in two studies, the effect of contact lens wear on myopia’s progression in children was examined. In a chart review by Andreo,¹⁷ myopic changes in 14- to 19-year-old patients who wore contact lenses were compared to those of control subjects who wore spectacles. All subjects were examined 11 to 13 months after the baseline examination, and there was not a significant difference in the progression of myopia between contact lens and spectacle wearers.¹⁷

In a separate study, Horner et al.¹¹ randomly assigned subjects between the ages of 11 and 14 years to wear low-Dk soft contact lenses or spectacles for 3 years. Cycloplegic autorefractometry was performed every 6 months, and the change in spherical equivalent refractive error was, on average, 0.15 D greater for the soft contact lens wearers; this difference was not statistically significant. There were no data reported on corneal curvature or axial growth during the investigation.

The purpose of this study was to compare the changes in ocular components and refractive error of soft contact lens wearers and spectacle wearers over 3 years, to determine whether soft contact lenses affect the progression of myopia in children.

METHODS

The subjects of this report participated in the Adolescent and Child Health Initiative to Encourage Vision Empowerment (ACHIEVE) Study, a randomized clinical trial designed to investigate the effects of contact lens wear on children’s self-perception. The protocols were approved by each clinical site’s Institutional Review Board and adhered to the tenets of the Declaration of Helsinki. Eligibility criteria and methods are reported in detail elsewhere,¹⁸ but they are briefly presented

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herein. Participants were 8 to 11 years old at baseline. All had between -1.00 and -6.00 D myopia with less than 1.00 D astigmatism, measured by cycloplegic autorefractometry. Best-corrected visual acuity at distance was 20/20 or better in both eyes, and no subjects had worn contact lenses within the month before the baseline examination. All participants had healthy eyes, and an anterior segment evaluation without contraindications of contact lens wear. At the time of eligibility determination, none was participating in any other vision studies that prescribed treatments of any kind. The participants also exhibited 250 seconds of arc global stereo acuity.

Refractive error was measured by cycloplegic autorefractometry (WR-5100K autorefractor; Grand Seiko Co., Ltd., Fukuyama, Japan). Cycloplegia was achieved with one drop of 0.5% proparacaine followed by two drops of 1.0% tropicamide, separated by 5 minutes. Measurements were taken 25 minutes after the second drop of tropicamide was instilled. At least 10 spherocylindrical autorefractions were taken while the subject fixated 6/9 (20/30)-size letters on a near-point test card viewed through a +4.00-D Badal lens. The letters were presented at optical infinity and then moved to a slightly blurred position to ensure relaxation of residual accommodation.¹⁹ The 10 printed spherocylindrical autorefractions were hand edited by the masked examiner to eliminate sphere or cylinder readings that were more than 1.00 D from the mode, and the remaining readings were averaged using the power vector analysis described by Thibos et al.²⁰

Corneal curvature was measured with the autorefractor. One reading of the curvatures of the flattest and steepest corneal meridians (hereafter referred to as the "steep corneal meridian") was recorded when autorefractometry was performed.

An A-scan system (A-5500; Sonomed, Inc., Lake Success, NY) was used to measure axial length with a handheld probe through a dilated pupil. Traces were examined for relatively equal lens peaks and properly marked retinal peaks. Poor traces were replaced with acceptable traces, as they appeared or after five recordings were made. Axial length was calculated as the mean of the five readings.¹⁹

The randomization assignment at each clinic site was stratified by the Spectacle Satisfaction Survey score (≤ 67.0 versus >67.0), amount of myopia (spherical component of the cycloplegic autorefractometry of -3.50 D or less myopia versus more than -3.50 D myopia), and sex. Within each stratum, a permuted block design was used with a block size of four.¹⁸

Multilevel modeling was used for each outcome variable. The process of model term selection was the same for each outcome. We

fit the model mean structure for the growth of the outcome over time by using a quadratic polynomial model. If the quadratic term was not statistically significant, the quadratic term was dropped, resulting in a linear model. The quadratic term was marginally significant ($P = 0.055$) only for axial length; the rest of the models were fit with a linear polynomial.

Data in the figures represent unadjusted means. All statistical models included the predictors baseline age, sex, site, and treatment group. All predictors were entered into the model as main effects and as interactions with the linear effect of time.

The data have two interesting structural features that the modeling had to accommodate: Subjects had repeated measures both over time and over eyes. Thus, a subject with no missing data could have eight measures of each outcome, one from each eye in each year. The structure of the repeated measures was modeled by including intercept and time random effects at the subject level, and an intercept random effect at the eye-within-subject level.

All modeling was performed in commercial software (SAS, ver. 9.1, with the MIXED procedure; SAS Institute, Cary, NC).

RESULTS

We enrolled 484 subjects at five clinical sites (in Boston, MA; Columbus, OH; Forest Grove, OR; Houston, TX; and Memphis, TN) between September 2003 and October 2004, and randomly assigned them to wear spectacles ($n = 237$) or contact lenses ($n = 247$) for 3 years. Girls comprised 58.5% of the sample, the mean \pm SD age was 10.4 ± 1.1 years, 47.1% were white, 21.5% were black, and 21.5% Hispanic, and 6.6% were Asian or Pacific Islander.

Figure 1 shows the flow of subjects during the ACHIEVE Study. Some subjects switched treatment groups during the study, but all data analyses were conducted according to the intent-to-treat principle.^{21,22} Subjects wore their originally assigned treatment to 95.6% of the potential annual visits, and we examined 96.5% of the subjects at the final visit. Contact lens wearers were fitted with 1-Day Acuvue (93.3%) or Acuvue 2 (6.7%) contact lenses (Vistakon; Johnson & Johnson, Jacksonville, FL). At the final visit, spectacle wearers reported wearing their spectacles 89 ± 28 h/wk, and contact lens wearers reported wearing their contact lenses 88 ± 19 h/wk.

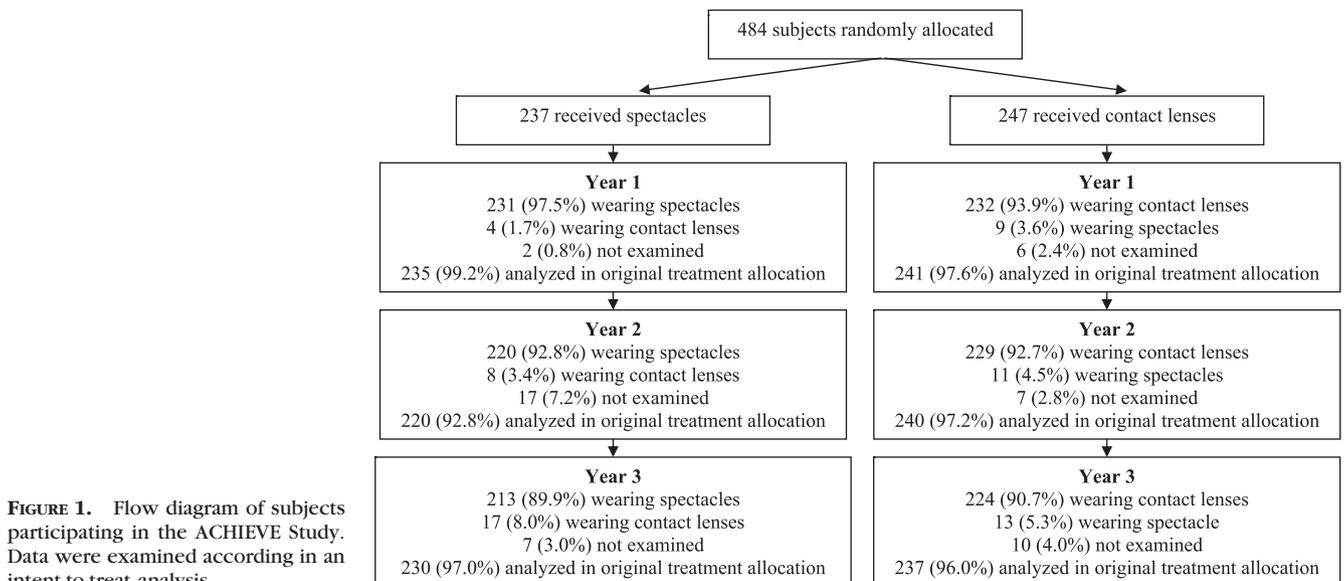


FIGURE 1. Flow diagram of subjects participating in the ACHIEVE Study. Data were examined according to an intent-to-treat analysis.

TABLE 1. Parameter Measurements for Each Treatment Group at Each Visit

	M (D)	J ₀ (D)	J ₄₅ (D)	Axial Length (mm)	Steep Corneal Curvature (D)
Spectacles					
Baseline	-2.38 ± 0.98	-0.06 ± 0.17	0.01 ± 0.18	24.32 ± 0.75	44.61 ± 1.50
1 Year	-2.80 ± 1.09	-0.05 ± 0.21	-0.02 ± 0.20	24.55 ± 0.80	44.70 ± 1.55
2 Years	-3.19 ± 1.21	-0.02 ± 0.24	0.00 ± 0.21	24.75 ± 0.83	44.71 ± 1.57
3 Years	-3.50 ± 1.29	0.01 ± 0.25	0.00 ± 0.23	24.91 ± 0.87	44.67 ± 1.57
Unadjusted mean change	-1.10 ± 0.71	0.07 ± 0.23	-0.01 ± 0.25	0.59 ± 0.37	0.05 ± 0.69
Contact Lenses					
Baseline	-2.43 ± 1.10	-0.06 ± 0.16	0.02 ± 0.17	24.32 ± 0.80	44.60 ± 1.53
1 Year	-2.91 ± 1.20	-0.06 ± 0.17	-0.03 ± 0.19	24.58 ± 0.82	44.66 ± 1.57
2 Years	-3.36 ± 1.30	-0.03 ± 0.20	-0.04 ± 0.21	24.77 ± 0.83	44.65 ± 1.59
3 Years	-3.73 ± 1.31	-0.01 ± 0.21	-0.03 ± 0.23	24.94 ± 0.88	44.69 ± 1.60
Unadjusted mean change	-1.29 ± 0.71	0.05 ± 0.23	-0.05 ± 0.24	0.63 ± 0.34	0.10 ± 0.70

Data are expressed as the mean ± SD.

Adverse events were defined as those that were unexpected or were more severe than anticipated. Six spectacle wearers experienced eight adverse events (two subjects experienced two events), including cases of trauma, preseptal cellulitis of unknown etiology, herpes simplex blepharconjunctivitis (one recurrence), subepithelial infiltrates of unknown etiology, contact dermatitis, and an internal hordeolum and viral conjunctivitis experienced at separate times by one subject. One subject assigned to wear spectacles reported with moderate SPK and admitted to being fit with contact lenses by an eye care practitioner outside of the study.

Nine contact lens wearers experienced 13 adverse events, including two cases of conjunctivitis (one bacterial and one viral), recurrent phlyctenulosis, corneal dystrophy not noted at baseline, recurrent nongranulomatous anterior uveitis, four cases of keratitis due to poor compliance and one of unknown etiology, and one case of keratitis due to a tight-fitting contact lens. All adverse events completely resolved without permanent decrease in best corrected visual acuity.

Table 1 shows the mean ± SD for refractive error components, axial length, and steep corneal curvature at each annual visit. Figure 2 illustrates the unadjusted mean spherical equivalent refractive error for contact lens and spectacle wearers at each annual visit. There was a statistically significant interaction between time and treatment for progression of myopia ($P = 0.002$). The average rate of change, controlling for base-

line age, sex, site, and treatment group, was 0.06 D per year greater for contact lens wearers than spectacle wearers. After 3 years, the adjusted difference between contact lens wearers and spectacle wearers was -0.22 D and not statistically significant (95% CI = -0.46 to 0.02). There was a statistically significant interaction between time and age at baseline, indicating a slower rate of change in those who were older at baseline ($P < 0.0001$).

Figure 3 shows the unadjusted mean axial length at each visit. There was no difference between the two treatment groups with respect to the adjusted change in axial length over time (ANCOVA, $P = 0.37$). As with refractive error, there was a time by baseline age interaction for axial growth ($P < 0.0001$), indicating that the axial length grew more slowly for those who were older at baseline.

The unadjusted change in steep corneal curvature is depicted in Figure 4. There was not a statistically significant difference between contact lens wearers and spectacle wearers for the adjusted change in steep corneal curvature (ANCOVA, $P = 0.72$).

Table 1 provides the unadjusted mean change in the two astigmatic components. J₀ did not change significantly over time (ANCOVA, $P = 0.10$), and there was not a significant difference between the treatment groups (ANCOVA, $P = 0.32$) when controlling for baseline age, sex, site, and treatment group. J₄₅ did not change significantly over time (ANCOVA, $P = 0.25$), and there was not a significant difference between

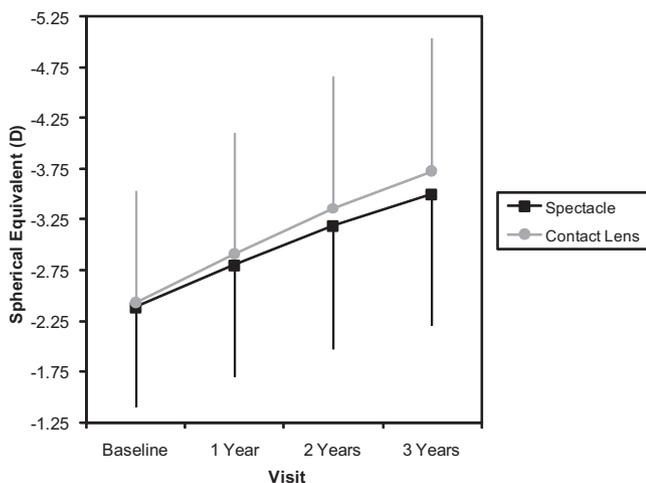


FIGURE 2. Mean ± SD unadjusted cycloplegic spherical equivalent refractive error in soft contact lens wearers and spectacle wearers.

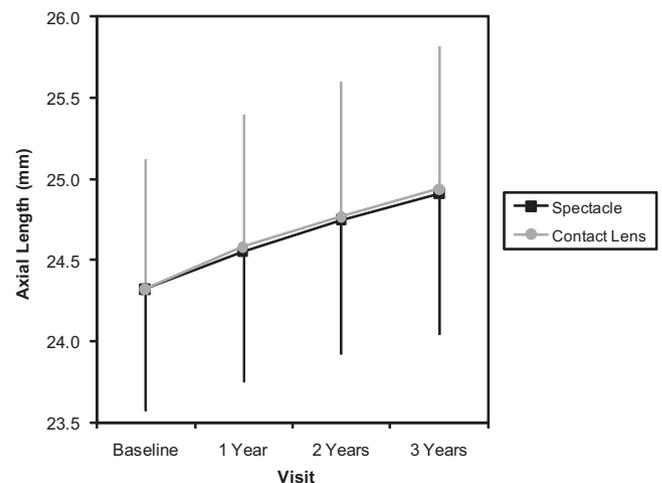


FIGURE 3. Mean ± SD unadjusted axial length in soft contact lens wearers and spectacle wearers.

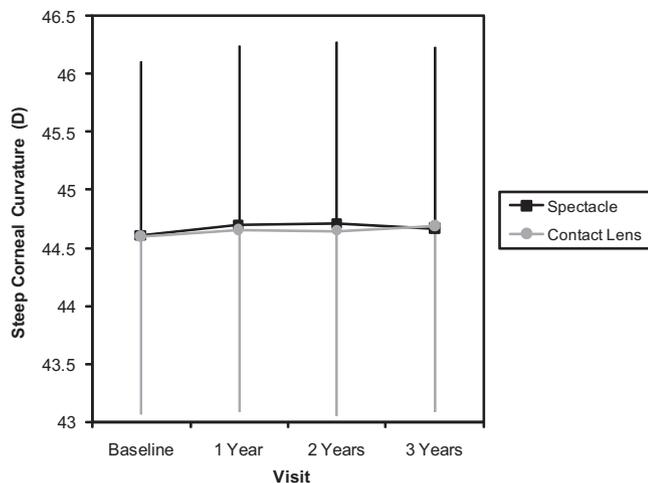


FIGURE 4. Mean \pm SD unadjusted steep autokeratometry reading in soft contact lens wearers and spectacle wearers.

the treatment groups (ANCOVA, $P = 0.84$) when controlling for baseline age, sex, site, and treatment group.

DISCUSSION

Although the progression of myopia was significantly greater (0.06 D per year greater) in contact lens wearers than spectacle wearers, the adjusted difference after 3 years, 0.22 D, was not quite statistically significant. This small difference is at the limit that is clinically measurable and does not represent a clinically meaningful difference. The statistically significant difference in progression rate was most likely found because multilevel modeling uses all time points and is therefore a more powerful approach than comparing difference at only one time point.

Even though the present study and Horner et al.¹¹ found similar differences in myopia progression between contact lens wearers and spectacle wearers, they found a greater increase in astigmatism in spectacle wearers than in soft contact lens wearers. One important protocol difference between these two studies may, at least in part, be responsible of this difference. Horner et al. evaluated refractive error by noncycloplegic manifest refraction. They hypothesized that the astigmatism increased more in the spectacle wearers than in the contact lens wearers because the spectacle wearers were more likely to accept increased cylinder power than the soft contact lens wearers who were typically corrected with sphere only. The use of cycloplegic autorefractometry in the current study prevents subjective assessments from affecting the outcome.

Previous investigations of 4 to 9 months in duration found that increased myopia progression caused by low-Dk contact lens wear was associated with greater corneal steepening or less corneal flattening than that reported for high-Dk contact lens wear.^{15,16} This study found no differences in corneal curvature between the contact lens wearers and spectacle wearers. The repeatability of corneal curvature measures with the autorefractor (WR-5100K; Grand Seiko) is similar to manual keratometry,²³ and so the difference in findings is not likely to be due to the method of measurement. Perhaps there is an initial adaptation to contact lens wear that causes corneal curvature to change, such as increased corneal curvature due to the initial adaptation to a relatively hypoxic condition after the initiation of contact lens wear, especially when contact lenses are worn on an extended-wear basis. After adjusting to the change caused by contact lens wear, the cornea may return to baseline curvature. This transient change could explain why

this long-term investigation with relatively infrequent visits may not have found the significant difference in refractive error or corneal curvature change that previous studies with frequent visits over the short period reported.

Axial growth has not been measured in previous studies examining the effect of soft contact lens wear on myopia progression. The similarity in axial growth between the two treatment groups confirms the fact that fitting young children with soft contact lenses will not lead to a permanent increase in myopia beyond that expected from the progression seen in spectacles.

This is the largest study to compare myopia's progression between children wearing contact lenses and those wearing spectacles and to evaluate corneal curvature and axial length changes in the two groups. Soft contact lens wear by children does not cause clinically relevant increases in axial length, corneal curvature, or myopia relative to spectacle lens wear. These data provide reassurance to eye care practitioners concerned with the phenomenon of "myopic creep."

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APPENDIX

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Data Safety Monitoring Committee: Donald O. Mutti (chair), G. Lynn Mitchell, and Sarita Soni.