

A Randomized Trial of the Effects of Rigid Contact Lenses on Myopia Progression

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Objective: To compare the effects of rigid gas-permeable contact lenses (RGPs) and soft contact lenses (SCLs) on myopia progression in children.

Methods: We randomly assigned 116 subjects to wear RGPs or SCLs. Subjects underwent cycloplegic autorefractometry, keratometry, and A-scan ultrasonographic axial length measurements at each annual visit. All analyses were conducted according to the original randomization assignment. The primary outcome measure was the 3-year change in spherical equivalent cycloplegic autorefractometry.

Results: The mean \pm SD spherical equivalent cycloplegic refractive error progressed -1.56 ± 0.95 diopters (D) for RGP wearers and -2.19 ± 0.89 D for the SCL wearers during the 3 years of the study (analysis of covariance [ANCOVA], $P < .001$). The axial growth of the eyes was

not significantly different between treatment groups (ANCOVA, $P = .57$). The steep corneal meridian of the RGP wearers steepened 0.62 ± 0.60 D, and that of the SCL wearers steepened 0.88 ± 0.57 D during the 3 years (ANCOVA, $P = .01$).

Conclusions: The RGP wearers' myopia progressed less than that of the SCL wearers. The corneal curvature of the SCL wearers steepened more than that of the RGP wearers, but the axial growth was not significantly different between the groups. Most refractive error treatment effect was limited to the first year of the trial. The results of the study provide information for eye care practitioners to share with their patients, but they do not indicate that RGPs should be prescribed primarily for myopia control.

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MYOPIA AFFECTS APPROXIMATELY 25% of the US population,¹ and it typically develops between 8 and 16 years of age.^{2,3} Controlling myopia progression during childhood may potentially affect cosmesis and comfort of spectacle wear, cost-effectiveness of spectacles and contact lenses, outcomes of refractive surgery, and ocular health.

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Previous studies have reported that rigid contact lenses slow myopia progression,⁴⁻⁶ but other studies have found that they increase⁷ or have no effect⁸ on myopia progression in children. All of these studies were limited by study designs that challenge the implications of the results. The Contact Lens and Myopia Progression (CLAMP) Study was designed to address the limitations of previous studies of the control of myopia by means of rigid contact lenses and to compare the effect of rigid gas-permeable contact lenses

(RGPs) and soft contact lenses (SCLs) on myopia progression in children.

METHODS

The study was conducted at The Ohio State University College of Optometry, Columbus. Parents provided consent for their child's participation after all study procedures were explained in accordance with the Declaration of Helsinki. The research was approved by the Biomedical Sciences Institutional Review Board at The Ohio State University. All subjects were aged 8 to 11 years at the initial visit and had a visual acuity of 20/20 or better OU. Both eyes had a spherical component of -0.75 to -4.00 diopters (D). Both eyes had less than 1.50 D astigmatism by cycloplegic autorefractometry and less than 1.00 D astigmatism by noncycloplegic manifest refraction, and there was less than a 1.00-D difference between the spherical components of the 2 eyes. All subjects were free of ocular and systemic disease that could affect vision or refractive error development, and they had not attempted contact lens wear before the investigation.

RUN-IN PERIOD

Subjects attended the initial visit to determine eligibility for the trial. One hundred forty-

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seven subjects were eligible to participate in the run-in period to determine whether they were able to adapt to RGPs. Adaptation to RGP wear was determined by the subject reporting a wearing time of at least 40 h/wk and contact lenses that were "usually comfortable" or "always comfortable" after 1 to 2 months of contact lens wear. Of the 147 subjects enrolled in the run-in period, 116 (78.9%) successfully adapted to RGPs and were randomly assigned to wear RGPs (n=59) or SCLs (n=57) for the clinical trial. The mean \pm SD run-in period lasted 65.7 \pm 33.1 days.

RANDOMIZATION

To maintain equal proportions of girls and boys in each treatment group, subjects were stratified by sex and randomly assigned in treatment blocks of 3 to ensure equal representation in each treatment group. After the treatment allocation was determined, we subsequently analyzed all data according to the original results of the randomization assignments.⁹⁻¹¹

OUTCOME MEASURES

The CLAMP Study was a 3-year, single-masked randomized clinical trial. The primary and secondary outcome measures were conducted annually. The anniversary dates of the annual examinations and the baseline data for the clinical trial were based on the date of the randomization visit, not the date of the initial visit. The primary outcome of the study was the 3-year change in spherical equivalent cycloplegic refractive error. We measured refractive error by means of cycloplegic autorefraction using an autorefractor (Canon R-1; Canon USA, Lake Success, NY; no longer manufactured). Cycloplegia was achieved using 1 drop of 0.5% proparacaine hydrochloride followed by 2 drops, separated by 5 minutes, of 1.0% tropicamide. Measurements were taken 25 minutes after the second drop of tropicamide was instilled. Ten spherocylinder autorefractions were averaged using the power vector analysis described by Thibos et al.¹²

Axial length was measured using the Humphrey Ultrasonic Biometer Model 820 (Humphrey Instruments, Inc, San Leandro, Calif). A handheld probe was used to measure the length of the eye through a dilated pupil. Traces were examined for equal lens peaks and properly marked retinal peaks. Poor traces were eliminated as they appeared or after 5 recordings were obtained, and they were replaced with acceptable traces. We calculated the axial dimensions as the average of the 5 readings.¹³ Subjects underwent measurement at the randomization visit and 3 annual follow-up visits.

We used a keratometer (Bausch & Lomb, Rochester, NY) to obtain 2 measures of each meridian of each eye. We averaged the power of the steep meridian and the power of the flat meridian from each measurement to yield 1 steep meridian reading and 1 flat meridian reading for each eye.

MASKING

All of the outcome measures were performed by an examiner who was masked to the treatment group assignment. At each visit, the subjects were reminded not to talk about their contact lenses when the masked examiner was in the room. The subjects wore only back-up spectacles or no correction when the masked examiner was in the examining room.

CONTACT LENSES

The RGPs were fitted to achieve central alignment. The contact lenses were 9.2 mm in diameter. The RGP material had extremely high oxygen permeability, and the children were given free solutions (Menicon Co, Ltd, Nagoya, Japan). Subjects ran-

domly assigned to wear SCLs were fitted with Focus 2-week disposable contact lenses, and they were given SOLO Care multipurpose solutions (CIBA Vision Care, Duluth, Ga).

STATISTICAL ANALYSIS

The target sample size of 110 subjects (55 participants per group) was selected to provide 90% power to detect a difference of 0.50 D in myopia progression during the 3-year study, with an SD of 0.75 D and a 2-sided error at $\alpha = .05$. The sample size also allowed for a 10% loss to follow-up. Our pooled SD of myopia progression was actually 0.92 D, which resulted in adequate power to detect the same difference, considering all subjects completed follow-up. All data were dually entered into Microsoft Access software (Microsoft Corporation, Redmond, Wash). Matching double entries were required before output to the final data file. All analyses are reported for the right eye only. Results that differ for the left eye are discussed in the text. We analyzed all data using intent-to-treat methods in the SAS statistical software package (SAS Institute, Inc, Cary, NC).^{9,10} Descriptive analyses were performed for the continuous (mean and standard deviations) and categorical (frequency) variables. The primary outcome of interest was the 3-year change in spherical equivalent compared between the treatment groups. We used an analysis of covariance, controlling for baseline spherical equivalent, to accomplish this. The same analysis was used for 3-year changes in axial length and corneal curvature. In addition, we assessed the effect of treatment assignment using all visits with a repeated-measures analysis of variance. The variance-covariance matrix used was the compound symmetry matrix or unstructured matrix, depending on which structure was most appropriate. This was determined by which structure minimized the Akaike information criteria values.¹⁴ Each outcome was modeled as a function of time, group, and the interaction of time and group. Statistically significant results were followed by the appropriate post hoc testing. Differences among times were assessed by means of the Tukey honestly significant difference test, whereas differences between groups were assessed using 2-sample *t* tests. To assess the contribution of the changes in axial length and corneal curvature to the change in refractive error, we performed a linear regression. Partial correlation coefficients based on the type II sums of squares were calculated to provide correlations that were adjusted for all of the other variables included in the model.

RESULTS

The mean age of the subjects enrolled in the clinical trial was 10.7 years; 59.5% were female; and 84.5% were white.¹⁵ At the randomization visit, the 2 groups were balanced with respect to all demographic and ocular variables reported (**Table 1**). We examined 116 subjects at the randomization visit, 114 subjects at the 1-year visit, 113 subjects at the 2-year visit, and all subjects at the final visit. One subject moved from the area and was not examined at year 1 or year 2 but returned for the final visit. The other 3 subjects missed 1 visit only.

No subjects in either treatment group experienced a sight-threatening adverse event. Four SCL wearers experienced an adverse event. Three of the events were due to tight-fitting SCLs. The corneal findings resolved completely after refitting the subjects with other brands of SCLs. The other adverse event was due to a contact lens solution allergy experienced by an SCL wearer, which resolved after changing the brand of contact lens solution.

Two subjects assigned to wear SCLs switched to RGPs during the trial. Eleven subjects (19%) switched from RGPs to SCLs during the trial. During the study, 7 subjects (12%) assigned to wear RGPs and 2 subjects (4%) assigned to wear SCLs were not wearing any contact lenses at the end of the study (**Figure 1**). Subjects were wearing their originally assigned treatment at 86.8% of the annual visits.

The primary outcome of the CLAMP Study was the 3-year change in cycloplegic spherical equivalent refractive error. The mean±SD 3-year change in spherical equivalent refractive error was -1.56 ± 0.95 D for the RGP wearers and -2.19 ± 0.89 D for the SCL wearers (analysis of covariance, $P < .001$) (**Figure 2A**). Progression of myopia in the RGP treatment group was 28.8% slower than in the SCL treatment group. The 3-year changes in the other ocular components are shown in **Table 2**. The change in refractive astigmatism and the axial growth were not significantly different between the 2 groups, but the corneas steepened

significantly more for the SCL wearers than for the RGP wearers (**Figure 2B**).

Table 3 shows the percentage of subjects who changed a given amount during the 3-year study. The distributions of the 2 groups are not significantly different (Fisher exact test, $P = .09$), indicating that the SCL and RGP wearers experienced similar progression during the 3-year trial.

To examine the differences between the 2 treatment groups over time, we conducted repeated-measures analysis of variance analyses. From randomization to the 3-year visit, there was no interaction between treatment group and visit for the cycloplegic spherical equivalent refractive error (**Figure 2A**). The change in spherical equivalent refractive error between each visit was not significantly different between the 2 groups, but during the entire 3-year period, the SCL wearers showed more progression than the RGP wearers. The axial growth was not significantly different between the 2 groups during the 3-year period (**Figure 2C**).

During the run-in period (initial visit to randomization visit), the cycloplegic refractive error did not change significantly (t test, $P = .89$), but the average steep meridian of the cornea flattened significantly (t test, $P < .001$) (**Figure 2B**). The average steep corneal meridian of the RGP wearers steepened significantly between randomization and each yearly visit and between years 1 and 3. The average steep corneal meridian of the SCL wearers steepened similarly to that of the RGP wearers, except that the SCL wearers' average steep corneal meridian also steepened significantly between years 1 and 2. From the initial visit to the year-3 visit, the RGP wearers' average steep corneal meridian did not change significantly (Tukey post hoc test, $P = .99$), but the SCL wearers' average steep corneal meridian steepened by a mean±SD of 0.31 ± 0.49 D (Tukey post-hoc test, $P < .001$). The pattern of change over time was similar for the flat corneal meridian, except that there was not a significant steepening of the cornea in the right eye of RGP wearers between randomization and year 1, but there was significant steepening of the flat corneal meridian of the left eye during the same period. In summary, all contact lens wearers' corneas flat-

Variables	Treatment Group	
	RGPs	SCLs
Male, No. (%)	24 (41)	23 (40)
White, No. (%)	49 (83)	49 (86)
Age, y	10.5 ± 1.2	10.5 ± 1.1
Spherical equivalent, D	-2.30 ± 0.91	-2.48 ± 0.86
J ₀ , D	+0.23 ± 0.24	+0.28 ± 0.26
J ₄₅ , D	+0.03 ± 0.19	+0.03 ± 0.16
Axial length, mm	24.16 ± 0.74	24.10 ± 0.69
Steep corneal meridian, D	43.89 ± 1.44	43.93 ± 1.16
Flat corneal meridian, D	43.28 ± 1.34	43.36 ± 1.12

Abbreviations: D, diopter; J₀, horizontal and vertical refractive astigmatism; J₄₅, oblique refractive astigmatism; RGPs, rigid gas-permeable contact lenses; SCLs, soft contact lenses.

*The 2 treatment groups did not differ significantly with regard to any of the variables at the randomization visit. Unless otherwise indicated, data are expressed as mean ± SD.

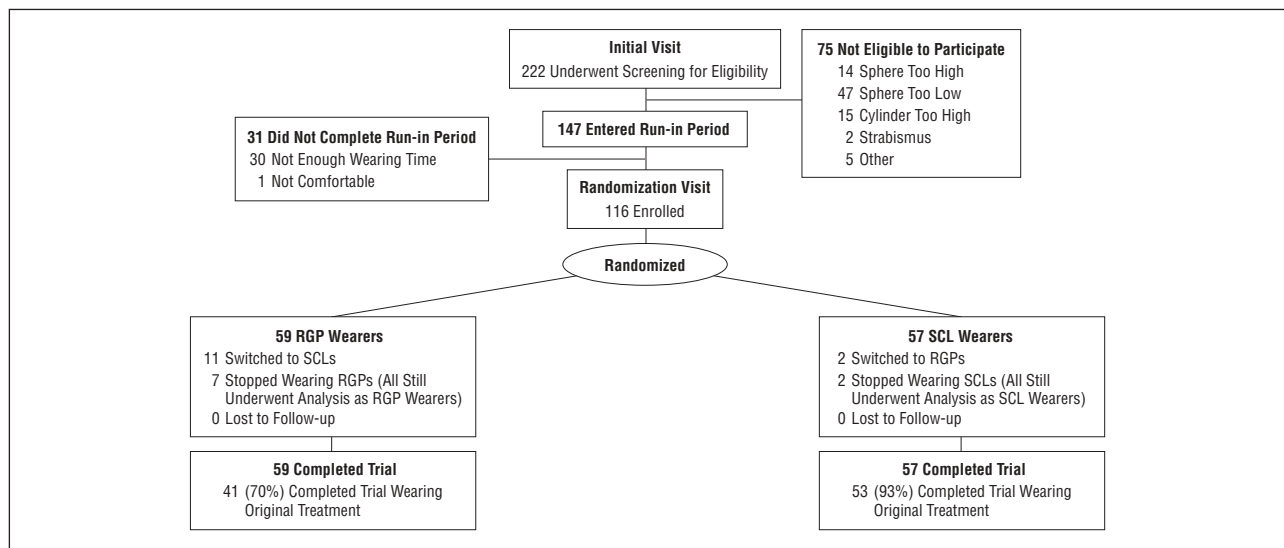


Figure 1. Flow diagram of subjects in the Contact Lens and Myopia Progression Study. RGPs indicates rigid gas-permeable contact lens; SCLs, soft contact lenses.

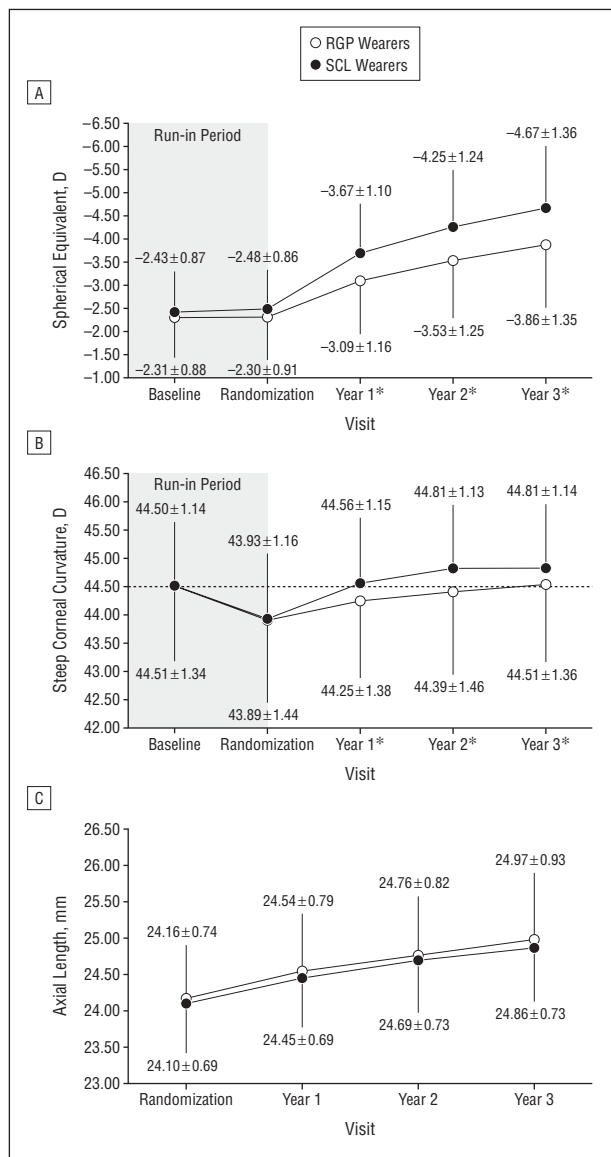


Table 3. Progression in Wearers of RGPs and SCLs During the 3-Year Study*

Progression, D	Treatment Group, No. (%) of Wearers†	
	RGP (n = 59)	SCL (n = 57)
<0.50	8 (14)	1 (2)
0.50-0.99	7 (12)	2 (4)
1.00-1.49	16 (27)	12 (21)
1.50-1.99	10 (17)	12 (21)
2.00-2.49	8 (14)	12 (21)
2.50-2.99	4 (7)	5 (9)
3.00-3.49	3 (5)	9 (16)
3.50-3.99	2 (3)	2 (4)
≥4.00	1 (2)	2 (4)

Abbreviations: D, diopter; RGPs, rigid gas-permeable contact lenses; SCLs, soft contact lenses.
*The distributions are not significantly different between the 2 treatment groups (Fisher exact test, P = .09).
†Because of rounding, percentages may not total 100.

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2.50-2.99	4 (7)	5 (9)
3.00-3.49	3 (5)	9 (16)
3.50-3.99	2 (3)	2 (4)
≥4.00	1 (2)	2 (4)

Abbreviations: D, diopter; RGPs, rigid gas-permeable contact lenses; SCLs, soft contact lenses.
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Figure 2. A, Mean ± SD cycloplegic spherical equivalent refractive error for wearers of rigid gas-permeable contact lenses (RGPs) and soft contact lenses (SCLs). The shaded portion represents the run-in period, when all subjects wore RGPs. The asterisks indicate a significant difference in refractive error between treatment groups ($P < .05$). B, Mean ± SD curvature of the steep corneal meridian for RGP and SCL wearers from the initial visit to the end of the study. The shaded portion represents the run-in period, when all subjects wore RGPs. The asterisks indicate a significant difference in corneal curvature between treatment groups ($P < .05$). The dashed line indicates the initial curvature of the steep corneal meridian. Corneal flattening is seen during the run-in period, with a return to the initial corneal curvature for the RGP wearers, and the additional steepening in the SCL wearers. C, Mean ± SD axial length for RGP and SCL wearers from the initial visit to the end of the study. Axial lengths were not measured at the initial visit, so no axial length data were available before randomization. There were no significant differences between the treatment groups at any of the visits ($P < .05$).

tened during the run-in period. The RGP wearers' corneal curvatures returned to baseline by the end of the study, whereas those of the SCL wearers continued to steepen until they were 0.31 D steeper than at baseline (Figure 2B).

To determine the role axial growth and corneal changes played in determining the refractive error change in subjects, we constructed a linear regression model using initial age, sex, ethnicity, initial refractive error, and 3-year

changes in the steep corneal meridian and axial length to explain the myopia progression of the subjects. Partial correlation coefficients were used to determine the association between the changes in the spherical equivalent refractive error and changes in the corneal curvature of the steep meridian, as well as changes in the axial length. The partial correlation coefficient for axial length change with the change in refractive error was -0.22. The corresponding coefficient for the steep corneal meridian change was -0.17, indicating that the change in axial length was only moderately more correlated with the change in refractive error than was the change in the steep corneal meridian. The unadjusted Pearson correlation coefficient between the change in axial length and the change in the spherical equivalent refractive error was -0.54, and the unadjusted Pearson correlation coefficient between the change in the steep meridian and the change in the spherical equivalent refractive error was -0.37.

We also examined the effect of initial age and baseline myopia on treatment effects (Table 4). There were no significant differences in mean myopia progression based on initial age ($P = .84$), baseline myopia

Table 4. The Effects of Initial Age and Amount of Refractive Error at Randomization on the 3-Year Progression of Myopia on Wearers of RGPs and SCLs

Characteristic	Treatment Group, Mean ± SD (No. of Wearers)		P Value*
	RGP	SCL	
Age, y			.84
≤10.6	-1.88 ± 1.04 (29)	-2.39 ± 0.89 (29)	
>10.6	-1.26 ± 0.77 (30)	-1.99 ± 0.86 (28)	
Myopia, D at randomization			.19
≤-2.32	-1.68 ± 0.88 (33)	-2.06 ± 0.62 (25)	
>-2.32	-1.41 ± 1.03 (26)	-2.30 ± 1.05 (32)	
Mixture			.29
Age ≤10.6 y			
Myopia			
≤-2.32 D at randomization	-1.89 ± 0.99 (19)	-2.03 ± 0.59 (15)	
Myopia			
>-2.32 D at randomization	-1.85 ± 1.16 (10)	-2.78 ± 1.00 (14)	
Age >10.6 y			
Myopia			
≤-2.32 D at randomization	-1.40 ± 0.63 (14)	-2.09 ± 0.70 (10)	
Myopia			
>-2.32 D at randomization	-1.14 ± 0.87 (16)	-1.93 ± 0.95 (18)	

Abbreviations: D, diopter; RGPs, rigid gas-permeable contact lenses; SCLs, soft contact lenses.

*Determined for the interaction between treatment group and the variables indicated.

($P = .93$), or the interaction of initial age, baseline myopia, and treatment group ($P = .29$).

COMMENT

The CLAMP Study has shown that RGPs produce a slower rate of progression of myopia in children. Although results from the CLAMP Study indicate that RGPs significantly slow the progression of myopia in children, the slowed change in refractive error may not be overwhelming from the clinical perspective. A portion of the treatment effect is likely to be due to corneal flattening that may be reversible; the decreased refractive error progression is not accompanied by slowed axial growth; and the initial treatment effect does not continue to accrue during the entire study. These factors lead to questions about the permanency of the effect. Data from this study do not warrant the fitting of myopic children with RGPs solely for the purpose of significant myopia control, but they do provide reliable information that eye care practitioners can use to counsel their patients on myopia control.

CLAMP STUDY DESIGN AND LIMITATIONS OF PREVIOUS INVESTIGATIONS

Previous studies of myopia control by means of RGPs experienced high rates of loss to follow-up, in the RGP group, because RGPs are initially less comfortable than SCLs.^{4,5,8} The CLAMP Study found smaller treatment effects than

did Khoo et al⁴ and Perrigin et al,⁵ possibly because both studies had high rates of loss to follow-up (47% for Khoo et al and 44% for Perrigin et al) in their RGP groups. The subjects' inability to adapt to RGP wear in the previous studies may be systematically associated with a higher rate of myopia progression. For example, younger children, whose myopia typically progresses more,¹⁶ may also be less likely to adapt to RGPs. Because there was no run-in period in the previous studies, the loss of the young children with faster-progressing myopia from the RGP group, but not the control group, may have led to the false impression that RGPs significantly slow the progression of myopia in children in previous studies. The run-in period used in the CLAMP Study should reduce the number of children who cannot adapt to RGP wear before randomization, thereby decreasing the chance of bias.

The control groups in the previous studies had a variety of problems. For example, the treatment groups in the study reported by Stone⁶ were not randomly assigned, so the contact lens group was slightly older than the spectacle group, the subjects were as old as 16 years at entry, and the subjects experienced various lengths of follow-up. Inclusion of older subjects may explain the lower rate of myopia progression for both treatment groups, and the age imbalance and unequal follow-up for all subjects may explain the apparent slowed myopia progression experienced by the RGP wearers.

The first randomized clinical trial conducted to examine the effects of RGPs on myopia progression was published recently. The authors reported no significant difference in myopia progression between RGP wearers and spectacle wearers.⁸ Although the treatment allocations were randomly assigned, myopia was more severe in the RGP group, they had steeper corneal curvatures, and more of them were girls. All of these factors are associated with higher amounts of myopia or greater myopia progression, which may explain why that study did not find a treatment effect. Furthermore, after 2 years, only 37.5% of the RGP wearers and 67.8% of the spectacle wearers remained in the study.

To reduce the control group problems of previous studies, the CLAMP Study included a run-in period before randomization. However, adapting subjects to contact lens wear during the CLAMP Study run-in period and then assigning them to wear spectacles for 3 years could have increased the loss to follow-up, as parents and children may have been disappointed at the switch from contact lenses to glasses. Using SCLs instead of spectacles for the control group of the CLAMP Study was intended to improve retention, make the study more appealing to the subjects and their parents, minimize the differences in accommodative responses between the experimental and control groups, and retain masking of the 2 groups to the examiner.

A critical review of the limitations of previous RGP myopia treatment studies enabled the CLAMP Study to attempt to avoid pitfalls encountered by previous investigators.

POTENTIAL LIMITATIONS OF THE CLAMP STUDY

Some may argue that the run-in period limits the generalizability of the study, because it limits the applicability

of the study to those children who can adapt to RGP wear. This hypothetical limitation is not important because the effects of RGPs on myopia progression are irrelevant for children who are not able to adapt to them.

Soft contact lenses have been reported to increase the progression of myopia,¹⁷⁻¹⁹ which would increase the relative treatment effect of RGPs in the CLAMP Study. However, a randomized clinical trial found no difference in myopic progression during a 30-month period between children who wore SCLs and children who wore spectacles,²⁰ and a medical record review of 14- to 19-year-old subjects who wore SCLs or spectacles found no difference in myopic progression between the 2 groups.²¹ In the long term, SCLs do not appear to significantly alter the progression of myopia in children, and an SCL control group would not increase the potential treatment effect of RGPs in a randomized clinical trial.

Although all of the subjects completed the 3-year study, some subjects did not wear their contact lenses and some switched treatment groups, which may alter the treatment effect of the clinical trial. Ninety-three percent of the SCL wearers completed the CLAMP Study wearing the originally assigned treatment, whereas only 69.5% of the RGP wearers completed the trial wearing their original treatment assignment. We did not conduct an analysis of the data according to the treatment that the subjects were actually wearing, because they wore their originally assigned treatment to 86.8% of the visits, and because the intent-to-treat analysis is important to avoid potentially misleading results due to biases associated with methods of treating crossovers.^{9,10}

The permanency of the treatment effect would be very difficult to study, because we cannot ask subjects who are assigned to use a treatment that works to discontinue use of the treatment to determine whether the effect is permanent. On the basis of evidence that corneal curvature changes during corneal-reshaping contact lens wear are reversible,²² we speculate that the treatment effect experienced in the CLAMP Study may not be permanent, but we did not specifically test that hypothesis.

IMPLICATIONS OF STUDY RESULTS

Most of the treatment effect results occurred during the first year of the CLAMP Study. Similar results were illustrated in previous myopia control studies that used RGPs⁴ and bifocal spectacle lenses.²³ The reasons for an initial treatment effect that does not accrue over a longer period of time are unknown and should be further investigated. One possible explanation for the transient treatment effect during the CLAMP Study is that corneal flattening induced by RGPs during the run-in period resolves during the first year of SCL wear.

The flattening of corneal curvature during the run-in period is expected with the fitting of RGPs.²⁴ We expected the corneal flattening experienced during the run-in period to remain stable during the 3-year study for the RGP wearers and to return to baseline corneal curvature for the SCL wearers. Instead, the RGP wearers returned to their baseline corneal curvature during the

3-year study, whereas the SCL wearers returned to their baseline corneal curvature within 1 year, then experienced steepening beyond the baseline corneal curvature (Figure 2C). The SCL wearers' corneas steepened 0.27 D more than those of the RGP wearers during the first year of the study. This explains approximately two thirds of the 0.40-D difference in refractive error progression between the treatment groups during the first year of the study. During the last 2 years of the study, the change in corneal curvature was similar between the 2 groups (the RGP wearers' corneas steepened 0.25 D, and the SCL wearers' corneas steepened 0.26 D), but the SCL wearers' spherical equivalent myopia progressed 0.23 D more than that of the RGP wearers during the same period. This illustrates that the difference in refractive error progression experienced during the first year of the study may have been influenced by corneal curvature changes that occurred during the run-in period, but the small differences in refractive error progression experienced during the last 2 years of the study were likely not due to a difference in corneal curvature changes between the 2 groups. Although the myopia progression was slower for RGP wearers than for SCL wearers, some of the effect was likely influenced by transient corneal curvature changes, and therefore decreased the likelihood of sustained differences in refractive error between the 2 treatment groups.

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REFERENCES

1. Sperduto RD, Seigel D, Roberts J, Rowland M. Prevalence of myopia in the United States. *Arch Ophthalmol*. 1983;101:405-407.
2. Blum HL, Peters HB, Bettman JW. *Vision Screening for Elementary Schools: The Orinda Study*. Berkeley: University of California Press; 1959.
3. Goss DA. Cessation age of childhood myopia progression. *Ophthalmic Physiol Opt*. 1987;7:195-197.
4. Khoo CY, Chong J, Rajan U. A 3-year study on the effect of RGP contact lenses on myopic children. *Singapore Med J*. 1999;40:230-237.
5. Perrigin J, Perrigin D, Quintero S, Grosvenor T. Silicone-acrylate contact lenses for myopia control: 3-year results. *Optom Vis Sci*. 1990;67:764-769.
6. Stone J. The possible influence of contact lenses on myopia. *Br J Physiol Opt*. 1976;31:89-114.
7. Baldwin WR, West D, Jolley J, Reid W. Effects of contact lenses on refractive corneal and axial length changes in young myopes. *Am J Optom Arch Am Acad Optom*. 1969;46:903-911.
8. Katz J, Schein OD, Levy B, et al. A randomized trial of rigid gas permeable contact lenses to reduce progression of children's myopia. *Am J Ophthalmol*. 2003; 136:82-90.
9. Peduzzi P, Wittes J, Detre K, Holford T. Analysis as-randomized and the problem of non-adherence: an example from the Veterans Affairs Randomized Trial of Coronary Artery Bypass Surgery. *Stat Med*. 1993;12:1185-1195.

10. Peduzzi P, Detre K, Wittes J, Holford T. Intent-to-treat analysis and the problem of crossovers: an example from the Veterans Administration Coronary Bypass Surgery Study. *J Thorac Cardiovasc Surg.* 1991;101:481-487.
11. Newell DJ. Intention-to-treat analysis: implications for quantitative and qualitative research. *Int J Epidemiol.* 1992;21:837-841.
12. Thibos LN, Wheeler W, Horner D. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. *Optom Vis Sci.* 1997;74:367-375.
13. Zadnik K, Mutti DO, Friedman NE, Adams AJ. Initial cross-sectional results from the Orinda Longitudinal Study of Myopia. *Optom Vis Sci.* 1993;70:750-758.
14. Bozdogan H. Model selection and Akaike's Information Criteria (AIC): the general theory and its analytical extensions. *Psychometrika.* 1987;52:345-370.
15. Walline JJ, Mutti DO, Jones LA, et al. The Contact Lens and Myopia Progression (CLAMP) Study: design and baseline data. *Optom Vis Sci.* 2001;78:223-233.
16. Braun CI, Freidlin V, Sperduto RD, Milton RC, Strahlman ER. The progression of myopia in school age children: data from the Columbia Medical Plan. *Ophthalmic Epidemiol.* 1996;3:13-21.
17. Harris MG, Sarver MD, Polse KA. Corneal curvature and refractive error changes associated with wearing hydrogel contact lenses. *Am J Optom Physiol Opt.* 1975;52:313-319.
18. Dumbleton KA, Chalmers RL, Richter DB, Fonn D. Changes in myopic refractive error with nine months' extended wear of hydrogel lenses with high and low oxygen permeability. *Optom Vis Sci.* 1999;76:845-849.
19. Binder PS. Myopic extended wear with the Hydrocurve II soft contact lens. *Ophthalmology.* 1983;90:623-626.
20. Horner DG, Soni PS, Salmon TO, Swartz TS. Myopia progression in adolescent wearers of soft contact lenses and spectacles. *Optom Vis Sci.* 1999;76:474-479.
21. Andreo LK. Long-term effects of hydrophilic contact lenses on myopia. *Ann Ophthalmol.* 1990;22:224-229.
22. Kerns RL. Research in orthokeratology, V: results and observations—recovery aspects. *J Am Optom Assoc.* 1977;48:345-359.
23. Gwiazda J, Hyman L, Hussein M, et al. A randomized clinical trial of progressive addition lenses versus single vision lenses on the progression of myopia in children. *Invest Ophthalmol Vis Sci.* 2003;44:1492-1500.
24. Polse KA, Sarver MD, Kenyon E, Bonanno J. Gas permeable hard contact lens extended wear: ocular and visual responses to a 6-month period of wear. *CLAO J.* 1987;13:31-38.

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