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ORIGINAL ARTICLE

The Children's Overnight Orthokeratology Investigation (COOKI) Pilot Study

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ABSTRACT: *Purpose.* Innovations in contact lens materials and designs allow patients to wear contact lenses during sleep to flatten the cornea and temporarily to reduce myopic refractive error and improve unaided visual acuity. We conducted the Children's Overnight Orthokeratology Investigation (COOKI) pilot study, a case series, to describe the refractive error and visual changes, as well as the slitlamp observations associated with overnight orthokeratology in children, over a period of 6 months. *Methods.* Twenty-nine 8- to 11-year-old children with myopia between −0.75 and −5.00 D and <−1.50 D corneal toricity were fitted with corneal refractive therapy contact lenses (Paragon Vision Sciences, Mesa, AZ). They were examined within 1 hour of awakening and about 6 hours later at 1 day, 1 week, 2 weeks, 1 month, 3 months, and 6 months after the first night of contact lens wear. At each visit, the logarithm of the minimum angle of resolution (logMAR) visual acuity, manifest refraction, slitlamp examination, and corneal topography were performed. *Results.* Twenty-three subjects completed the 6-month study. Three subjects decided not to wear contact lenses, two did not achieve acceptable fits, and one moved from the area. At the 6-month afternoon visit, the mean ± SD uncorrected high-contrast visual acuity was +0.08 ± 0.15 logMAR (Snellen equivalent, 20/24), and the mean ± SD spherical equivalent refraction was −0.16 ± 0.66 D. The corneas of three-fifths of the subjects showed mild staining at the morning visit, and one-third of the patients showed mild corneal staining at the afternoon visit. The most common type of stain was central punctate staining. No subjects experienced lasting adverse visual effects from cornea-reshaping contact lens wear during the study period. *Conclusions.* Overnight cornea-reshaping contact lenses are efficacious for young myopic patients, and no children experienced a serious adverse event during the study. (Optom Vis Sci 2004;81:407–413)

Key Words: orthokeratology, corneal reshaping, children, contact lenses, myopia, overnight

About 25% of the U.S. adult population is myopic,[1] yet only 2% of the children entering elementary school are nearsighted.[2] About 15% of children become myopic between the ages of 6 and 14 years,[1] and myopia progression generally continues until about age 15 years for females and 16 years for males.[3] Slowing the progression of myopia in this age group could ultimately impact the lives of roughly 42 million adults in the United States, because there are fewer ocular health risks associated with low myopia.[4–7]

Rigid gas-permeable (RGP) contact lenses provide clear, comfortable vision with relatively few ocular health risks and are a standard management option for correcting nearsightedness. Although RGP contact lenses are used to optically correct myopic refractive error and provide clear distance vision, they may also slow the progression of myopia,[8–13] although there is evidence that RGP contact lenses may not slow myopia progression.[14, 15]

Relatively recently, orthokeratology was revived due to innovations in design and materials. The concept of altering refractive error by changing the shape of the cornea was initially reported in the early 1960s.[16] As shown in Table 1, the early studies reported an incomplete treatment effect and transient, unpredictable refractive error reduction.[17–28] None of the studies reported significant adverse events resulting from orthokeratology contact lens wear.[21, 25, 27]

Three studies from the late 1970s to the mid-1980s used spherical design (the base curve is steeper than the secondary curve) contact lenses worn during waking hours only. While treating subjects with a mean spherical equivalent refractive error of about −2.50 D (Table 1), the time to maximal orthokeratological effect ranged from 132 days[28] to 17.7 months.[25] In all three studies, the achieved myopia reduction was <75% (Table 1). All three studies

reported a return toward baseline values for corneal curvature, refractive error, and unaided visual acuity after orthokeratology was discontinued.[22, 25, 28] Due to the unpredictable results and minimal benefits of early orthokeratology procedures, orthokeratology was not evaluated again until the mid-1990s. Innovative materials and designs allowed for quicker, more predictable treatment effects and nighttime contact lens wear.[29–31]

The advent of high-Dk materials (greater oxygen permeability) allows most patients to wear RGP contact lenses during sleep, with fewer complications due to hypoxia.[32] Nighttime wear of contact lenses also allows the patient to benefit from orthokeratological effects without having to wear contact lenses during the day.

Reverse-geometry contact lens designs (the base curve is flatter than the secondary curve) provide an improved ability to mold the cornea with better lens centration. This enables a quicker treatment effect and fewer contact lens-related visual complications. Orthokeratology studies using reverse-geometry contact lenses reported a more complete treatment effect, ranging from 70 to 100%, and a shorter time to accomplish the treatment effect: 7 to 40 days (Table 1).[29–31, 33]

The short-term safety and efficacy of overnight orthokeratology have been established, but there is only one study of myopic adolescents fitted with reverse-geometry contact lenses.[34] The study included children with up to −10.75 D spherical equivalent myopia, but they did not achieve >5.00 D correction for myopia in any of the 105 eyes.[34] A calculation gleaned from the data estimated only a 57% mean reduction of myopia in the subjects, but no lasting adverse events were reported over a period of 6 months.

Overnight orthokeratology contact lens wear allows children to participate in sports and other activities without the use of spectacles, sports goggles, or contact lenses during the daytime. Limiting the use of refractive-error-correction devices during various activities may help prevent loss or breakage, which helps to lessen the burden of time and money spent replacing them. Overnight orthokeratology contact lenses may prove to be a safe, convenient, cost-effective means of providing clear vision for nearsighted children. If overnight orthokeratology contact lenses also slow the progression of myopia, they could become a new standard of care for nearsighted children.

Before we can examine the effects of overnight orthokeratology on myopia progression, we must examine the safety and efficacy of the procedure in children. The goal of the Children's Overnight Orthokeratology Investigation (COOKI) pilot study is to describe the refractive error and visual changes, as well as the slitlamp observations associated with overnight orthokeratology, in children over a 6-month period.

METHODS

The COOKI pilot study is a prospective, nonmasked case series. Subjects enrolled in the COOKI pilot study met the entry criteria in Table 2. Parents provided consent for their child's participation after all study procedures were explained. The research was approved by the institutional review boards at The Ohio State University and the New England College of Optometry. All subjects received free materials and services during the entire study.

During the baseline visit, subjects were fitted with corneal refractive therapy (CRT) contact lenses made of HDS-100 material (Paragon Vision Sciences, Mesa, AZ). The CRT contact lens was recently approved by the U.S. Food and Drug Administration for overnight corneal reshaping for the temporary reduction of myopia in all ages.[35]

At the baseline visit, the subjects underwent tests of uncorrected high- and low-contrast visual acuity, corneal topography, manifest refraction, slitlamp examination, and a contact lens fitting. At the contact lens dispensing visit, the subjects underwent a slitlamp examination and contact lens training. The subjects were evaluated 1 day, 1 week, 2 weeks, 1 month, 3 months, and 6 months after the first night of contact lens wear. At each of these visits, the subjects underwent an evaluation within 1 hour of waking and another at least 6 hours later. At each visit, the subjects underwent tests for uncorrected high- and low-contrast visual acuity, corneal topography, and manifest refraction and a slitlamp examination.

High- and low-contrast (8% Michelson) visual acuities were measured using a Bailey-Lovie visual acuity chart with a luminance between 96 and 102 cd/m^2. The subjects read letters while standing 4 m away from the chart unless they could not read the entire top line of the chart; in those cases, they stood 1 m from the chart. Subjects were instructed to read every line in its entirety, beginning at the top of the chart. After the line in which the subject missed three or more letters was completed, the total number of letters read correctly and the test distance were recorded. Visual acuities were reported as logMAR with Snellen visual acuity equivalents.

To fit the contact lenses, the flat keratometry reading, the sphere component of the manifest refraction, and the target refractive error were entered into a handheld computer. The initial base

TABLE 1.
Review of previous orthokeratology studies

Author (year)	Contact Lens Design	Wear Schedule	Spherical Equivalent Baseline Refractive Error (D) (Mean ± SD)	Percent Spherical Equivalent Refractive Error Reduction (%)	Time to Maximum Effect
Kerns[21]	Spherical	Day	−2.31 ± 0.80	57.6	300 days
Binder et al.[25]	Spherical	Day	−2.50 ± 1.10	71.8	17.7 months
Polse et al.[28]	Spherical	Day	−2.66 ± 1.08	62.6	132 days
Mountford[29]	Reverse geometry	Overnight	−2.19 ± 0.79	100.0	Not available
Lui and Edwards[33]	Reverse geometry	Day	−2.12 ± 0.51	70.1	40 days
Nichols et al.[30]	Reverse geometry	Overnight	−1.84 ± 0.81	98.9	7 days
Rah et al.[31]	Reverse geometry	Overnight	−2.37 ± 0.93	102.5	<1 month

TABLE 2.
Entry criteria for the COOKI Pilot Study

Refractive error	Noncycloplegic manifest refraction
Sphere	−0.75 to −5.00 D, inclusive
Cylinder	Axis 180 ± 20 degrees, up to −2.00 DC; all other axes, up to −1.00 DC
Age	8 to 11 years, inclusive, at baseline examination
Contact lenses	No previous or current rigid contact lens wear
Visual acuity	20/20 or better, best-corrected in each eye
Ocular health	Free of eye disease and binocular vision problems (e.g., strabismus, amblyopia, oculomotor nerve palsies, corneal disease) that may affect vision or contact lens wear
Systemic health	Free of systemic disease that may affect vision or vision development (e.g., diabetes, Down syndrome)
Spectacles	Single-vision spectacle wearer at the time of the baseline visit

curve was calculated by the computer, and lenses were evaluated on the eye with fluorescein to determine the most appropriate base curve. The horizontal iris visible diameter and the lens number were entered into the handheld computer to determine the first trial lens with the appropriate midperipheral touch and edge lift. Once the appropriate base curve lens and the appropriate midperipheral touch lens were determined, the final lens order could be determined. This method of fitting the contact lenses is no longer in use; a dispensing fitting set is now available.

Noncycloplegic manifest refraction was completed with Jackson cross-cylinder and von Graefe balance using the maximum plus to maximum visual acuity theory. Corneal topography was performed using the Humphrey ATLAS corneal topography system model 990 (Humphrey Instruments, San Leandro, CA). One measurement with a "high confidence" level was recorded for each eye.

A slitlamp examination was performed at each visit, the results of which were recorded on forms that established the presence or absence, type, location, and severity of corneal staining, as well as other corneal findings. The severity of the staining was graded from 1.0 (trace) to 4.0 (severe) in 0.5 steps, using clinical guidelines but no standardized grading scale.

Contact lens refittings took place if the subject's vision was not as good as would be expected, if the subject had a problem that affected ocular health, if the corneal topography indicated a decentered contact lens, or if the manifest refraction yielded an undesirable result. New contact lenses were ordered on the basis of expected contact lens changes to improve the results.

Data Analysis

All data were dual-entered into Microsoft Access (Microsoft Corp., Redmond, WA). Matching double entries were required before output to the final data file. All analyses were reported for the right eye only. Data were analyzed by repeated-measures analysis of variance (ANOVA), using Proc Mixed. P values presented were adjusted using the Tukey-Kramer multiple-comparison adjustment. All data were analyzed using the SAS statistical software package (SAS Institute, Inc., Cary, NC).

RESULTS

Twenty-nine subjects were enrolled in the COOKI pilot study (Fig. 1). Two subjects were unable to be successfully fitted with CRT contact lenses. Two subjects chose not to wear contact lenses within the first 2 weeks for reasons unrelated to poor vision or poor comfort. One subject stopped wearing contact lenses just before the 6-month visit. Data from these subjects were included in the analyses until the subjects stopped wearing the contact lenses.

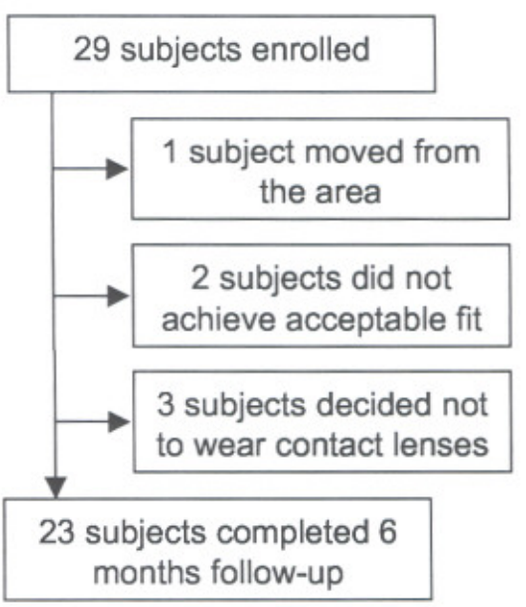

FIGURE 1.
Flow diagram of the subjects enrolled in the COOKI pilot study.

The mean ± SD age of the children enrolled in the COOKI pilot study was 10.3 ± 1.0 years, and 63.3% were girls. Whites comprised 46.7% of the subjects, and 40.0% were Asian. The mean (± SD) spherical equivalent manifest refraction at the beginning of the study was −2.44 ± 1.38 D (range, −0.75 to −6.00 D), and the highest amount of refractive astigmatism was +0.50 D (J_0) and −0.47 D (J_{45}). J_0 is the with-the-rule and the against-the-rule components of astigmatism, and J_{45} is the oblique components of astigmatism. None of the subjects showed corneal staining before the study. The baseline spherical equivalent refractive error was significantly different from all of the afternoon visits, except for the 1-day afternoon visit (repeated-measures ANOVA, $p < 0.0001$). The spherical equivalent refractive error did not change significantly between the morning and afternoon for any of the visits (repeated-measures ANOVA, $p > 0.05$).

The mean ± SD spherical equivalent refractive errors of the right eye at each visit are shown in Fig. 2. A similar plot for the two astigmatism components, J_0 and J_{45}, is shown in Fig. 3. The mean

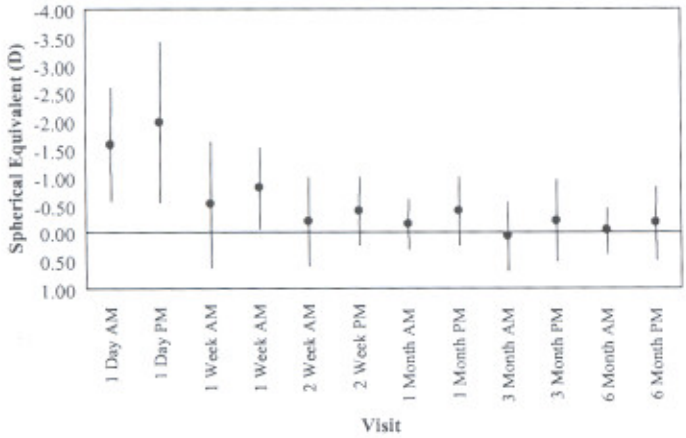

FIGURE 2.

Mean ± SD spherical equivalent manifest refraction at each visit of the COOKI pilot study. The horizontal dashed line represents a planorefraction.

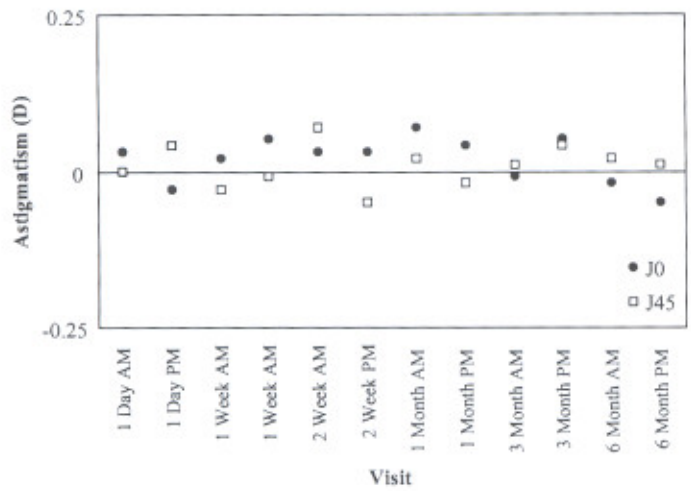

FIGURE 3.

Mean astigmatism components (J_0 and J_{45}) at each visit of the COOKI pilot study.

± SD spherical equivalent refractive error of the right eye before contact lens wear was −2.44 ± 1.38 D, and it was −0.16 ± 0.66 D at the 6-month afternoon visit. The subjects had very little astigmatism at the beginning of the study, and no astigmatism was induced with contact lens wear. The astigmatism did not change significantly between baseline and any subsequent afternoon visit, nor did it change significantly between the morning and afternoon during any visits (repeated-measures ANOVA, $p > 0.05$).

The uncorrected high-contrast and low-contrast visual acuities of the right eye at the afternoon visits are shown in Table 3. The uncorrected visual acuity at every afternoon visit was significantly improved from the baseline uncorrected visual acuity (repeated-measures ANOVA, $p < 0.0001$). At the 6-month afternoon visit, the mean Snellen equivalent of the logMAR visual acuity was 20/24; 47.4% of the right eyes were 20/20 or better, and all eyes were 20/40 or better. There was a 14-letter difference between the high- and low-contrast visual acuity at the 6-month afternoon visit (Table 4). For the roughly 6-hour period between morning and afternoon visits, the mean ± SD change in uncorrected visual acuity is shown in Table 4. The high-contrast visual acuity in the right eye did not change significantly between the morning and afternoon at any visit (repeated-measures ANOVA, $p > 0.05$).

The proportion of right eyes that showed any staining and the proportion of specific types of staining at each visit are shown in Table 5. During the morning visits, 58.8% of the subjects exhibited corneal staining, and 35.3% of the subjects exhibited corneal staining during the afternoon visits. When staining was present, the mean severity in the morning was 1.6, and the mean severity was 1.3 in the afternoon. The most common type of staining pattern was punctate; about 69.9% of all staining recorded was of the punctate type. In the morning, 77.8% of the staining was central, but in the afternoon 47.5% was central and 45.0% was inferior.

DISCUSSION

We have shown that the majority of our sample of 8- to 11-year-old children were able to wear CRT contact lenses. After 6 months, the mean reduction in myopia was −2.48 ± 1.57 D (98%). This reduction in myopia is a great improvement over spherical corneareshaping lens designs,[21, 25, 28] and it is similar to that of other reverse-geometry designs.[29–31, 33] About 2 weeks after the induction of contact lens wear, the subjects exhibited near resolution of nearsightedness throughout the day, which is in the range of times reported by other studies.[30, 31, 33]

The percentage of myopia reduction presented in our sample of

TABLE 3.

Snellen equivalent from logMAR uncorrected high- and low-contrast visual acuities at the baseline visit and the afternoon visits and the change in logMAR uncorrected high-contrast visual acuity over the approximate 6-hour period between the morning and afternoon visits

Visit	High Contrast (Mean ± SD)	Low Contrast (Mean ± SD)	Change in High-Contrast logMAR Acuity over 6-Hour Period (Mean ± SD)
Baseline	0.67 ± 0.22 (20/94)	0.81 ± 0.21 (20/129)	Not applicable
1 Day	0.50 ± 0.22 (20/63)	0.78 ± 0.21 (20/121)	+0.06 ± 0.19
1 Week	0.28 ± 0.21 (20/38)	0.55 ± 0.22 (20/70)	+0.03 ± 0.10
2 Weeks	0.16 ± 0.21 (20/29)	0.41 ± 0.24 (20/52)	+0.08 ± 0.13
1 Month	0.14 ± 0.15 (20/28)	0.38 ± 0.23 (20/48)	−0.01 ± 0.12
3 Months	0.14 ± 0.22 (20/28)	0.33 ± 0.22 (20/43)	+0.07 ± 0.15
6 Months	0.08 ± 0.15 (20/24)	0.36 ± 0.19 (20/46)	−0.05 ± 0.14

TABLE 4.
Amount of regression in the spherical equivalent of the manifest refraction between the morning visit and the afternoon visit

Visit	Change in Spherical Equivalent (D) (Mean ± SD)
1 Day	−0.22 ± 0.90
1 Week	−0.44 ± 0.96
2 Weeks	−0.30 ± 0.39
1 Month	−0.13 ± 0.45
3 Months	−0.26 ± 0.51
6 Months	−0.17 ± 0.62

The minus number indicates that the average subject became more myopic over the course of a day.

children was greater than that estimated from the study of Lu et al.[34] We limited the range of myopia in our study to include only those subjects we believed could achieve complete resolution of myopic refractive error. Lu and colleagues included subjects with refractive errors of up to −10.75 D, whom you would expect not to achieve complete myopia reduction. This may explain why the percentage of myopia reduction estimated from their data was much lower than what other studies achieved.

Due to the high correlation between uncorrected refractive error and uncorrected visual acuity,[36] the pattern of improvement in visual acuity is very similar to the pattern of reduction of refractive error. After about 2 weeks of overnight contact lens wear, the subjects were able to see clearly throughout the entire day. After 1 month of contact lens wear, some subjects reported that they were able to wear their contact lenses every other night rather than every night, and they still experienced clear vision throughout the second day.

Two subjects chose not to wear contact lenses within the first 2 weeks, primarily because they were not motivated to insert and remove their contact lenses. Their spherical equivalent refractive errors ranged from −1.25 to −2.25 D, so they were satisfied either with their uncorrected vision or with their glasses. The subject who wore her contact lenses for nearly 6 months stopped wearing them due to poor vision, poor comfort, and difficulty with insertion and removal of the contact lenses. At the 3-month visit, the subject had no visual or asthenopic complaints, but over the next 2 months she became dissatisfied with contact lens wear. The two subjects who could not be fitted properly with CRT contact lenses had flat corneal meridians of 41.50 and 39.50 D, with spherical equivalent refractive errors of −4.25 and −1.00 D, respectively. Their corneas were too flat to achieve a good contact lens fit that would allow us to correct the given myopic refractive error with contact lenses.

The uncorrected visual acuity reached acceptable levels within 1 week, but it took about 2 weeks to sustain this effect throughout the day. Low-contrast visual acuity is a sensitive indicator of vision loss due to ocular disease, but the difference between high- and low-contrast visual acuity is unaffected by optical blur. The mean difference between the low-contrast visual acuity and the high-contrast visual acuity at the 6-month afternoon visit was 0.29 ± 0.09 logMAR (about three lines). This result is similar to the difference found for adult subjects wearing spectacles, soft contact lenses, or rigid contact lenses[37] and also similar to that of subjects after photorefractive keratectomy.[38]

An adverse event was defined as any symptomatic eye problem that required one or more nights without contact lens wear for resolution of the problem. Although subjects lost or broke their contact lenses, these were not considered adverse events because they were not symptomatic eye problems. One subject experienced an adverse event during the 6-month study. That subject felt like he had sand in the eye after making a picture with sand and glue, but he inserted the contact lens that night. The eye was red and irritated upon awakening. After seeking care from the study doctor, the subject discontinued contact lens wear for one night. The abrasion completely resolved, and the subject was able to resume contact lens wear one night later.

About three-fifths of the subjects exhibited corneal staining immediately after contact lens removal, and one-third still exhibited corneal staining in the afternoon. These proportions are relatively high, but the staining was not serious enough to warrant discontinuation of contact lens wear. On a scale of 1 to 4, with 1 representing trace staining, the mean grade of stain in the morning was

TABLE 5.
Proportion of right eyes with staining at each visit and the number of subjects with specific types of staining

Visit	No. of Eyes (%) with Staining	Arc (n)	Punctate (n)	Foreign Body (n)	Coalesced (n)
1 Day, morning	20 (42.3)	8	10	2	0
1 Day, afternoon	7 (23.8)	4	2	0	1
1 Week, morning	23 (68.4)	8	15	0	0
1 Week, afternoon	18 (55.6)	0	15	3	0
2 Weeks, morning	20 (66.7)	4	15	0	1
2 Weeks, afternoon	9 (40.0)	0	8	1	0
1 Month, morning	28 (70.6)	12	15	0	1
1 Month, afternoon	9 (39.1)	0	8	0	1
3 Months, morning	10 (47.1)	2	8	0	0
3 Months, afternoon	6 (35.7)	0	6	0	0
6 Months, morning	13 (57.9)	0	11	2	0
6 Months, afternoon	3 (17.7)	0	3	0	0
Total	166 (47.1)	38	116	8	4

only 1.6. Subjects wore their contact lenses to most morning visits, and an assessment of staining was made about 15 minutes after contact lens removal. Most corneal staining evaluations do not occur within 15 minutes of contact lens removal after night wear, so a lower proportion of patients who show corneal staining is typically observed. Furthermore, we evaluated the corneal staining using a Wratten filter, which highlights corneal staining better than a cobalt blue filter alone. Although the prevalence of corneal staining does seem relatively high, the severity is very low and does not pose a threat to the patients' wearing the contact lenses.

During this study, we encountered some situations that required unique solutions. During the first 2 weeks of CRT contact lens wear, subjects were allowed to wear their contact lenses to alleviate the blur that they experienced later in the day. Subjects who lost or broke their contact lenses after they wore them for about 1 month were able to wear the contact lens in one eye for one night and then in the other eye for the next night; they continued contact lens wear in alternating eyes until a new contact lens arrived if the parameters of the two contact lenses were similar. This allowed them to continue CRT contact lens wear without having to restart the process when a lens was lost. Clean contact lenses were also important for patient comfort, so routine use of a protein-removing drop like SupraClens (Alcon, Fort Worth, TX) helped to prevent problems. Routine use of artificial tears at bedtime also made the contact lenses more comfortable upon awakening and less likely to cause problems upon removal of the contact lenses.

In summary, CRT contact lenses are efficacious for young, myopic children, and no children experienced a serious adverse event during the study. The children were able to see clearly throughout the day without glasses or contact lenses, and none of them experienced serious problems during the study.

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