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Adverse Events during 2 Years of Daily Wear of Silicone Hydrogels in Children

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Abstract

Purpose—Type and incidence of adverse events and rate of discontinuations for 2 years of daily wear with silicone hydrogel contact lenses in Chinese children with myopia.

Methods—Two hundred forty children aged 7 to 14 years were enrolled in a prospective randomized clinical trial from November 2008 to April 2009. Children with myopia of up to −3.50 diopters (D) spherical equivalent with astigmatism less than or equal to −0.75 D were randomized to one commercial and three experimental lens designs of Lotrafilcon B silicone hydrogel lenses (four groups) used bilaterally on a daily wear, monthly replacement schedule. The main outcome measures were incidence per 100 patient-years (incidence, in percentage) of adverse events and rate of discontinuations.

Results—There were no events of microbial keratitis. Fifty-five adverse events (incidence, 14.2%) were seen. There were also 12 recurrent events. The type and incidence percentage were contact lens papillary conjunctivitis (16 events, 4.1%), superior epithelial arcuate lesions (SEALs, six events, 1.5%), corneal erosions (eight events, 2.1%), infiltrative keratitis (five events, 1.3%), asymptomatic infiltrative keratitis (seven events, 1.8%), and asymptomatic infiltrates (13 events, 3.42%). There were differences in the incidence of SEALs between groups ($p = 0.023$), with the incidence of SEALs being greater with one of the experimental designs. No event resulted in any vision loss. Seventy participants (29.2%) discontinued, with one-third (26 participants, 10.8%) occurring in the first month of lens wear. Discomfort and non-lens-related reasons such as safety concern and disinterest were frequently cited reasons for discontinuations.

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Conclusions—Adverse events with daily wear of silicone hydrogels in children were mainly mechanical in nature, and significant infiltrative events were few. The large number of dropouts in the early days of lens wear and their reasons for discontinuation suggest that adaptation and patient motivation are critical for survival in lens wear.

Keywords

contact lenses; children; adverse events; dropouts; silicone hydrogel contact lenses

A range of childhood disorders of the eye such as keratoconus, amblyopia, pediatric aphakia, and common refractive errors such as myopia can be effectively managed with contact lenses.^{1–9} Also, importantly, evidence suggests that contact lenses may play a significant role in controlling the progression of myopia.^{10–13} Despite the utility of contact lenses in children, there exists a general perception that contact lenses are not suitable for use in children. This concern stems from two areas (1) handling and care of contact lenses by children and (2) safety of contact lens wear, that is, the risk of developing contact lens–related complications. With regard to handling and managing contact lens wear, there now exists evidence that children aged 8 years and older can independently manage lens insertion and removal and also successfully wear contact lenses.^{7,9} There have been reports of microbial keratitis with contact lens wear in children and were mainly case reports or case series attending emergency departments and involving overnight lens wear or other predisposing risk factors.^{14–16} Although this information is useful in identifying the issues, there is little evidence from large well-designed clinical trials on the rate of complications with long-term use of contact lens wear in children.

Since their introduction in 1999, the use of silicone hydrogel contact lenses has increased significantly.¹⁷ Originally introduced for overnight and continuous use, it was anticipated that the increased oxygen transmissibility would result in a healthier cornea that was capable of withstanding infections. Although the lenses eliminated hypoxia-related complications, it was not clear if silicone hydrogels used on an overnight wear basis impacted on the rate of microbial keratitis or inflammatory events.¹⁸ This led to a shift, with silicone hydrogels increasingly prescribed for use on a daily wear basis rather than continuous wear.^{19,20} A single study reported that the risk of developing adverse events was reported to be lower with daily wear of silicone hydrogels compared with that with continuous wear.²¹ Another study found the incidence of adverse events to be low with daily wear and to vary with the lens care system used.²² However, the latter study was short-term, and the lenses were used by an adult population. There have been no studies that have evaluated the incidence of adverse events with daily wear of silicone hydrogels in children.

We initiated a prospective clinical trial in November 2008 involving the use of both standard and novel design silicone hydrogel lenses in Chinese children with myopia. Two hundred forty children were enrolled in the trial, and the aim was to determine the rate of progression of myopia with both standard and novel contact lenses. In the present article, we report the incidence and type of adverse events that occurred during the first 2 years of lens wear. The rate of discontinuations from lens wear and the reasons are also reported.

METHODS

Two hundred forty Chinese children aged 7 to 14 years were enrolled in a prospective clinical trial conducted at Zhongshan Ophthalmic Centre, Guangzhou, China. Enrollment for the study was conducted from November 2008 to April 2009. The eligibility criteria for enrollment in the study were (1) myopia in both eyes with up to -3.50 diopters (D) of spherical equivalent, with astigmatism no more than 0.75 D based on cycloplegic subjective refraction; (2) willing to comply with the wearing and clinical trial visit schedule as directed by the investigator; (3) have ocular health findings considered to be “normal” and that would not prevent the subject from safely wearing contact lenses; (4) have vision correctable to at least 6/9.5 or better in each eye with study contact lenses; and (5) be accompanied by a parent who can read Chinese, understand Mandarin, and provide informed consent. Also, children were excluded from the trial if they had (1) any preexisting ocular or systemic condition that would preclude contact lens fitting and safe wearing of contact lenses; (2) had undergone corneal refractive surgery, myopia control procedures with atropine, or orthokeratology or other procedures; (3) had keratoconus; or (4) any known allergy to, or a history of intolerance to, tropicamide or topical anesthetics. None of the children had any previous experience with contact lens wear. Approval was obtained from the Institutional Ethics Committee, Zhongshan Ophthalmic Centre, and the trial was registered with the Chinese Clinical Trial Registry (Chi CTR-TRC-00000232). All procedures were conducted to the principles and guidelines within the Helsinki Declaration for experimentation on humans.

In the study, all children were randomized to four equally sized groups to wear silicone hydrogel contact lenses (Lotrafilcon B; CIBA VISION, Duluth, GA) that were of (a) standard commercially available design (AIR OPTIX) (single group) or (b) investigational designs aimed at reducing myopia progression (three groups designated I, II, and III, respectively). All lenses had a base curve of 8.6 mm and a diameter of 14.2 mm. With the investigational lenses, the lenses had a central zone to correct for the distance refractive error of the eye and a peripheral optical zone that was relatively positive in power (at 1.5 -mm semichord, a relative plus of 0.0 and $+0.25$ D; at 2.0 -mm semichord, a relative plus of $+0.1$ D, $+0.1$ D, and $+1.0$ D and $+4.0$ D, $+2.0$ D, and $+2.0$ D at the edge of the peripheral treatment zone for I, II, and III, respectively). The total treatment zone was 9.0 mm and was aimed at reducing peripheral retinal hyperopic defocus. All lenses were used on a daily wear basis for a minimum of 8 hours per day, five days per week, and a monthly replacement wear schedule. A hydrogen peroxide-based disinfecting system (AO SEPT or Clear Care; CIBA VISION, USA) was used, and unit dose saline was provided to be used as needed to rinse the lenses or alleviate symptoms of dryness.

Once dispensed with contact lenses, children were examined at 1 month and then at three monthly intervals thereafter. At each visit, best-corrected visual acuity was measured, and a slit lamp examination was performed with and without the contact lens on eye. A detailed evaluation of lids, lid margins, bulbar, limbal, and tarsal conjunctiva and cornea was conducted and included the examination of the cornea and conjunctiva with sodium fluorescein 1%, cobalt blue filter, and Wratten no. 15 filter. Participants were advised to

return to the clinic in the event of any adverse event to lens wear and encouraged to report all symptoms and signs that were unusual.

The management of an adverse event varied depending on the condition. Initially, all events were managed with a temporary discontinuation from lens wear. Children were monitored until resolution of the condition and recommenced lens wear. If recurrence was a feature of the condition; for example, contact lens papillary conjunctivitis (CLPC), participants and their guardians were advised of this possibility before recommencing lens wear.

Statistical Analysis

Adverse events observed during the first 2 years of lens wear were recorded and categorized using the BHVI/LVPEI (formerly the CCLRU/LVPEI) categorization systems of serious, significant, and nonsignificant events (Table 1).²³ Briefly, an event was considered to be serious if it produced or has the potential to cause significant visual impairment and was of sufficient clinical concern to warrant a permanent discontinuation from lens wear (e.g., microbial or infectious keratitis). A significant event was a reaction of sufficient clinical concern to warrant temporary or permanent discontinuation from lens wear (e.g., CLPC, infiltrative keratitis [IK], corneal erosion). A nonsignificant adverse event was not of sufficient clinical concern and may not warrant discontinuation from lens wear (e.g., asymptomatic IK [AIK] and asymptomatic infiltrates [AIs]).

Events were considered per patient. The duration in lens wear for each participant for the 2 years of lens wear was determined, and the total number of patient-years was calculated. Incidence of an adverse event was calculated as the number of adverse events divided by the total number of patient-years and reported as the incidence per 100 patient-years (incidence, in percentage). Differences in the incidence of adverse events between the groups were analyzed using two-sided Fisher exact mid p test for incidence rates, and when significant, further comparisons were made using *post hoc* comparisons with p values corrected for multiple comparisons using Bonferroni correction. Significance was set at $p < 0.05$.

As the study was designed to test myopia progression and not specifically adverse event rates, a *post hoc* power analysis is presented. The average patient-years per lens type is 97. For all adverse events, assuming the least incidence to be 10%, the power to detect a difference of 5, 10, and 15% between lens types was 18, 50, and 79%, respectively, at the 5% level of significance. For individual adverse events, assuming the least incidence to be 0%, the power to detect a difference of 3, 5, 7, and 9% between lens types was 37, 58, 74, and 85%, respectively, at the 5% level of significance.

RESULTS

Of the 240 children enrolled in the trial, 189 children completed 12 months of contact lens wear, and 170 children completed 24 months of lens wear. The demographic data of children who commenced lens wear are given in Table 2. The patient-years for 24 months of lens wear was 388 for all participants, 108 for participants with the commercial design, and 97, 87, and 96 for participants wearing investigational lens I, II, and III, respectively.

Adverse Events

A total of 48 participants experienced 55 events, giving an incidence of 14.2 per 100 patient-years. In addition, there were 12 recurrent events.

The incidence with the commercial lens was 16.7 per 100 patient-years and 9.3, 20.7, and 10.4 with the experimental lenses I, II, and III, respectively. There was no difference in the incidence between the groups ($p = 0.085$).

There were no serious adverse events, that is, microbial keratitis, seen during the study period.

The individual events and the differences between the groups are explored in the following sections.

Significant Adverse Events

A total of 35 significant adverse events were seen and include CLPC, superior epithelial arcuate lesions (SEALs), corneal erosions, and IK. There were an additional eight recurrent events. Fig. 1 details the incidence for first and recurrent events for each of the event types for each of the four groups.

Contact Lens Papillary Conjunctivitis—Sixteen events of CLPC were observed (seven bilateral and nine unilateral) and accounted for the highest number of individual events. Eight of these events were local, and the remaining eight were general CLPC. There were seven recurrent events. One participant with a bilateral event had a further two recurrent episodes (total of four recurrent events). The participants were managed with 0.02% fluoromethalone four times a day for the last episode and discontinued from the study. Others were managed by temporary discontinuation from lens wear ranging from 2 to 7 weeks and recommenced lens wear. Two participants dropped out from the study, citing discomfort with lenses and another subject for non-lens-related reasons (they were living in a hostel and could not practice good hygiene).

Superior Epithelial Arcuate Lesions—There were six events of SEALs (one bilateral and five unilateral). There were three recurrent events. All events were observed at scheduled visits. The incidence of SEALs between the lens types was significant ($p = 0.023$), with investigational lens II showing a high incidence compared with the other lens-wearing groups. All events were managed by temporary discontinuation from lens wear and use of unit dose saline as required. The advised period of discontinuation was usually 1 week. Three participants returned to the clinic at 1 week, and the event was found to have resolved. The remaining three participants returned at 14 days, 25 days, and 3 months from the visit at which time all events were found resolved.

Corneal Erosions—There were eight events of corneal erosions (one bilateral event). There were no differences in the incidence of corneal erosions between the lens types ($p = 0.296$). All events were managed by temporary discontinuation from lens wear ranging from 2 to 7 days. Vision was not affected in any event. Except for one event that occurred at an unscheduled event, all events were diagnosed at scheduled visits and were mostly mild

events (five mild and four moderate in severity). The event that occurred at the unscheduled visit was treated with antibiotics and patching. This participant later discontinued from the trial (1 day later), and the reason cited was that the teacher did not want the child to wear contact lenses.

Infiltrative Keratitis—There were five events of IK (one bilateral presentation). There were no events of IK in the group wearing experimental lens III, and the differences between groups were not significant ($p = 0.386$). Vision was not affected in any of the events. One event was continued in lens wear and monitored 14 days later at which time the event was found to have resolved. The remaining patients were managed by temporary discontinuation from lens wear, and one patient was managed with naphazoline eyedrops and hyaluronate sodium eyedrops four times a day each and 0.3% tobramycin eyedrops four times a day for 21 days. All participants continued in the study after resolution of the event.

Nonsignificant Events

Asymptomatic IK and AIs were the nonsignificant events seen during the study period. A total of 20 nonsignificant events were seen. There were four recurrent events. The incidence is presented in Fig. 2.

Asymptomatic Infiltrative Keratitis—Seven events of AIK were observed (two bilateral events). And there were two recurrent events. There were no differences in the incidence of AIK between the groups ($p = 0.058$). All patients were managed by temporary discontinuation from lens wear and ranged from 7 to 14 days. All participants continued lens wear on resolution of the event.

Asymptomatic Infiltrates—Thirteen events of AIs were seen (two bilateral presentations). Also, there were two recurrent episodes. There were no differences in the incidence of AIs between groups ($p = 0.609$). All participants continued lens wear and were examined at their next scheduled visit, except for one participant where lens wear was discontinued for 1 day. Two participants discontinued from the study for other reasons (one participant cited discomfort and another participant was not willing to continue as it was heard that contact lens wear was not safe).

Time of Occurrence of Events—Fig. 3 represents the time of occurrence of the events. A number of SEALs occurred in the first month of lens wear, with no further events after 8 months of lens wear. Similarly, corneal erosions occurred in the first few months of lens wear, with no events after 11 months of lens wear. The number of IK was low, but there seemed to occur through the study period and not related to time in lens wear. The first event of CLPC occurred at 2 months and AIK at 3 months. Events of CLPC, AI, and AIK continued to be observed through the study period.

Discontinuations and Dropouts from Lens Wear—A total of 70 participants (29.2%) discontinued lens wear during 24 months of lens wear. The discontinuation rate was 20.6% with the commercial lens compared with the experimental groups, with 25.9, 36.2,

and 34.4 for groups I, II, and III respectively. The differences between the groups were not significant ($p = 0.192$).

Table 3 lists the reasons for discontinuations and dropouts and as seen, discomfort, non-product-related reasons, and disinterest were the most frequently cited reasons. One of the participants with discomfort had an event of CLPC. The primary reason for non-product-related discontinuation was related to safety concerns (eight of 15 participants). Interestingly, three of these eight participants reported that their teachers did not want them to wear lenses because of safety reasons.

Of the three participants discontinued from lens wear citing symptomatic lens wear, two participants reported redness with lenses. No reason was provided by the other participant.

As seen from Fig. 4, nearly one-third of the discontinuations occurred in the first month of lens wear and half by 3 months of lens wear.

Of the 70 discontinuations and dropouts, only eight participants had experienced an adverse event. Of the study population, the discontinuation rate was significantly greater in those who did not experience an event (62 of 189) compared with those who experienced an event (eight of 51) ($p = 0.023$).

DISCUSSION

The current study found an incidence of 14.2 per 100 patient-years for adverse events with daily wear of silicone hydrogels in children. When only the commercially marketed lens was considered, it was 16.6 per 100 patient-years and not different to other groups. No events of microbial keratitis were seen. The incidence of significant events, that is, CLPC, corneal erosions, SEALs, and IK was 9.0 per 100 patient-years, with the incidence of significant corneal infiltrative events (IK) small at 1.3 per 100 patient-years.

The most frequently encountered adverse event was CLPC, followed by corneal erosions and SEALs. The incidence of CLPC at 4.1 per 100 patient-years is similar to that reported with the use of Lotrafilcon A lenses on a continuous wear basis.^{23,24} Other studies reported the incidence as the number of events per eyes rather than patients, and therefore, it was not feasible to compare with the rate from this series, but generally, the incidence of CLPC is seen to vary widely.^{21,23,25,26} Lens material properties, replacement frequency, follow-up frequency, consideration of recurrent and bilateral events, care systems, and patient-related factors may all play a role and may account for the variation between studies. And indeed, in the current study, using a similar lens material, care system, protocol of lens wear, the incidence between the groups varied from 2.1 to 7.3 per 100 patient-years. Whereas patients with CLPC are normally permanently discontinued from lens wear, in the current study, they were temporarily discontinued, monitored, and reintroduced to lens wear when the condition subsided. Recurrent events were observed in six of the 16 participants. Such high recurrence indicates that lens wear may be fraught with symptoms and periods of break from lens wear and may lead to discontinuation from lens wear. Indeed, CLPC is recognized as one of the leading causes of discontinuations from lens wear and led to discontinuation for three of the 16 participants with CLPC in the study. From the present data (Fig. 3), CLPC is seen to

occur throughout the study. Contact lens papillary conjunctivitis with silicone hydrogels is known to present as either a generalized response involving the entire tarsus or present with papillae localized to specific areas, and it was thought that the etiology may be different for the two responses.²⁷ In the current study, an equal number of general and local responses were seen. Also, in a previous study, we found increased levels of IgE in worn silicone hydrogels retrieved from eyes with local and general CLPC,²⁸ suggesting that both local and general CLPC may share similar pathways, that is, an immune response to unknown antigens either from the lens or the tear film during contact lens wear. Eyes with a frequent history of allergy are considered to be more susceptible to CLPC,²⁹ and as children are more likely to develop atopic conjunctivitis, contact lens wear may increase the risk of developing papillary conjunctivitis in children with a predilection for atopy.

Events of corneal erosions and SEALs were generally asymptomatic and were diagnosed at scheduled visits, except for one symptomatic event of corneal erosion. Events of SEALs and corneal erosions have been reported with the use of silicone hydrogels.^{21,23–26,30} Superior epithelial arcuate lesions were typically found in the superior cornea close to the limbus, whereas corneal erosions were noted all over the cornea. Interestingly, unlike in the present series, where many corneal erosions were asymptomatic, corneal erosions are commonly symptomatic. During extended wear, corneal erosions are observed on or soon after waking, and it is thought that a combination of factors, including a thin tear film behind the lens, possibly an adhered lens, and the mechanical forces imparted by the lid on the lens and eye with blink, leads to a shearing effect and a painful eye. Although the factors underlying the development of a corneal erosion during daily wear of contact lenses are unclear, because of the decreased risk of there being an adhered lens, it is possible that the symptoms and the signs are not as acute as observed with overnight wear. All of the events in this series were rated to be mild in severity. And it is also possible that the lens itself may have acted as a bandage lens. Although there were no differences between the lens types for corneal erosions, a significant difference was found for SEALs between the lens types. Of the experimental groups, eyes wearing lens type II witnessed more SEALs. There were no events with the commercial lens and experimental lens III. Given the lack of events with the commercial lens and increased incidence with an experimental lens design, it is possible that lens design played a role. It was previously suggested that one should consider a different lens design to prevent recurrence of SEALs.²⁵ Interestingly, both SEALs and corneal erosions occurred early on during the study especially in the first month of lens wear and were not observed after a few months of lens wear. A similar decrease in the event rate was observed for SEALs in other studies. The reason for this is not clear but suggests an adaptation mechanism of the ocular surface to lens wear. Despite the mild nature of these events, such episodes require temporary discontinuation and breaks from lens wear and follow-up visits to the clinic and may encourage dropouts from lens wear because of the associated inconvenience.

The incidence of significant corneal infiltrative events was small at 1.3 per 100 patient-years. Very few events were seen, and there were no differences between the groups. No events of active contact lens peripheral ulcer were observed. It has been reported that events of contact lens peripheral ulcer may be asymptomatic, resolve even with lens wear, and present as scars at follow-up visits.³¹ It is a limitation of the current study that scars were not

recorded, and thus, it is possible that the incidence of significant infiltrative events is underestimated. Many more asymptomatic infiltrative events (AIK and AIs) were seen, usually at scheduled visits, and were mild in nature. However, we believe that the AIs are of little clinical significance because these events are also observed in normal non-contact lens-wearing eyes. Using the same categorization system, in an earlier study conducted at Hyderabad, India, we found 1.6% of normal, adult, and non-contact lens-wearing population to have these infiltrates and recorded these events at a rate of 11.3 events per 100 eyes per year of spectacle wear.³¹ In the current study, when all the infiltrative events were combined (both symptomatic and asymptomatic events across all lenses), the incidence was 6.4 events per 100 patient-years. A review of all corneal infiltrative events from various studies involving mainly adult wearers found the incidence of symptomatic events during daily wear of silicone hydrogels to range from 2 to 3% and increased to 7 to 20% when asymptomatic events were included,³² and the values from the current study seem to be within this range. It should be noted that a study that involved the use of low Dk soft contact lenses during a 3-month period in Singaporean children aged 8 to 11 years on a daily disposable basis did not report any infiltrative events.³³ And a multicenter retrospective chart review of 3549 soft contact lens wearers for significant infiltrative and inflammatory events found that use of soft contact lenses in young patients aged 8 to 15 years was associated with a lower risk of events compared with teens and young adults.³⁴ Whatever the mechanism, the low incidence, the asymptomatic nature of the majority of infiltrates, and the mild nature of the condition are promising for the use of daily wear contact lenses in children.

Although the low incidence and the less severe nature of adverse events are promising, approximately 30% of the study population discontinued during 24 months of lens wear. The differences between the groups for discontinuation were not significant. Discontinuations/dropouts for daily wear of soft lenses in children and adolescents ranged from 4 to 10%^{33,35,36} and 15.1% involving adults and both daily and extended wear with silicone hydrogels.²¹ When we charted the time to discontinuations, one-third of all dropouts were found to occur in the first month of lens wear (10.8% of the study population by the end of the first month). As with other reports,³⁷ discomfort with lens wear was the most frequently cited reason. Except for one child who reported itching with lenses and another child who reported discomfort soon after an event of CLPC, no further description of “discomfort” was provided. Other cited reasons for discontinuations were “disinterest.” In addition, a substantial number of participants discontinued citing safety reasons. This was expected given the general concern with contact lens wear for a young population. But we found no association between adverse events and discontinuations. And, of all the participants who discontinued, only 11% had adverse events. But given these reasons for discontinuation and the high discontinuation rate in the first month of lens wear, it seems that adaptation and motivation to wear contact lenses are significant factors for survival in lenses. The current study did not institute any adaptation period, and willing participants who met the inclusion criteria were enrolled. We believe this reflects the normal practice in the general population and, thus, the observed trends with dropouts applicable to the wider population.

In summary, the incidence of adverse events with daily wear of silicone hydrogels seems to be low, and the events seem to be mainly mechanical in nature. However, it is still desirable that the incidence is further reduced and the children are managed with appropriate lens and care systems. The data also suggest that a high percentage of children are likely to drop out in the initial period of lens wear because of adaptation issues such as discomfort and handling, convenience, and safety concerns. In addition, certain mechanical events such as SEALs and corneal erosions are more likely to occur in the first few months of lens wear. Supporting the children and their parents during this critical period with appropriate lens care and management techniques and more frequent contact to address these concerns may help improve the survival rates.

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FIGURE 1.
Incidence of significant adverse events.

FIGURE 2.
Incidence of nonsignificant adverse events.

FIGURE 3.
Time of occurrence of events.

FIGURE 4.
Cumulative discontinuation rate (%).

TABLE 1

Brien Holden Vision Institute-LV Prasad Eye Institute (formerly Cornea and Contact Lens Research Unit-LV Prasad Eye Institute) classification of contact lens–related adverse events

Classification	Adverse event	Signs	Symptoms
Serious	MK	Large, irregular focal infiltrate (>1 mm); satellite lesions; significant diffuse infiltration, loss of overlying epithelium	Pain, redness, decreased vision, tearing, discharge, photophobia, swollen lids
Significant (infiltrative)	CLARE	Diffuse infiltration in peripheral cornea; multiple small focal infiltrates; overlying corneal staining uncommon	Pain, irritation, redness, tearing, photophobia, symptoms on or soon after waking
	CLPU	Single, circular focal infiltrate (up to 2 mm); peripheral or midperipheral location; overlying corneal staining; surrounding diffuse infiltration	May range from pain, irritation, redness, tearing to asymptomatic
	IK	Diffuse or small focal infiltration in anterior stroma, with overlying corneal staining	Irritation, redness, tearing, and discharge
Significant (mechanical)	CLPC	Papillae on upper tarsus, localized to one region or evenly distributed across tarsus	Itchiness, stringy discharge, excessive movement of contact lens on eye, redness, blurred vision with contact lens (because of discharge or deposition on lens)
	SEAL	Arc shaped, grayish white, peripheral lesion in the superior cornea. Corneal staining and surrounding diffuse infiltration	Commonly asymptomatic. May sometimes present with irritation or edge awareness
	CE	Discrete area of full thickness loss of epithelium; may be single or multiple	Pain, watering, redness, photophobia
Nonsignificant	AIK	Mild infiltration—small, focal, or diffuse infiltrates with overlying corneal staining	Asymptomatic
	AI	Mild infiltration—small, focal (0.2 mm), with occasional diffuse infiltrates. No corneal staining	Asymptomatic

AI, asymptomatic infiltrate; AIK, asymptomatic infiltrative keratitis; CE, corneal erosion; CLARE, contact lens acute red eye; CLPC, contact lens papillary conjunctivitis; CLPU, contact lens peripheral ulcer; IK, infiltrative keratitis; MK, microbial keratitis; SEAL, superior epithelial arcuate lesion.

TABLE 2

Biometric data of participants in the study (N = 240)

Demographic data	Value
Age, yr	
Mean $\pm$ SD (range)	10.9 $\pm$ 1.8 (7–14)
Sex	
Female:male	118:122
Sphere, D	
Mean $\pm$ SD (range)	–2.18 $\pm$ 0.81 (–0.25 to –3.50)
Cylinder, D	
Mean $\pm$ SD (range)	–0.20 $\pm$ 0.29 (plano to –0.75)
Cycloplegic spherical equivalent, D	
Mean $\pm$ SD (range)	–2.28 $\pm$ 0.82 (–0.50 to –3.88)
Axial length, mm	
Mean $\pm$ SD (range)	24.57 $\pm$ 0.80 (22.21–27.04)
Previous contact lens wear experience	None

TABLE 3

Reasons for discontinuations and dropouts

Reason	No. participants (% of all participants)
Discomfort	20 (8.3)
Non-lens-related reasons	15 (6.3)
Disinterest	12 (5.0)
Lost to follow-up	5 (2.1)
Relocated	6 (2.5)
Could not find time to attend visits	4 (1.7)
Handling issues	2 (0.8)
Symptomatic lens wear	3 (1.3)
Dryness	1 (0.4)
Systemic allergies	1 (0.4)
Lens wear troublesome	1 (0.4)
Total	70 (29.2)