

ORIGINAL ARTICLE

# Risk Factors for Interruption to Soft Contact Lens Wear in Children and Young Adults

Heidi Wagner\*, Robin L. Chalmers†, G. Lynn Mitchell‡, Meredith E. Jansen§, Beth T. Kinoshita†, Dawn Y. Lam||, Timothy T. McMahon†, Kathryn Richdale¶, Luigina Sorbara||, and The CLAY Study Group

## ABSTRACT

**Purpose.** The purpose of this study was to describe age and other risk factors for ocular events that interrupt soft contact lens (SCL) wear in youth.

**Methods.** A retrospective chart review of SCL wearers aged 8 to 33 years at the first observed visit was conducted at six academic eye care centers in North America. Data were extracted from all visits during the observation period (>3 years). Clinical records that documented conditions resulting in an interruption of SCL wear "events" were scanned, masked for age and SCL parameters, and then adjudicated to consensus diagnosis. Generalized estimating equations were used to examine the effect of selected covariates, including age, on the risk of an event.

**Results.** Chart review of 3549 SCL wearers yielded 522 events among 426 wearers (12%). The risk of an event increased from ages 8 to 18 years, showed modest increases between ages 19 and 25 years, and then began to decline after age 25 years. New lens wearers (<1 year) were less likely to experience events ( $p = 0.001$ ). Lens replacement schedule and material were also predictive of interruptions to SCL wear with the lowest risk in daily replacement and hydrogel lens wearers (both  $p < 0.0001$ ).

**Conclusions.** These results suggest that the risk of events that interrupt SCL wear peaks in late adolescence and early adulthood and reflects risk factors identified in prospective contact lens studies. Relative to older teens and young adults, patients younger than 14 years presented with significantly fewer events resulting in interrupted lens wear. (Optom Vis Sci 2011;88:973-980)

Key Words: cornea, contact lens, age, complications, risk

Controlled randomized prospective soft contact lens (SCL) clinical trials and observational studies have found that SCL wearers younger than 25 years are at increased risk for corneal infiltrative events.<sup>1-6</sup> The contact lens literature has established the pattern of and risks for adverse events in older teens and

adults, but there is little information regarding contact lens-related safety outcomes for children and young adolescent lens wearers. The shape of the age-related risk profile, particularly at the lower end of the age spectrum, is unknown.

In addition to age-related risk with SCL wear, clinical case series and retrospective studies of orthokeratology in Asia and the United States suggest that children and teens comprise the main patient pool that develops microbial keratitis with orthokeratology.<sup>7-14</sup> Because of the inherent differences between orthokeratology and SCL wear, the information from the orthokeratology case series has limited utility in comparing the rate of complications with cosmetic SCL wear. However, the orthokeratology experience serves as a reminder that the safety profile of a device adopted for widespread use may differ from the profile garnered during preapproval studies, and that age may be an important variable. In the United States, few adolescents were included in the first preapproval trials of overnight orthokeratology lenses (tisilfocon A; Paragon Vision Sciences, Mesa, AZ),<sup>15</sup> although many teens are prescribed these lenses in practice.

\*OD, MPH, FAAO

†OD, FAAO

‡MAS, FAAO

§OD, MS

||MSc, OD, FAAO

¶OD, MS, FAAO

College of Optometry, Nova Southeastern University, Ft. Lauderdale, Florida (HW), School of Optometry, Indiana University, Bloomington, Indiana (RLC, MEJ), College of Optometry, The Ohio State University, Columbus, Ohio (GLM, KR), College of Optometry, Pacific University, Forest Grove, Oregon (BTK), Southern California College of Optometry, Fullerton, California (DYL), and School of Optometry, University of Waterloo, Waterloo, Ontario, Canada (TTM, LS).

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Myopia control studies suggest that progression of myopia in animals, and possibly in humans, can be tempered by correcting both central and peripheral refractive error.<sup>16–20</sup> Contact lenses may provide an alternative option whereby the adapted optics can be applied directly on the corneal surface for children and young adolescent SCL wearers to maintain a more precise alignment of central and peripheral optics on the retina. If contact lenses become the means of delivering the adapted optics, it will be important to further characterize the factors associated with contact lens-related conditions that interrupt lens wear in children and teenagers.

The FDA encourages health professionals and consumers to voluntarily report serious adverse events related to medical devices, although it requires manufacturers to do so. However, there is a dearth of information available regarding the less serious SCL complications encountered in clinical practice that can interrupt lens wear, and there are no studies that report these events in children and teens.

The specific aim of the Contact Lens Assessment in Youth (CLAY) Study was to ascertain whether, outside of clinical studies, children and teenagers have a higher risk than adults of SCL complications that interrupt SCL wear, and if so, to determine the age at which the risk abates. In this article, we describe age as an independent risk factor along with other risk factors for ocular events that interrupt SCL wear in youth.

## METHODS

### Study Design

A retrospective chart review of SCL patients who received clinical care at six academic eye care centers in North America was conducted to characterize the events that interrupted SCL wear. The observation period for most wearers was from early 2006 to the final date of data entry in the fall of 2009. A secondary sampling protocol was used to enrich the sample for wearers younger than 18 years by including records of wearers whose first visit was in 2005 or 2007. Patient age and pertinent parameters from all clinical visits were entered into a menu-driven online database.

### Subjects

This study followed the tenets of the Declaration of Helsinki. The Institutional Review Board at each participating institution approved the research and granted a waiver of consent before data collection. In the context of this retrospective record review, the terms “subject,” “patient,” and “wearer” were used interchangeably.

At the time of the first observed visit, patients were (1) between the ages of 8 and 33 years; (2) wearing soft lenses (hydrogel or silicone hydrogel); and (3) prescribed lenses with powers between +8.00 D and –12.00 D in either meridian (toric and multifocal lenses allowed). Patients wearing gas-permeable lenses, including orthokeratology or corneal reshaping contact lenses, were excluded, as were patients with a history of refractive or other corneal surgery, a diagnosis of keratoconus, pellucid marginal degeneration or other corneal dystrophy or degeneration, or aphakia.

## Sample Size Calculation

Sample size requirements were modeled to compare the risk of events for the youngest group of SCL wearers (aged 8 to 12 years) to that of older SCL wearers. Although the study was designed to characterize the risk for many different ocular conditions related to SCL wear, the sample size calculations were based on the incidence of infiltrative events from a university clinic reported in a prior study.<sup>5</sup> The primary outcome measure for this calculation was the presence or absence of an inflammatory SCL-related complication in patients aged 18 to 25 years during a similar period of observation. The incidence rate was estimated at 6.7% from that historical dataset.<sup>5</sup> The assumed alpha (two-sided significance test) was 0.05 with 80% power.

Thus, we planned to sample 3324 wearers with oversampling ( $n = 243$ ) in the youngest subgroup aged 8 to 12 years. By sizing the study this way and including an oversampling of the youngest SCL wearers, we could detect a 50% difference in the overall event rate for the youngest wearers (aged 8 to 12 years) and a 40% difference in the inflammatory event rate between the three larger age groups (8 to 17, 18 to 25, and 26 to 33 years). Additional information related to the sampling protocol is described elsewhere.<sup>21</sup>

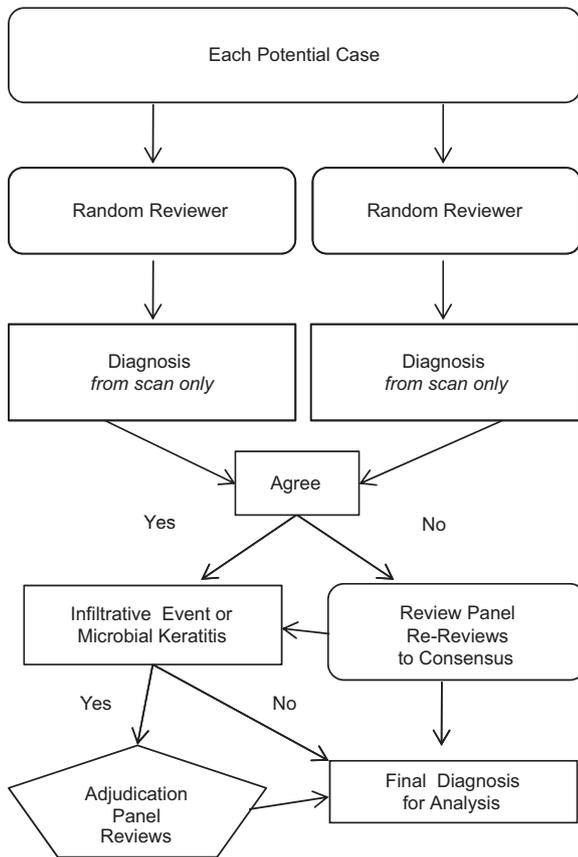
## Identification and Classification of Events

Office visits that resulted in an interruption in SCL wear were identified as an “event” visit; subsequent office visits related to the event were classified as “follow-up visits.” Clinical records from event and follow-up visits were scanned after being redacted for patient privacy information. After receipt at the Data Management Center, patient age, contact lens type, power, and brand were also redacted. All peripheral references to patient age (i.e., “mother says” or “8th grade”) were also removed from the record before preparing the scan for adjudication.

To enhance the precision of the diagnosis and to adopt common diagnostic rubric, masked reviewers adjudicated events to a common diagnosis. Events were adjudicated in two rounds of review that we refer to as the “Review Panel” (initial round) and “Adjudication Panel” (expert panel). Each event was independently diagnosed by two members of the Review Panel (Fig. 1). The co-chair (RC) served as a tie-breaker for the non-agreement and was masked to the previous results when the initial pair of reviewers did not agree; tie-breaker agreement with either reviewer was accepted as agreement. The full Review Panel adjudicated remaining disagreements during a face-to-face meeting. All events without agreement from the initial review stage and all events deemed to be potentially serious and significant (infiltrative and microbial keratitis) were then reviewed to consensus by the Adjudication Panel.

## Analysis

All data analyses were performed using SAS (version 9.2, Cary, NC). Generalized estimating equations were used to characterize the risk of an event with respect to demographic and clinical measures. Generalized estimating equations allow for the specification of the correlation structure introduced when repeated observations on the same subject are used. Univariate models were used to test



**FIGURE 1.**  
Case adjudication process.

the independent effect of each measure on the odds of experiencing an event. A final multivariate model was then determined including all significant factors ( $p < 0.01$ ). Only the first event for wearers with multiple events was used in the analysis. The follow-up visits where the event was resolving were excluded, as were any follow-up visits related to subsequent events. Visits for new wearers who were dispensed lenses but did not return for follow-up were excluded from the analysis of risk for interruption in lens wear. All other visits were included in the analysis. With more than 13,000 visits, it is possible that small effects could be statistically significant but not clinically relevant. The level of significance was set at 0.01 in an attempt to limit the number of spurious findings. To examine the interaction between lens replacement schedule and lens material, the multivariate analysis was repeated with the exclusion of all events associated with daily disposable lenses.

## RESULTS

Age-specific enrollment targets were met and exceeded with charts reviewed for 3549 SCL wearers. There were a total of 260 wearers (7%) aged 8 to 12 years, 879 wearers (25%) aged 13 to 17 years, 1274 wearers (36%) aged 18 to 25 years, and 1136 wearers (32%) aged 26 to 33 years. Additional demographic information regarding the cohort is described elsewhere.<sup>21</sup> This study directly observed 4662.5 years of wear, with an average of 1.3 years per patient (range, 0 to 4.5 years).

The chart review yielded 522 events that interrupted SCL wear among 426 individuals (12% of all wearers). Because only the first

event was used, the analysis encompassed 13,010 visits, including 426 event visits and 12,584 non-event visits. Four percent of the overall events occurred in 8 to 13 year olds whose visits comprised 8.1% of the total. Nearly one third (31.2%) of the events occurred in 14 to 19 year olds (29.8% of visits). In addition, more than one half (51.6%) of the events were observed among the college-aged and young adult wearers (20 to 28 year olds) with 44.3% of visits. The overwhelming majority (88%) of patients exhibited no clinical events that resulted in interruptions in SCL wear during the observation period, whereas a small proportion (1.2%) of total wearers experienced multiple events.

The broad range of conditions that interrupted SCL wear ranged from serious and significant to mild and self-limiting (Table 1). The composition of event types across age groups was similar but the frequency of events by age group varied. Inflammatory conditions were the primary reason for interruption of lens wear across all age groups (34.1% of all events affecting 1.4% of patient visits overall), whereas 18% were allergic in nature (0.7% of patient visits). Almost 12% of events in 0.5% of patient visits were classified as other infectious conditions (not microbial keratitis) that were not necessarily directly associated with use of SCLs, such as bacterial conjunctivitis and viral keratoconjunctivitis. Nearly 10% (0.4% of patient visits) were attributed to mechanical responses to SCLs.

The percentage of visits with an event was  $<2.5\%$  at the youngest ages (8 to 13 year olds) and peaked at 4.5% in the 20 to 22 year olds (Fig. 2). The percentage of events approached 3.5% for the 23 to 29 year olds. The proportion of visits with events that caused interruption of lens wear increased from ages 8 to 18 years, showed only modest increases between ages 19 and 25 years, and then began to decline after age 25 years. The smooth curve shown in Fig. 2 is the representation of the modeled odds of an event at each age. As an example, from the univariate model, the odds of experiencing an event at age 20 relative to age 10 (i.e., a 10 year increase in age) was 2.62 [95% confidence interval (CI), 1.67 to 4.13], whereas the odds of an event at age 20 relative to age 30 (another 10 year increase in age) was only 1.40 (95% CI, 1.31 to 1.49).

Years of CL wear, lens type, lens power, lens material, self-reported replacement schedule, care system, and history of overnight wear were also found to be significantly related to the risk of an event in the univariate models (Table 2). More than 1 year of SCL wear was associated with a twofold increase in risk of an event when compared with new lens wearers ( $<1$  year of wear). The risk of an event was 37% greater among spherical lenses when compared with toric lenses. Levels of ametropia  $>5.00$  D were associated with a 25% decrease in the odds of an event. This is not likely a consequence of age. The mean age of those with ametropia  $>5.00$  D was 23.7 years (range, 8 to 36 years), which compares with the mean for those with ametropia of 5.00 D or less (22.2 years, ranges from 8 to 37 years). Hydrogel lenses were associated with a decrease of one third in the risk of an event. The odds of an event were increased more than twofold for both 1 to 2 weeks and monthly replacement schedules when compared with daily replacement, as well as more than threefold for other replacement schedules. Overnight wear before the event increased the odds of an event by 69%. The effect of overnight wear on risk of event was not mediated by lens material ( $p$  value for interaction = 0.74).

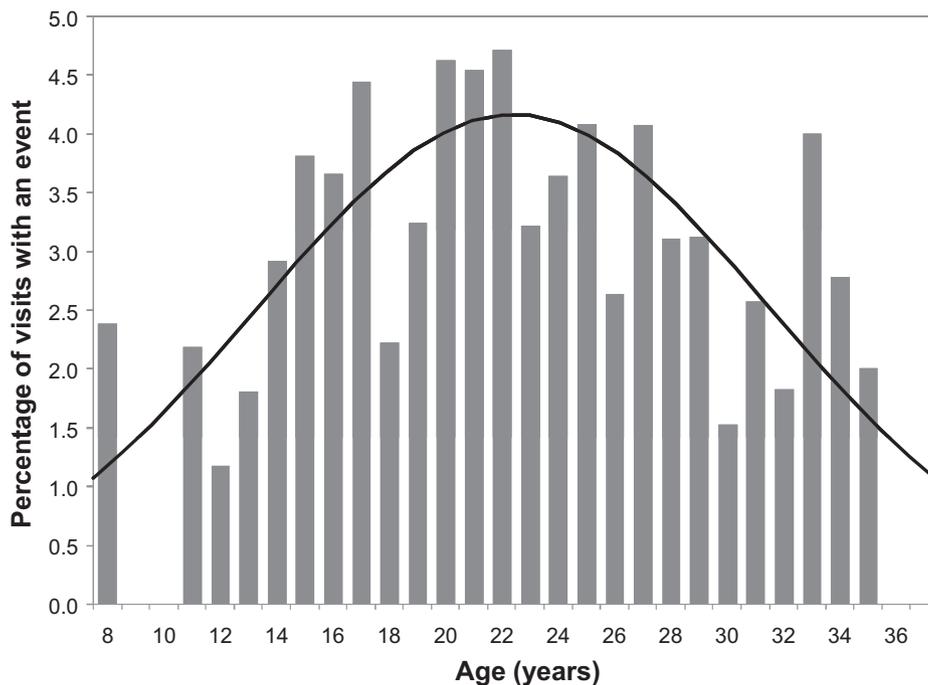
**TABLE 1.**  
Age distribution for incident events

Diagnosis	Total (% visits)	Age at event (yr)			
		8–13 (% visits by age)	14–19 (% visits by age)	20–27 (% visits by age)	28–37 (% visits by age)
All events	522 (4.0)	17 (1.6)	162 (4.2)	246 (4.8)	97 (3.2)
Microbial keratitis	8 (0.1)	1 (0.1)	2 (0.1)	4 (0.1)	1 (0.03)
Inflammatory conditions					
Infiltrative keratitis	110	5	41	48	16
CLPU	41	2	16	16	7
CLARE with infiltrates	14	0	4	6	4
CLARE without infiltrates	13	0	7	5	1
All	178 (1.4)	7 (0.7)	68 (1.8)	75 (1.5)	28 (0.9)
Other infectious conditions					
Herpes simplex keratitis	2	0	2	0	0
Viral keratoconjunctivitis	8	0	1	4	3
Viral conjunctivitis	26	0	7	12	7
Bacterial conjunctivitis	26	0	4	17	5
All	62 (0.5)	0 (0.0)	14 (0.4)	33 (0.6)	15 (0.5)
Conjunctival conditions					
Subconjunctival hemorrhage	3	0	0	3	0
Toxic conjunctivitis	15	0	5	7	3
Conjunctival injection	10	0	3	4	3
Conjunctival abrasion	2	0	0	0	2
Pingueculitis	1	0	0	1	0
All	31 (0.2)	0 (0.0)	8 (0.2)	15 (0.3)	8 (0.3)
Corneal conditions					
Corneal stain, asymptomatic	13	0	4	5	4
Corneal stain, symptomatic	27	1	9	14	3
Microcystic edema	3	0	1	0	2
Corneal laceration	1	0	1	0	0
Thygeson's SPK	1	1	0	0	0
SLK	1	0	0	0	1
All	46 (0.4)	2 (0.2)	15 (0.4)	19 (0.4)	10 (0.3)
Mechanical conditions					
SEAL	15	1	8	5	1
Corneal abrasion	31	1	9	9	12
Foreign body	4	0	0	3	1
Lens stuck/torn	1	0	1	0	0
All	51 (0.4)	2 (0.2)	18 (0.5)	17 (0.3)	14 (0.5)
Allergic conditions					
Allergic conjunctivitis	56	0	15	33	8
Phlyctenulosis	8	0	0	7	1
CLPC/GPC	30	2	11	14	3
All	94 (0.7)	2 (0.2)	26 (0.7)	54 (1.1)	12 (0.4)
Abnormality of lid and adnexa					
Blepharitis	1	0	0	1	0
Trichiasis	1	0	0	1	0
Preseptal cellulitis	1	1	0	0	0
Lice	1	1	0	0	0
Lid inflammation	2	0	1	1	0
Hordeolum	19	1	6	11	1
Chalazion	3	0	0	2	1
Contact dermatitis	2	0	0	1	1
All	30 (0.2)	3 (0.3)	7 (0.2)	17 (0.3)	3 (0.1)

**TABLE 1.**  
Continued

Diagnosis	Total (% visits)	Age at event (yr)			
		8–13 (% visits by age)	14–19 (% visits by age)	20–27 (% visits by age)	28–37 (% visits by age)
<b>Tear abnormalities</b>					
Dry eye	11 (0.1)	0 (0.0)	1 (0.03)	8 (0.2)	2 (0.1)
<b>Other presentations</b>					
Symptoms w/o signs	1	0	0	1	0
Itching	1	0	1	0	0
CL intolerance	4	0	0	1	3
Iritis	1	0	1	0	0
Episcleritis	4	0	1	2	1
All	11 (0.1)	0 (0.0)	3 (0.1)	4 (0.1)	4 (0.1)

The percentage of visits is calculated based on the number of events in the given age group divided by the number of overall visits. CLPU, contact lens peripheral ulcer; CLARE, contact lens acute red eye; SLK, superior limbic keratitis, SPK, superficial punctate keratitis; CLPC, contact lens papillary conjunctivitis; GPC, giant papillary conjunctivitis.

**FIGURE 2.**

The percentage of visits with an event at each age and the odds of having an event from the univariate model.

In a multivariate model, patient age, years of SCL wear, lens material, and self-reported replacement schedule remained significant risk factors (Table 2). As in the univariate model, the risk of an event increased with age until around age 20 and then began to decrease. In fact, from the multivariate model, the odds of experiencing an event at age 20 relative to age 10 (i.e., a 10 year increase in age) was 2.00 (95% CI, 1.15 to 3.47), whereas the odds of an event at age 20 relative to age 30 (another 10 year change in age) was 1.33 (95% CI, 1.25 to 1.42). The multivariate model for the odds of an event at different ages, using the first event only, is illustrated in Appendix (available online at <http://links.lww.com/OPX/A60>).

Experienced lens wearers (>1 year) were more likely to experience an event causing interruption in lens wear [odds ratio (OR) =

2.03, 95% CI, 1.29 to 3.20 for 1 to 5 years; OR = 1.80, 95% CI, 1.07 to 3.02 for 6 to 10 years]. Hydrogel lens wear was again associated with a decrease in the risk of an event compared with silicone hydrogels (OR = 0.72, 95% CI, 0.57 to 0.90). It is noteworthy that when the daily disposables were removed from the model, lens material was still significantly associated with a reduction in the odds of an event ( $p = 0.0001$ ). Although replacement schedule was significantly associated with the odds of an event, this was not due to a difference between daily replacement and either 1 to 2 weeks or monthly wear ( $p > 0.05$ ). Other replacement schedules compared with daily replacement were associated with a 2.69 odds of an event (95% CI, 1.41 to 5.13). Overnight wear, although significant in the univariate model,

**TABLE 2.**

Model for risk of any event, using first event only

Characteristic	Level	Univariate model			Multivariate model				
		p	OR	95% CI	p	Adjusted OR	95% CI		
Age	20 vs. 10 year old	<b>&lt;0.001</b>	<b>2.62</b>	<b>1.67</b>	<b>4.13</b>	<b>0.003</b>	<b>2.00</b>	<b>1.15</b>	<b>3.47</b>
	20 vs. 30 year old		<b>1.40</b>	<b>1.31</b>	<b>1.49</b>		<b>1.33</b>	<b>1.25</b>	<b>1.42</b>
Gender	Female	0.11	1.17	0.95	1.44				
Years of CL wear	1–5 vs. <1	<b>&lt;0.0001</b>	<b>2.01</b>	<b>1.28</b>	<b>3.14</b>	<b>0.001</b>	<b>2.03</b>	<b>1.29</b>	<b>3.20</b>
	6–10 vs. <1		<b>1.92</b>	<b>1.16</b>	<b>3.17</b>		<b>1.80</b>	<b>1.07</b>	<b>3.02</b>
	≥11 vs. <1		1.45	0.75	2.77		1.51	0.77	2.98
Lens type	Sphere vs. toric	<b>0.003</b>	<b>1.37</b>	<b>1.08</b>	<b>1.74</b>				
Lens power	1 D difference in power	0.095	0.98	0.94	1.01				
	>5 vs. ≤5 D	<b>0.012</b>	<b>0.75</b>	<b>0.57</b>	<b>0.97</b>				
Lens material	Hydrogel vs. silicone hydrogel	<b>&lt;0.0001</b>	<b>0.66</b>	<b>0.53</b>	<b>0.82</b>	<b>0.001</b>	<b>0.72</b>	<b>0.57</b>	<b>0.90</b>
Replacement schedule	1–2 weekly vs. daily	<b>&lt;0.0001</b>	<b>2.24</b>	<b>1.30</b>	<b>3.87</b>	<b>&lt;0.0001</b>	1.69	0.95	2.99
	Monthly vs. daily		<b>2.12</b>	<b>1.23</b>	<b>3.67</b>		1.68	0.95	2.96
	Other vs. daily		<b>3.37</b>	<b>1.79</b>	<b>6.36</b>		<b>2.69</b>	<b>1.41</b>	<b>5.13</b>
Care system	H <sub>2</sub> O <sub>2</sub> vs. MPS	<b>0.015</b>	0.85	0.58	1.24				
	Generic vs. MPS		1.17	0.69	2.00				
	None/saline vs. MPS		<b>0.56</b>	<b>0.36</b>	<b>0.88</b>				
Overnight wear	Yes	<b>&lt;0.0001</b>	<b>1.69</b>	<b>1.31</b>	<b>2.18</b>				

Values in bold indicate significance ( $p < 0.01$ ).

MPS, multipurpose solution.

was not associated with an increased risk of event in the multivariate model ( $p = 0.96$ ).

## DISCUSSION

The advantage of using practice-based data in a multicenter study is that it provides a broad view of SCL prescribing, management and treatment patterns. The limitations are a lack of standardization of clinical record keeping and diagnoses. This study sought to overcome these limitations by centralizing the diagnoses in a masked and disciplined adjudication process. The serious and significant corneal complications were classified according to the Cornea and Contact Lens Research Unit Classification System.<sup>22</sup> However, the clinical charts generated a much broader list of complications, in part because they included ocular health conditions unrelated to SCL wear.

The CLAY Study results suggest that age-related risk for events that interrupt SCL wear peaks in late adolescence and early adulthood. Relative to older teenagers and young adults, a smaller proportion of patients younger than 14 years presented with events that interrupted lens wear. The CLAY results show that older teenage and young adult SCL wearers are a group that merits additional study and support because of their tendency to present with infectious and inflammatory events that require more clinical management and utilization of medical resources. An increase in inflammatory corneal events among teenagers may be driven either by the up-regulation of autoimmune mediators or by environmental and behavioral factors such as poor compliance with lens care and replacement schedules.<sup>22</sup>

There are a number of challenges in representing events from a retrospective chart review such as the CLAY dataset. Because it is derived from clinical charts, the data may vary for each patient in terms of observation time, number, and frequency of visits and reason for visits, although they likely do not vary in a way that creates systematic bias. In addition, the observed cohort aged during the 3+ years of potential observation. Age at event was known with a high degree of certainty, but the movement of patients from one age “group” to another as events occurred and varying reasons for visits (changes in refractive error for younger patients) make it difficult to easily visualize the proportion of patients affected by those events.

Normalizing to the number of visits at which patients were a certain age can help this issue, but the data still must not be construed to be reporting an incidence rate, per se. Use of the multivariate analysis controls for many of these factors and therefore is the primary data reported here.

In addition to patient age, years of CL wear, silicone hydrogel lens material, and lens replacement schedule other than daily disposable increased the likelihood of an event. Although use of hydrogel daily disposable lenses was associated with fewer events and silicone hydrogel materials were associated with more events, this pattern remained the same after all events associated with daily disposable lenses were removed from the model. The frequency of events was in keeping with other literature.<sup>23</sup> Some undocumented factors associated with silicone hydrogel lenses may be responsible, such as a tendency for unreported overnight wear (with or without clinician recommendation) or higher lens modulus.

We can anticipate an increase in SCL prescribing among children and teenagers along with the translation of myopia control technologies from animal models to human clinical trials. Sustained delivery of peripheral optical signals may have an influence on the efficacy of myopia control SCL treatments in children and teenagers, and therefore it is critical to understand and anticipate factors associated with interruption of lens wear. Both the low rate of interrupting events and the safety profile of SCLs in this study shows their promise as a method of delivering advanced optics designed to prevent progression of myopia.

In conclusion, in terms of safety and low rates of events that interrupt lens wear, SCLs appear to be an acceptable method to manage refractive error in children, because 98% of the visits by 8 to 13 year olds were not related to contact lens complications during the time of review. Older teens and young adults had a significantly higher rate of events. In addition to age, lens replacement schedule and material were also predictive of interruptions to SCL wear. Therefore, additional study is merited to identify the associated risk factors particularly in wearers more than age 14 and to further characterize the clinical outcomes with contact lens wear. This information can be used to enhance the safety and efficacy of contact lens wear in youth.

## APPENDIX

The appendix is available online at <http://links.lww.com/OPX/A60>.

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## Members of the CLAY Study Group as of August 13, 2010:

### Clinical sites

*Indiana University School of Optometry, Bloomington, IN:* Meredith E. Jansen, OD, MS (Principal Investigator); Angelina Bonner (Data Entry); Kristen Burkholder (Data Entry); and Carolyn Masters (Data Entry).

*Nova Southeastern University College of Optometry, Ft. Lauderdale, FL:* Heidi Wagner, OD, MPH (Principal Investigator); Perla Najman (Co-Investigator); Thuy-Lan Nguyen, OD (Co-Investigator); Steven Warne (Data Entry 2009); and Margi A. Patel (Data Entry).

*The Ohio State University College of Optometry, Columbus, OH:* Kathryn L. Richdale, OD, MS (Principal Investigator); and Austin L. Tanner (Data Entry).

*Pacific University College of Optometry, Forest Grove, OR:* Beth T. Kinoshita, OD (Principal Investigator); and Evelyn Y. Hu (Data Entry).

*Southern California College of Optometry, Fullerton, CA:* Dawn Y. Lam, MSc, OD (Principal Investigator); and Jamie Lam (Data Entry).

*University of Waterloo School of Optometry, Waterloo, ON, Canada:* Luigina Sorbara, OD, MSc (Principal Investigator); Gerry Giddens (Data Entry); and Jyotsna Maram (Data Entry).

### Resource centers

*Data Coordinating Center: The Ohio State University College of Optometry, Columbus, OH:* G. Lynn Mitchell, MAS (Director).

*Event Data Management Center: Robin L. Chalmers, OD (Director); Julia Purser (Data Management); and Lucas Henneman (Data Management).*

### Committees

*Executive Committee:* Robin L. Chalmers, OD (Co-Chair); G. Lynn Mitchell, MAS; Heidi Wagner, OD, MPH (Co-Chair).

*Event Review Team:* Robin L. Chalmers, OD; Meredith E. Jansen, OD, MS; Beth T. Kinoshita, OD; Dawn Y. Lam, MSc, OD; Kathryn Richdale, OD, MS; Luigina Sorbara, OD, MSc; and Heidi Wagner, OD, MPH.

*Serious and Significant Event Adjudication Team:* Mark A. Bullimore, MCOptom, PhD; Robin L. Chalmers, OD; Timothy T. McMahon, OD; and Heidi Wagner, OD, MPH.

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**Heidi Wagner**

*Nova Southeastern University*

*3200 S University Dr.*

*Ft. Lauderdale, Florida 33328*

*e-mail: wagner@nova.edu*