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ORIGINAL ARTICLE

Contact Lens Assessment in Youth: Methods and Baseline Findings

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ABSTRACT

Purpose. To describe the Contact Lens Assessment in Youth (CLAY) Study design and report baseline data for a multicenter, retrospective, observational chart review of children, teenagers, and young adult soft contact lens (SCL) wearers.

Methods. Clinical charts of SCL wearers aged 8 to 33 years were reviewed at six colleges of optometry. Data were captured retrospectively for eye care visits from January 2006 through September 2009. Patient demographics, SCL parameters, wearing schedules, care systems, and biomicroscopy findings and complications that interrupted SCL wear were entered into an online database.

Results. Charts from 3549 patients (14,276 visits) were reviewed; 78.8% were current SCL wearers and 21.2% were new fits. Age distribution was 8 to <13 years (n = 260, 7.3%), 13 to <18 years (n = 879, 24.8%), 18 to <26 years (n = 1,274, 36.0%), and 26 to <34 years (n = 1,136, 32.0%). The sample was 63.2% females and 37.7% college students. At baseline, 85.2% wore spherical SCLs, 13.5% torics, and 0.1% multifocals. Silicone hydrogel lenses were worn by 39.3% of the cohort. Daily wear was reported by 82.1%, whereas 17.9% reported any or occasional overnight wear. Multipurpose care systems were used by 78.1%, whereas another 9.9% indicated hydrogen peroxide solutions use.

Conclusions. This data represent the SCL prescribing and wearing patterns for children, teenager, and young adult SCL wearers who presented for eye care in North American academic clinics. This will provide insight into SCL utilization, change in SCL refractive correction, and risk factors for SCL-related complications by age group.

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Key Words: soft contact lenses, children, teenagers, retrospective, chart review, demographics, age

Despite their young age, children can be successful at rigid gas-permeable and soft contact lens (SCL) wear.[1–4] A comparison of SCL fittings for children (8 to 11 years) and teens (13 to 17 years) demonstrated an increase in the time required to train SCL application and removal.[5] However, once trained, children were equally adept at lens application and removal and their lens wear schedules were similar to the teenage group.[6] Children also benefited from significantly improved quality of life with contact lens wear and improvement in their perception of appearance and participation in activities.[6,7] Regardless, there is still a perception that children may be too young to be prescribed with cosmetic SCLs. Although this is not documented in the literature, this hesitation may stem from fear of non-compliance or the risk of contact lens-related complications, which could lead to loss of vision. There have been no large postmarket evaluations of children and SCL wear in North America. Controlled prospective trials have shown children can succeed with lens wear, but often postmarket evaluation is a truer reflection of health outcomes after the patient is actually using the lens in the marketplace.[8]

Complications such as corneal infiltrative events[9–13] and microbial keratitis[9–18] have often been associated with SCL wear. In addition to factors such as overnight wear and lens material, age (<25 years) is also a significant risk factor for complications with 30 night continuous wear silicone hydrogel lenses and SCLs in general.[10,13,19] The study populations in the randomized prospec-

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tive clinical trials were limited to SCL wearers 18 years or older and as such, it is uncertain if age <18 years is a risk factor for corneal infiltrative events in SCL wearers. The risk and safety profile of any device in children is always a concern. Although the literature is limited on SCL safety studies in North America, a 2010 report by Wang et al.[20] examined the relationship between emergency department visits and medical devices causing adverse effects in children and found a large proportion of corneal abrasions and conjunctivitis in contact lens wearing children (age, 6 to 21 years). Orthokeratology case series in the pediatric population (age, <18 years) report corneal infectious events (microbial keratitis including both *Acanthamoeba* and *Pseudomonas*) originating in East Asia and in association with tap water usage.[21–24] A retrospective study from Taiwan reports 66% of 12- to 16-year olds diagnosed with microbial keratitis were SCL wearers who did not properly disinfect their lenses or who wore their lenses overnight.[25] Despite these case series, there is little research examining normal wearing habits and safety outcomes of young (age, <25 years) SCL wearers. Targeted study of this age group will help determine their risk and safety profile.

Eye care practitioners may be more willing to prescribe SCLs to pediatric patients for medically necessary indications such as anisometropia,[26,27] aphakia,[28] or myopia management with rigid contact lenses.[29–31] Myopia management, whether with spectacles or contact lenses, has been naturally directed toward the pediatric population and is especially popular in Asian cultures with their high prevalence of myopia.[32,33] Recent research in myopia development suggests that peripheral myopic defocus may slow the progression of myopia in the developing eye in both animal and human models.[34–37] If peripheral defocus technology is to be applied to SCLs, it is important to fully characterize and understand the risk for SCL-associated complications and to understand the types of events that interrupt lens wear in children and teenagers.

The Contact Lens Assessment in Youth (CLAY) Study was a multicenter, retrospective, observational study designed to investigate risk factors that interrupt SCL wear among children, teenagers, and young adults in North America. The goal of this observational study was to assess the safety profile of SCL wear in a pediatric population outside the confines of a prospective clinical study. These patients presented to academic eye care clinics for routine and problem-oriented eye care and included both habitual and newly prescribed SCL wearers. This article describes the methodology, the demographics, and clinical characteristics of this observed cohort at the first observed visit.

METHODS

A retrospective chart review of 3549 SCL wearers was conducted for patients aged 8 to 33 years at six academic clinics in North America. Institutional Review Board (IRB) approval was obtained from study sites before data collection. Site specific standard operating procedures were developed to meet IRB requirements, protect patient confidentiality, enhance efficiency, and facilitate data integrity. This research followed the tenets of the Declaration of Helsinki.

Data Collection

At the onset of data collection, an on-site training visit was performed by one of the study co-chairs (RC or HW) to ensure uniform methods of data collection. Patient charts were selected based on clinical visit date and procedure codes. Charts were reviewed without bias to gender, race, or ethnicity. Data capture commenced with charts of SCL wearing patients who received clinical eye care from January 1, 2006, through December 31, 2006. Although retrospective, the first visit entered in the database was referred to as the baseline visit. Data from all subsequent clinical visits were entered up to the final date of data entry (Fall 2009) for each patient. This period is referred to as the observation period.

Age, gender, ethnicity, history of smoking, student status, contact lens history, history of diabetes, allergies, autoimmune diseases, and current medications were collected for each patient chart. Clinical visits were categorized as routine, event, or event follow-up visits and were entered chronologically onto a menu-driven online data collection form. Definitions used in the study are listed in Table 1. For each clinical visit, habitual contact lens power (sphere and cylinder), lens brand, lens replacement schedule, presence of overnight wear, usage of artificial tears, lens care system, biomicroscopy findings and new SCL parameters were recorded. For each event or follow-up visit, presence or absence of SCL wear, biomicroscopy signs, recorded diagnosis, and treatment were collected. The frequency and number of clinical and or event visits per individual varied depending on how often the patient presented to the clinic during the observation period.

Inclusion/Exclusion Criteria

Patients who were aged 8 to 33 years, with a 2006 office visit, wearing SCL powers from +8.00 D to −12.00 D (in either meridian) were included in the study. Current use of rigid gas-permeable lenses, orthokeratology or other corneal reshaping contact lenses, history of refractive or other corneal surgery, diagnosis of keratoconus, pellucid marginal degeneration, other corneal dystrophy or degeneration, and aphakic patients were excluded from the study.

TABLE 1.
Definitions

Current wearers	Patients who had worn SCLs before the enrollment visit.
New wearers	Patients who had never worn SCLs before the enrollment visit.
Routine visit	Clinical visits that were related to routine and or preventative contact lens care.
Event visit	Clinical visit, which resulted in a recommendation to temporarily discontinue lens wear, oftentimes associated with a contact lens-associated complication as diagnosed by the optometric provider.
Follow-up visits	Subsequent clinical visits related to the event visit.
Age	All age bins represent the age at the baseline visit (which could be a study or an event visit).

Sample Size

The study was designed to assess the risk of any ocular complications that resulted in interruption of SCL wear as related to age, with particular emphasis on study of children younger than 18 years. Sample size calculations were based on the estimated incidence of SCL interrupting events (16.9%) and corneal infiltrative events (6.7%) for patients at an academic clinic who were 18- to 25-years old from an historical dataset.[10,19] A total of 1108 patients were required in each age group (8 to 17 years, 18 to 25 years, and 26 to 33 years) to detect a 40% difference in the inflammatory event rate. Within the 8- to 17-year-old group, over-sampling of 8- to 12-year olds was necessary to allow meaningful analysis and comparisons of the overall event rate in this group to that in other age groups. To detect a 50% reduction in the overall event rate, 243 SCL wearers aged 8 to 12 years was required.

Enriching the Sample for the 8 to 17 Age Group

Every effort was made to find and identify all patients with documented SCL-related office visits in 2006 to fulfill the sample size. Each site encountered difficulties locating sufficient children and teenagers (8 to 17 years) who received SCL care for that year. A protocol was developed to enrich this age group by expanding the search to include 2005 and 2007 (Fig. 1). This strategy allowed patients who were 13 years old in 2006 to be enrolled as 12 year olds in 2005 and patients who were 7 years old in 2006 as 8 year olds in 2007. This protocol was applied to the 13- to 17-year-age group where individuals who were 18 years old in 2006 were enrolled as 17 year olds in 2005. If the enrollment targets were still not met, the next step involved a further search for 8- to 12- and 13- to 17-year-old patients who had a clinic visit in 2005 or 2007, but who might not have presented for a 2006 office visit. Site specific procedures ensured that patient charts were not enrolled twice. The enrollment of only young patients in 2005 and 2007 could have caused unequal follow-up times between the age groups. To maintain balance, the sites were instructed to enroll equal numbers of children and adults who had clinical visits from 2005 and 2007.

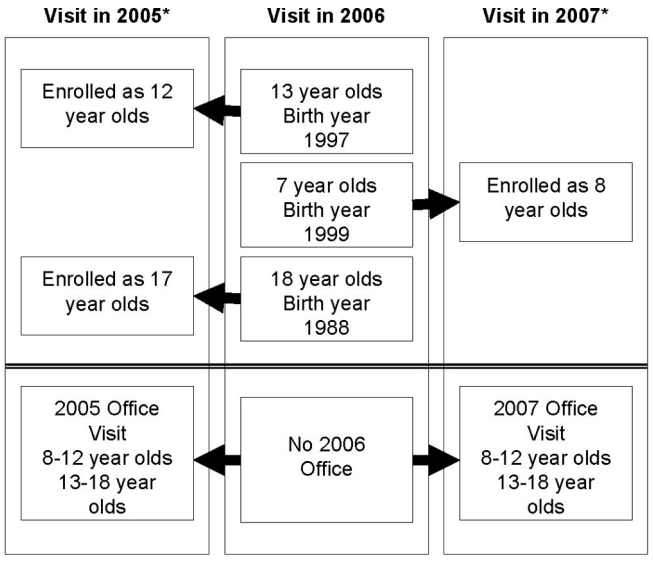

FIGURE 1.

Protocol to enrich the sample of young SCL wearers. The window for data entry was expanded from 2006 to 2005 and 2007 to capture sufficient numbers of 8- to 17-year olds.

Events and Follow-Up Visits

Event visits were defined as clinical visits that resulted in interruption of SCL wear. The recommended treatment plan was entered into the database. Ideally, clinical diagnosis would be standard and equal at all sites; however, because of the retrospective nature of a review, the CLAY Study protocol included a masked adjudication process for the events to be assigned a final diagnosis. Clinical charts for events and all subsequent follow-up visits were scanned (ScanSnap S1500, Fujitsu Computer Products of America, Sunnyvale, CA) after all patient identifying information were masked. Results of the event review process will be described in future CLAY articles.

RESULTS

Enrollment Across Sites

Enrollment goals and target age distribution were met by each site. A total of 3549 patient charts (14,276 visits) with 4663 years of SCL wear (time between first and last observed visits) were reviewed in this data set. All sites enriched the 8 to 17 age group by enrolling patient charts from 2005 and 2007 clinical visits. Thirty-seven percent of 8- to 12-year old and 23.3% of 13- to 17-year-old SCL wearers were enrolled either in 2005 or 2007 (Table 2).

Demographics

Table 3 summarizes the demographic and health history data at the baseline visit. Seventy-nine percent were current SCL wearers with the majority of current SCL wearers between 18 and 33 years whereas the majority of new SCL wearers were between 8 and 12 years. More than 60 percent were females with an increasing proportion of females between 18 and 33 years.

Race and ethnicity were only collected from the five investigational sites in the United States because of IRB restrictions at the University of Waterloo. The largest ethnic group was white (62.2%), followed by Hispanic (14.1%), Asian (10.8%), and Black (10.2%). Among the Hispanic SCL wearers (current and new), there was a disproportionately higher number of patients between 8 and 17 years. In contrast, the Asian SCL wearers showed increasing percentage of wearers from 8- to 33-year olds. Analysis of ethnicity by location revealed Nova Southeastern University, College of Optometry (NOVA), Pacific University College of Optometry (PUCO), and Southern California College of Optometry (SCCO) to be the locations with the most Hispanic SCL wearers with NOVA and PUCO having a disproportionately higher number in the 8 to 17 age range.

Health history, student status, and history of smoking are also reported in Table 3. Thirty-seven percent of the cohort was college students. If the occupation of college student was ambiguous, patients who were ≥18 years with the occupation of student were classified as college students. At baseline, the majority of SCL

TABLE 2.
Number (%) of subjects at each site by age category and enrollment year

Age at first visit	8–12 N (%)	13–17 N (%)	18–25 N (%)	26–33 N (%)	Total N (%)
Clinical site					
NOVA	55 (8.9)	182 (29.5)	186 (30.1)	194 (31.4)	617 (17.4)
OSU	24 (4.3)	158 (28.3)	154 (27.4)	223 (39.9)	559 (15.8)
SCCO	59 (9.4)	173 (27.7)	180 (28.8)	213 (34.1)	625 (17.6)
PUCO	52 (8.8)	147 (24.9)	189 (32.0)	202 (34.2)	590 (16.6)
UWSO	32 (6.1)	116 (22.1)	188 (35.9)	188 (35.9)	524 (14.8)
IUSO	38 (6.0)	103 (16.2)	377 (59.5)	116 (18.3)	634 (17.9)
Total	260 (7.3)	879 (24.8)	1274 (35.9)	1136 (32.0)	3549
Year enrolled					
2005	45 (17.3)	95 (10.8)	53 (4.2)	45 (4.0)	238 (6.7)
2006	165 (63.5)	674 (76.7)	1186 (93.1)	1034 (91.0)	3059 (86.2)
2007	50 (19.2)	110 (12.5)	35 (2.7)	57 (5.0)	252 (7.1)

OSU, Ohio State University, College of Optometry; UWSO, University of Waterloo, School of Optometry; IUSO, Indiana University School of Optometry.

wearers (65.8%) reported 1 to 5 years of contact lens wearing experience. Not surprisingly, the lens wearing experience varied across the age groups with more than 90% of 8- to 17-year olds having 1 to 5 years of experience compared with 56.5% of the 18- to 25-year olds and only 46.8% of the 26- to 33-year olds.

Lens Types, Replacement Schedules, and Solutions

Table 4 summarizes the SCL-related characteristics of patients at the baseline visit. Data were reported for the OD only because there were minimal and not significant differences in the findings for OD and OS. Eighty-five percent (n = 2383) of current SCL wearers wore spherical SCLs and almost 40% (n = 969) wore silicone hydrogels.

Seventy-seven percent of current SCL wearers had a documented replacement schedule. Patient-reported replacement schedules were entered into the database rather than manufacturer-recommended schedules. Daily replacement composed the smallest percentage (9.9%) across all age groups; however, this mode of replacement was most prevalent (15.8%) among the youngest SCL wearers (8 to 12 years). Any reported overnight wear was entered into the database as overnight wear (17.9%).

The following results for lens care systems excluded wearers of daily replacement lenses. Seventy-eight percent of remaining SCL wearers reported using multipurpose solutions whereas hydrogen peroxide (H_2O_2) was used by only 9.9% of wearers. The 26- to 33-year-old group had the most prevalent H_2O_2 use (13.8%).

At the baseline visit, 18.5% of 8- to 12-year olds were wearing SCL powers $>+4.00$ D compared with only 0.7% of 26- to 33-year olds. In contrast, 40.4% of 26- to 33-year olds presented with SCL powers ≥-4.00 D compared with only 16% of 8- to 12-year olds. Anisometropia of $\geq$1.00 D difference between the two eyes was only found in 11.4% of the overall SCL wearing cohort; however, among 8- to 12-year olds, 31.6% had $\geq$1.00 D of anisometropia.

DISCUSSION

The CLAY Study was designed to collect information related to risk and safety of SCL wear in children, teenagers, and young adults. This article presents data from the first observed visit of the study observation window for 3549 SCL wearers. The contact lens literature lacks large observational studies focused on SCL wearing habits of those $<$18 years old. Although recent studies have shown a high rate of CL-related pediatric adverse events in emergency rooms,[20] microbial keratitis in SCL wearing children,[25] and orthokeratology complications in Asia,[21–24] all these studies have lacked any estimate of the size of the wearer group of similar age. This article presents the demographics and clinical characteristics of a study designed to measure safety outcomes in a postmarket setting for 8- to 33-year-old patients who presented for routine and problem focused eye care in eye care clinics outside the confines of a prospective clinical study.

The clinical sites in this study encompassed broad geographic areas in North America with all six investigational sites at academic clinics. The retrospective nature of this study limits our control for the number or the periodicity of follow-up visits per patient. Additionally, because the study observation is more than 3 years, subjects would have aged during this period. Missing information in the clinical chart was a hindrance as well, and in those circumstances, we do not report on findings with a high rate of missing data. However, a retrospective design allows an unbiased view of recent prescribing habits and adverse events in SCL wearers. Because the objective was to collect information on routine and or problem focused SCL wear data, academic clinics with multiple practitioners and interns may capture a broad spectrum of SCL prescribing and management of associated complications. In addition, clinical documentation may be more complete in an academic health care setting. Although academic clinics may serve a higher proportion of specialty contact lens patients, this study's exclusion criteria eliminated these complex patients from the dataset. This dataset is a good reflection of the general SCL wearing population.

Although safety outcomes with SCL wear are well established in young adults $>$18 years of age, published data for children and teenagers are relatively limited. The sample size and age distribution in this study was selected to ensure sufficient data for those $<$18 years of age. Our carefully constructed sample size manipulated age distribution to study the role of age in

TABLE 3.
Demographic characteristics of patients enrolled in the CLAY study by age at the baseline visit

Age at first visit	8–12 N (%)	13–17 N (%)	18–25 N (%)	26–33 N (%)	Total N (%)
Contact lens experience, N = 3549					
Current wearer	104 (40.0)	568 (64.6)	1105 (86.7)	1020 (89.8)	2797 (78.8)
New wearer	156 (60.0)	311 (35.4)	169 (13.3)	116 (10.2)	752 (21.2)
Gender, N = 3549					
Male	119 (46.7)	363 (42.2)	403 (32.1)	403 (35.8)	1288 (36.8)
Female	136 (53.3)	497 (57.8)	854 (67.9)	722 (64.2)	2209 (63.2)
Not recorded	5	19	17	11	52
Race/ethnicity, N = 3025					
Black	12 (5.9)	91 (12.8)	97 (9.6)	81 (9.7)	281 (10.2)
Asian	9 (4.4)	55 (7.7)	120 (11.9)	113 (13.6)	297 (10.8)
Hispanic	44 (21.5)	163 (22.9)	83 (8.3)	99 (11.9)	389 (14.1)
Whites	136 (66.3)	386 (54.3)	672 (66.8)	519 (62.5)	1713 (62.2)
Other	4 (2.0)	16 (2.3)	34 (3.4)	19 (2.3)	73 (2.7)
Not recorded	23	52	80	117	272
History of diabetes, N = 3549					
No	258 (100.0)	868 (99.4)	1257 (99.4)	1109 (98.9)	3492 (99.3)
Yes	0 (0.0)	5 (0.6)	7 (0.6)	12 (1.1)	24 (0.7)
Not recorded	2	6	10	15	33
History of allergies, N = 3549					
No	193 (74.8)	642 (73.6)	813 (64.6)	693 (61.9)	2341 (66.8)
Yes	65 (25.2)	230 (26.4)	445 (35.4)	426 (38.1)	1166 (33.2)
Not recorded	2	7	16	17	42
History of autoimmune disease, N = 3549					
No	247 (100.0)	806 (99.6)	1150 (99.6)	961 (99.0)	3164 (99.4)
Yes	0 (0.0)	3 (0.4)	5 (0.4)	10 (1.0)	18 (0.6)
Not recorded	13	70	119	165	367
College student, N = 3549					
No	260 (100.0)	807 (92.7)	337 (27.7)	732 (67.5)	2136 (62.3)
Yes	0 (0.0)	64 (7.3)	878 (72.3)	353 (32.5)	1295 (37.7)
Not recorded	0	8	59	51	118
Smoker, N = 3549					
No	182 (100.0)	637 (98.3)	933 (93.2)	758 (91.7)	2510 (94.4)
Yes	0 (0.0)	11 (1.7)	68 (6.8)	69 (8.3)	148 (5.6)
Not recorded	78	231	273	309	891
Years of CL wear, N = 2797					
<1	7 (7.5)	18 (3.8)	20 (3.3)	17 (3.5)	62 (3.8)
1–5	87 (92.6)	432 (92.1)	339 (56.5)	226 (46.9)	1084 (65.9)
6–10	0 (0.0)	19 (4.1)	200 (33.3)	130 (27.0)	349 (21.2)
11–15	0 (0.0)	0 (0.0)	37 (6.2)	76 (15.8)	113 (6.9)
≥16	0 (0.0)	0 (0.0)	4 (0.7)	31 (6.4)	35 (2.1)
Not recorded	10	99	505	538	1152

contact lens-associated complications. Patients who were 8 to 12 and 13 to 17 years were deliberately over-sampled because they may not provide sufficient numbers to make statistical comparisons if left to the natural age distribution in these practices. A few age-related trends were reported at the baseline visit. There were a lower percentage of male SCL wearers between the ages of 18 to 33 years than among those younger than 18 years. Factors such as contact lens care and convenience may be deterring males from continuing with SCL wear as they mature. They may be less sensitive to the cosmetic advantages offered by contact lens wear. There were also a higher percentage of Hispanic SCL wearers between the ages of 8 and 17 years, which may be correlated to the demographics of the clinic sites or to the refractive errors for this population.

Daily lens replacement represented the smallest group of lens replacement schedules and the 8- to 12-year group was most likely to present with this replacement modality. Practitioners from these clinics may be fitting daily disposable lenses for ease of care and to eliminate concerns over compliance with SCL hygiene. In addition, lens power range, oxygen permeability of

TABLE 4.
Clinical characteristics of current contact lens wearers by age at baseline

Age at first visit	8–12 N (%)	13–17 N (%)	18–25 N (%)	26–33 N (%)	Total N (%)
Lens type, N = 2797					
Sphere	72 (69.2)	472 (83.1)	927 (84.0)	849 (83.4)	2320 (83.1)
Toric	22 (21.1)	89 (15.7)	165 (15.0)	159 (15.6)	435 (15.6)
Multifocal	0 (0.0)	3 (0.5)	1 (0.1)	2 (0.2)	6 (0.2)
Other	10 (9.6)	4 (0.7)	10 (0.9)	8 (0.8)	32 (1.1)
Not recorded	0	0	2	2	4
Lens material, N = 2797					
Hydrogel	50 (58.1)	309 (58.9)	587 (60.8)	550 (62.0)	1496 (60.7)
Silicone hydrogel	36 (41.9)	216 (41.1)	378 (39.2)	337 (38.0)	967 (39.3)
Not recorded	18	43	140	133	334
Reported replacement schedule, N = 2797					
Daily	12 (15.8)	52 (11.4)	69 (8.7)	79 (9.7)	212 (9.9)
1–2 weeks	28 (36.8)	222 (48.5)	272 (34.3)	313 (38.4)	835 (39.0)
Monthly	23 (30.3)	146 (31.9)	346 (43.6)	311 (38.2)	826 (38.5)
Other	13 (17.1)	38 (8.3)	107 (13.5)	112 (13.7)	270 (12.6)
Not recorded	28	110	311	205	654
Reported wearing schedule, N = 2797					
Daily wear	68 (81.9)	389 (81.9)	642 (79.0)	690 (85.3)	1789 (82.1)
Overnight wear	15 (18.1)	86 (18.1)	171 (21.0)	119 (14.7)	391 (17.9)
Not recorded	21	93	292	211	617
Care system, N = 2797					
Multipurpose	48 (85.7)	363 (85.0)	652 (79.6)	563 (72.1)	1626 (78.1)
Hydrogen peroxide	4 (7.1)	25 (5.9)	70 (8.5)	108 (13.8)	207 (9.9)
Generic/other	4 (7.1)	37 (8.7)	84 (10.3)	99 (12.7)	224 (10.8)
None/saline	0 (0.0)	2 (0.5)	13 (1.6)	11 (1.4)	26 (1.2)
N/A (daily replacement)	12	52	69	79	212
Not reported	36	89	217	160	502
Lens power (OD), N = 2797					
−6.00 to −12.00 D	7 (8.5)	18 (3.6)	97 (10.8)	139 (16.6)	261 (11.2)
−4.00 to −5.75 D	6 (7.3)	107 (21.1)	224 (24.9)	200 (23.8)	537 (23.1)
−2.00 to −3.75 D	25 (30.5)	200 (39.4)	356 (39.6)	306 (36.4)	887 (38.1)
−1.75 to +2.00 D	18 (22.0)	156 (30.8)	207 (23.0)	181 (21.6)	562 (24.1)
+2.25 to +4.00 D	10 (12.2)	16 (3.2)	12 (1.3)	8 (1.0)	46 (2.0)
+4.25 to +6.00 D	8 (9.8)	10 (2.0)	2 (0.2)	6 (0.7)	26 (1.1)
≥+6.25 D	8 (9.8)	0 (0.0)	2 (0.2)	0 (0.0)	10 (0.4)
Not recorded	22	61	205	180	468
Anisometropia, N = 2797					
<1.00 D	53 (68.8)	451 (90.4)	792 (88.3)	750 (89.7)	2046 (88.6)
≥1.00 D	24 (31.2)	48 (9.6)	105 (11.7)	86 (10.3)	263 (11.4)
Not recorded	27	69	208	184	488

the material, and cost of lenses may have also influenced the types of lenses prescribed.

Approximately 40% of current wearers presented at the baseline visit wearing a silicone hydrogel lens. This is similar to other 2006 data (41% silicone hydrogel),[38] but lower than the current industry reported 60% of silicone hydrogel wearers in the United States (2009 data).[39] Increasing international trends in silicone hydrogel prescribing were found from 4% in 2000 to 36% in 2008.[40] We would expect as we analyze later visits from the CLAY Study data that over time there will be an increase in the proportion of silicone hydrogel lens wearers in our cohort.

The CLAY Study describes a large postmarket group of young (age, 8 to 33 years) SCL wearing patients in North America. This unique dataset characterizes this young population's SCL types and wearing habits. Future analyses will report on SCL-associated risk factors as they relate to the age of the SCL wearer. The size of this observational study allows for meaningful comparisons for the entire age range of this cohort. In addition, the longitudinal data

collected can illustrate the change in SCL parameters over time. As research continues in the area of myopia control, children are likely to be the target population in which a SCL device is placed on the eye. Anecdotal information or case series are not sufficient information for the clinical practitioner to make a determination about the probability of safety issues with a medical device. By analyzing the SCL wearing habits of this group of patients, we hope that we can make recommendations on best practices for SCL wear.

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