



Characterization of patients who report compliant and non-compliant overnight wear of soft contact lenses

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ABSTRACT

Purpose: To describe compliant and non-compliant overnight wear (EW) of soft contact lenses from a large observational study.

Methods: A retrospective chart review of 3211 SCL patients with known EW status (aged 8–33 yrs, SCL power +8.00 to –12.00 D) captured data from 10,516 clinical visits (2006–2009). Status of EW was either daily wear (DW), compliant EW (overnight wear of US Food & Drug Administration (US FDA) EW-approved lenses), non-compliant EW (overnight wear of DW-approved lenses). The effect of demographic and clinical characteristics on the likelihood of reporting EW was examined using logistic regression. Additionally, the effect of these same characteristics on the likelihood of non-compliant EW was assessed with logistic models.

Results: Eight-hundred and eight patients (25.2%) reported EW. Non-compliant EW was reported by 6% of wearers (13 hydrogel, 2 silicone hydrogel brands) In multivariate models, patient age and lens replacement schedule were significant factors for EW (vs. DW) and for non-compliant (vs. compliant) EW ($p < 0.0001$). Other factors significantly related to EW were gender, smoking, lens material, sphere power, and years of CL wear ($p \leq 0.007$, all).

Conclusions: Young people (ages 18–25 yrs), males, smokers, myopes, silicone hydrogel lens wearers and patients with >1 yr of CL wear were significantly more likely to report EW. Non-compliant EW occurred often in young people and daily disposable wearers, though many brands had non-compliant EW use. Understanding who is likely to wear EW and non-compliant EW will help clinicians pointedly counsel patients more at risk on best practices with EW.

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1. Introduction

Overnight or extended wear (EW) of soft contact lenses (SCLs) was first approved by the United States Food and Drug Administration (US FDA) in 1971. Approval for EW has become increasingly common with the introduction of many silicone hydrogel (SiHy) lenses. Many of the top SCLs on the market today carry a US FDA approval for some degree of EW. Although US FDA approval for EW strictly applies only in the United States, regulatory agencies and global companies that operate in other parts of the world often follow the lead of US FDA in these approvals. The nomenclature surrounding EW approval has been confused over the decades by a

number of imprecise promotional terms such as flex wear, which refers to occasional EW, and more recently, continuous wear a term used to describe 30 nights of EW. Neither of these terms, flex wear or continuous wear, relate to the regulatory approval for overnight wear, as the US FDA grants only two classifications in approval of CLs: daily wear (DW) or EW only 6 or 30 nights of wear [1]. Fig. 1 details the relationship between US FDA approvals for EW, marketing terms, and the appropriate wearing schedules for each.

In the early decades of SCL use, EW lenses were granted approval for 30 nights. In 1989 results from a study commissioned by the Contact Lens Institute showed increased risk of microbial keratitis with EW usage [2]. Results of that study prompted the US FDA to decrease the approved overnight wear time to 6 nights for all SCLs and to enforce stronger warning labels on lenses. Thirty nights of EW was not re-implemented until 2001, with the introduction and testing of silicone hydrogel (SiHy) lens materials. Today, not

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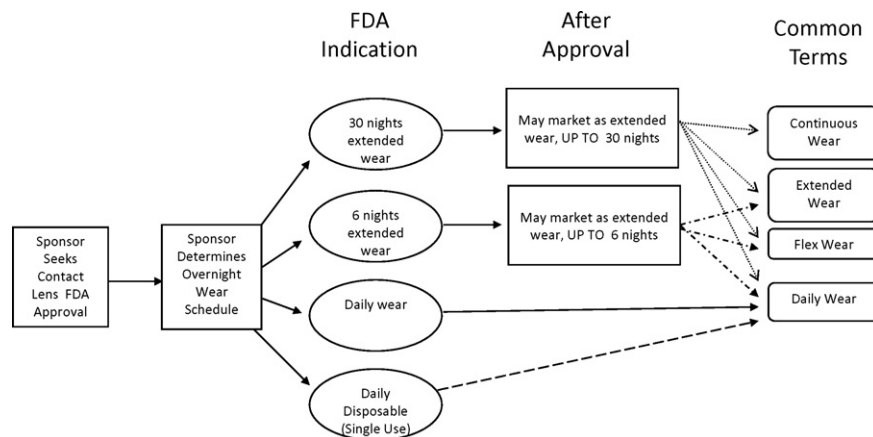


Fig. 1. US Food and Drug Administration contact lens approval process and commonly used terms for wearing schedules.

all SiHy lenses carry US FDA approval for EW which may have led to some confusion among patients and practitioners. To date, the proportion of patients wearing modern SCLs on an EW basis with or without an FDA EW indication has not been established. Indeed, non-compliant EW has never been studied in a large post-market surveillance study. Knowing what type of patient uses EW is especially relevant since most epidemiology studies have shown that EW with SCLs leads to an increased risk of microbial keratitis (MK) and corneal infiltrative events (CIEs), regardless of lens material [3–8].

The purpose of this study was to describe differences between patients who report daily wear (DW) and extended wear (EW) and, secondarily to describe risk factors for and prevalence of non-compliant EW use from a large, multi-center, retrospective clinical chart review.

2. Method

This is a secondary analysis of data from an observational, retrospective chart review described elsewhere as the Contact Lens Assessment in Youth (CLAY) study [9–11]. The Clay Study group personnel are listed in Appendix A. Data from 3211 SCL patients with known self-reported EW status (aged 8–33 yrs, wearing +8.00 to –12.00 D SCLs) were included in this analysis, comprising 10,516 clinical visits from 2006 to 2009.

Gender, race, history of allergies, student status, and smoking were recorded for each observed patient. For every visit in the observation period, notation was made if patient wore lenses EW (yes, no, or unknown) based either on the information in the case history or tick-box entry. Each site had unique clinical record forms and data was entered by a team from that clinical site, including one optometric member of the CLAY study team. Patients were given

EW status if they reported wearing a lens overnight at any visit. Patients with no EW at any visit were given DW status. All patients with “unknown” as the response at all visits were excluded from analysis. The number of EW nights per week or month was entered if available, but was not included in the present analysis.

Lenses were classified as EW if the material was approved for either 6 or 30 night EW by the US FDA and non-compliant EW if the lens was approved for only DW but worn as EW [12].

The effect of demographic and clinical characteristics on the likelihood of reporting EW was examined using logistic regression. Additionally, logistic models were used to assess the effect of these same characteristics on the likelihood of non-compliant EW.

3. Results

The demographics and refractive status of the observed patients are shown by EW status in Table 1. Eight hundred and eight (25.2%) of the 3211 eligible patients reported EW at some visit. Based on the entering sphere CL powers, 707 of these 808 patients wore minus powers, 69 wore plus powers, 5 wore lenses with plano spherical power, and 27 wore unknown powers.

3.1. Significant factors for EW

Compared to those reporting DW, patients reporting EW during at least one visit were more likely to be male (41.4% vs. 35.6%, $p=0.003$), college students (41.6% vs. 34.1%, $p=0.0001$), smokers (8.4% vs. 4.6%, $p<0.0001$) and wearing silicone hydrogel lenses (64.1% vs. 43.5%, $p<0.0001$).

The distribution of patient age showed significantly different patterns between DW and EW wearers ($p<0.0001$) (Fig. 2). At a finer level of detail, the probability of a patient reporting overnight

Table 1
Demographics and lens summary for observed wearers by EW status.

	Wearers, N (%)	Age in yrs mean (SD)	Males, N (%)	College student, N (%)	Smoker ^b , N (%)	Years of CL wear mean (SD)	Silicone hydrogel, N (%)	Lens replacement ^c , N (%)		
								Daily	2 week	Month
DW	2403 (74.8)	21.6 (6.4)	845 (35.6)	790 (34.1)	84 (4.6)	3.1 (3.8)	1011 (45.3)	260 (13.9)	876 (46.8)	737 (39.3)
All EW	808 (25.2)	21.0 (5.6)	329 (41.4)	326 (41.6)	45 (8.4)	4.0 (4.1)	490 (64.1)	27 (5.0)	233 (43.0)	282 (52.0)
Non-compliant EW ^a	198 (6.0)	19.5 (5.3)	84 (43.3)	72 (37.5)	8 (5.8)	3.5 (3.9)	119 (60.1)	27 (18.9)	83 (58.0)	33 (23.1)

^a Non-compliant EW group is a subset of the All EW group.

^b Smokers – excludes unknowns (DW 570, EW 272, non-compliant EW 42).

^c Lens replacement – excludes unknowns (DW 358, EW 174, non-compliant EW 37), and other (no EW 172, EW 92, non-compliant EW 18).

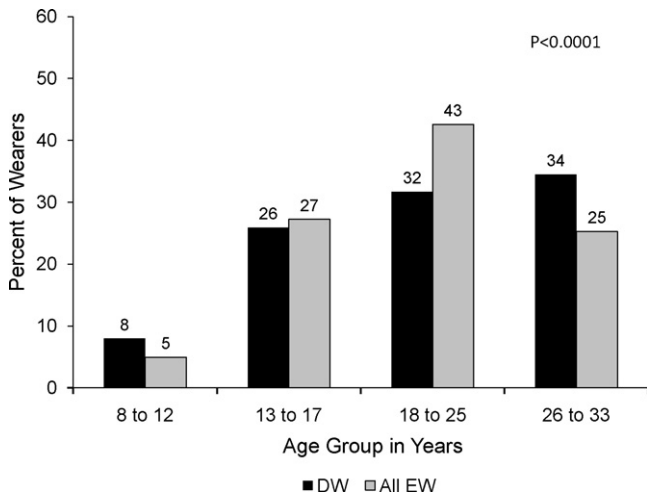


Fig. 2. Frequency distribution of daily wear (DW) and all extended wear (All EW) by age group. Black bars represent DW. Grey bars represent EW.

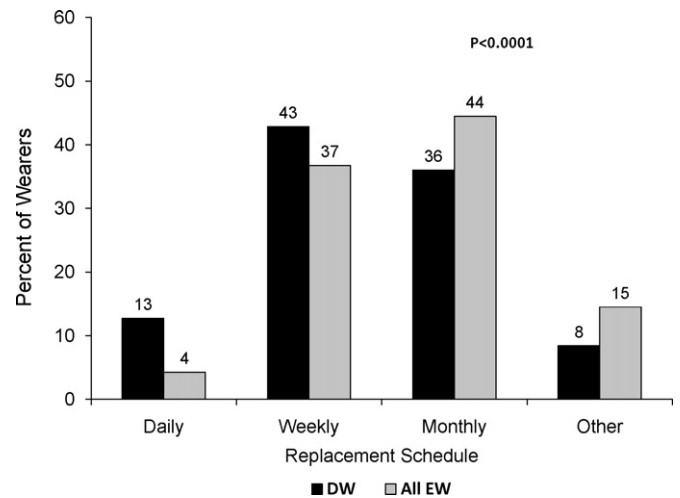


Fig. 4. Frequency distribution of daily wear (DW) and all extended wear (all EW) by lens replacement schedule. Black bars represent DW. Grey bars represent EW.

wear increased until 20 yrs of age and then decreased. The number of years a patient had been wearing CLs was also significantly associated with reported EW ($p < 0.0001$), as shown in Fig. 3. New wearers with less than 1 yr of SCL wear were significantly less likely to report EW than patients who had worn lenses for more than 1 yr, with the highest likelihood occurring after 6 yrs of CL wear.

Wearers who reported a daily disposable lens replacement schedule were significantly less likely to report any EW than those reporting a 2 week or monthly replacement schedule, as shown in Fig. 4 ($p < 0.0001$). However, whenever the daily disposable lenses were reported as EW, they were non-compliant extended wear.

The results of univariate and multivariate analysis for any report of EW are shown in Table 2. Any EW includes the patients with non-compliant EW.

3.2. Significant factors for non-compliant EW

Non-compliant EW was reported by 198 wearers, 6.0% of all wearers and 25.1% of the 808 EW patients. Thirteen hydrogel brands and two silicone hydrogel brands without FDA EW approval were worn for EW.

Figs. 5 and 6 show, patient age and lens replacement schedule did show a significant difference between compliant EW and

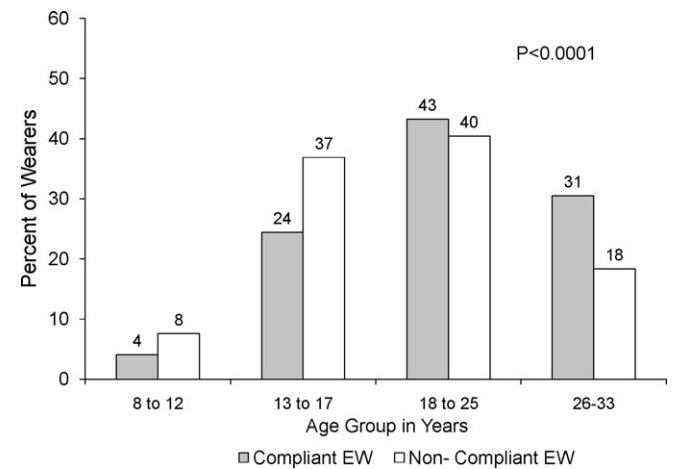


Fig. 5. Frequency distribution of compliant extended wear (compliant EW) and non-compliant extended wear (non-compliant EW) by age group. Grey bars represent EW. White bars represent non-compliant EW.

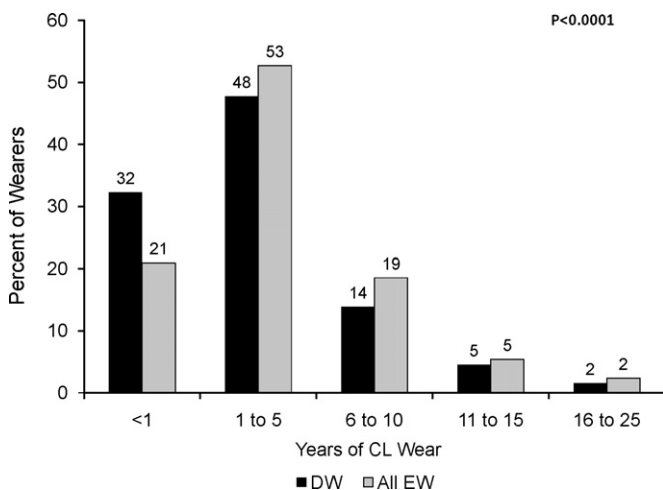


Fig. 3. Frequency distribution of daily wear (DW) and all extended wear (all EW) by years of CL wear. Black bars represent DW. Grey bars represent EW.

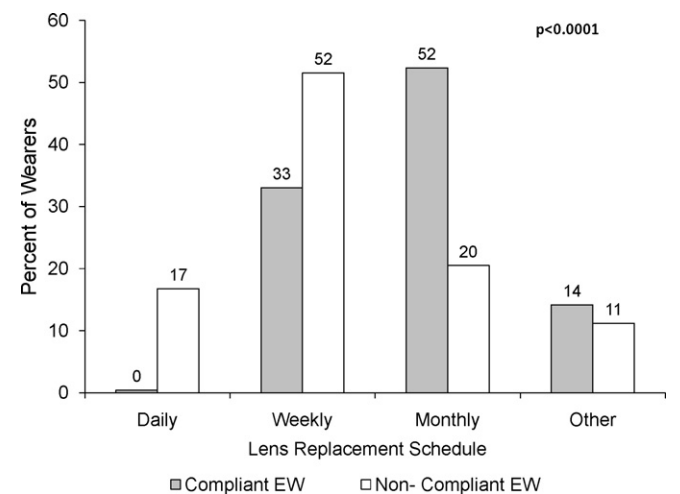


Fig. 6. Frequency distribution of compliant extended wear (compliant EW) and non-compliant extended wear (non-compliant EW) by lens replacement schedule. Grey bars represent EW. White bars represent non-compliant EW.

Table 2
Univariate and multivariate analysis for Any EW.

	Univariate		Multivariate	
	Odds ratio	p-Value	Odds ratio	p-Value
Age (18–25 yrs referent)		<0.0001		<0.0001
8–12 yrs	0.46 (0.32, 0.67)	<0.0001	0.87 (0.56, 1.35)	0.53
13–17 yrs	0.78 (0.64, 0.96)	0.016	1.17 (0.92, 1.49)	0.21
>26 yrs	0.54 (0.45, 0.66)	<0.0001	0.50 (0.40, 0.63)	<0.0001
Male gender	1.28 (1.09, 1.52)	0.003	1.32 (1.10, 1.59)	0.003
College student	1.38 (1.17, 1.63)	0.0001	n.s.	n.s.
Smoker	1.91 (1.31, 2.78)	<0.0001	2.08 (1.35, 3.21)	<0.001
Years of CL wear (<1 yr referent)		<0.0001		<0.0001
1–5 yrs	1.70 (1.32, 2.19)	<0.0001	1.77 (1.34, 2.32)	<0.0001
6–10 yrs	2.06 (1.50, 2.83)	<0.0001	2.58 (1.77, 3.77)	<0.0001
11–15 yrs	1.83 (1.13, 2.98)	0.015	2.44 (1.39, 4.28)	0.002
16–25 yrs	2.38 (1.17, 4.87)	0.017	3.96 (1.75, 8.97)	0.001
Silicone hydrogel lens material	2.15 (1.82, 2.55)	<0.0001	2.32 (1.91, 2.82)	<0.0001
Sphere power (+ power referent)		<0.0001		0.007
–0.01 D to –1.99 D	1.63 (1.00, 2.64)	0.051	1.96 (1.16, 3.31)	0.012
≥–2.00 D	2.46 (1.55, 3.90)	0.0001	2.49 (1.51, 4.11)	0.001
≥–4.00 D	1.61 (0.92, 2.79)	0.094	2.07 (1.09, 3.94)	0.027
Lens replacement (daily referent)		<0.0001		<0.0001
2 weekly	2.56 (1.68, 3.90)	<0.0001	1.25 (0.79, 1.96)	0.35
Monthly	3.68 (2.42, 5.60)	<0.0001	2.04 (1.30, 3.20)	0.002
Other	5.15 (3.22, 8.24)	<0.0001	3.29 (1.99, 5.44)	<0.0001

Odds ratio estimate (95% C.I.). Bold indicates $p < 0.05$.

non-compliant EW patients. Two-weekly and monthly replacement schedules were less likely to be worn as non-compliant EW compared with daily disposable lenses.

Table 3 shows the univariate and multivariate results for non-compliant EW compared with those using compliant EW.

4. Discussion

For all its study of EW as a risk factor for complications with SCL wear, the contact lens scientific literature has surprisingly little information that describes the type of patient who wears SCLs on an EW basis. A better understanding of who may be likely to begin EW without supervision will help clinicians predict who should be targeted to receive additional counselling. There are a number of factors associated with EW and non-compliant EW usage. This study used a robust but conservative analytical approach and a wide range of both demographic factors such as age, smoking, and gender, as well as prescribing factors including lens material, replacement schedule, and minus power.

4.1. Age

The age of contact lens wearers who used their lenses on an EW basis was normally distributed with an average age of 20 yrs. Younger patients in the 8–12 yrs of age range were more likely to report DW, possibly due to a more conservative prescribing approach by their eye care practitioner or a stronger desire on the patients' part to comply with eye care practitioner's instructions. Also, the 8–12 yr old's parents can oversee and enforce compliance to the recommended DW wearing schedule. The peak of EW from 18 to 25 yrs is near the age when these patients may be entering university or leaving home for the first time. In addition to a young person's inexperience handling their own health decisions, this time is often accompanied by a dangerous sense of invincibility [13]. As they mature to their late twenties, SCL wearers may better understand the importance of following instructions, make better lifestyle choices, and begin to take responsibility for their healthcare.

4.2. Age and non-compliance

Wearer age, which showed a fairly normal distribution for EW, was slightly flatter for those using non-compliant EW (Figs. 2 and 5). Interestingly, the 18–25 age group, which was significantly more likely to report EW than the younger groups, was not significantly more likely to do so in a non-compliant fashion. Practitioners may know that older teens and young adults want EW and therefore prescribe EW approved lenses for them. On the other hand, patients under age 18 were more likely to report non-compliant EW. This is at least in part because a higher proportion of children and teens wear daily disposable lenses [14], which are always considered non-compliant if worn on an EW basis.

4.3. Lens replacement schedule

Daily disposable wearers reported less EW overall, probably because no daily disposable lenses are approved for EW. But the daily disposable wearers comprised approximately 18% of the patients in the non-compliant EW category, an over-representation compared to their 9% presence in the entire observed population. So, although more than 90% of the daily disposable wearers complied with the DW recommendation at all of their visits in the study, when there was any infraction it was always a non-compliant EW behaviour.

4.4. Years of CL wear

Similarly to younger wearers reporting less EW, wearers who are new to SCL wear were also less likely to report EW. Eye care practitioners may prescribe DW for new SCL wearers more often as a conservative way to start lens wear and to ensure that the patient knows how to handle their lenses. In addition, newer wearers may pay more attention to patient education they receive and the eye care practitioner's DW recommendation. After years of SCL wear, veteran wearers may either be instructed to be more flexible with their wearing schedule or they may be less compliant with a practitioner's DW only instructions. Non-compliance is not unique to CL wearers; it is a common finding among long-term use of most medical treatments needed for chronic conditions such as

Table 3
Univariate and multivariate analysis for non-compliant EW.

	Univariate		Multivariate	
	Odds ratio	p-Value	Odds ratio	p-Value
Age (18–25 yrs referent)		<0.0001		<0.0001
8–12 yrs	1.99 (1.00, 3.98)	0.051	1.83 (0.86, 3.90)	0.12
13–17 yrs	1.62 (1.11, 2.36)	0.013	1.45 (0.96, 2.18)	0.077
>26 yrs	0.57 (0.36, 0.91)	0.018	0.52 (0.31, 0.86)	0.012
Male gender	1.15 (0.83, 1.59)	0.42	n.s.	n.s.
College student	0.80 (0.57, 1.11)	0.18	n.s.	n.s.
Smoker	0.59 (0.27, 1.31)	0.20	n.s.	n.s.
Years of CL wear (<1 yr referent)		0.20	n.s.	n.s.
1–5 yrs	0.87 (0.53, 1.43)	0.58		
6–10 yrs	0.86 (0.47, 1.61)	0.64		
11–25 yrs	0.52 (0.21, 1.29)	0.16		
Silicone hydrogel lens material	0.74 (0.53, 1.03)	0.076	n.s.	n.s.
Sphere power (+ power referent)		0.37	n.s.	n.s.
–0.01 D to –1.99 D	0.57 (0.24, 1.39)	0.22		
≥–2.00 D	0.76 (0.34, 1.71)	0.51		
≥–4.00 D	0.41 (0.12, 1.41)	0.16		
Lens replacement (daily referent)		<0.0001		<0.0001
2 weekly	0.04 (0.01, 0.17)	<0.0001	0.04 (0.01, 0.16)	<0.0001
Monthly	0.01 (0.002, 0.04)	<0.0001	0.01 (0.002, 0.04)	<0.0001
Other	0.02 (0.004, 0.09)	<0.0001	0.02 (0.004, 0.09)	<0.0001

Odds ratio estimate (95% C.I.). Bold indicates $p < 0.05$.

glaucoma [15,16]. This study captured only the patient self-report of EW, so no direct comparison to the prescribed schedule can be made.

4.5. Lens material group

Not surprisingly, since many SiHy lenses are approved for EW wearing schedules, SiHy wearers were significantly more likely to report EW. Because of their high oxygen transmissibility (Dk/t), clinicians may be more comfortable prescribing SiHys on an EW basis [17,18]. However, even with the strong presence of SiHy lenses for EW use, many mid-water hydrogel lenses are also approved for EW although they are not marketed for that wearing schedule. Lens material class was not significantly different for those in the compliant EW and non-compliant EW groups.

4.6. Smoking

Many studies have found that smokers have a risk-taking personality [19,20]. These thrill-seeking behaviours and feelings of invincibility may explain the increased proportion of smokers who report wearing lenses on an EW basis. Smokers may simply not hear or heed the correlation of EW to an increased incidence of corneal inflammation and infection [3,4,7]. Smokers may also care less about their overall health and be oblivious to the consequence of their unhealthy or risky actions. The small overall number of smokers in the North American population made the comparison between EW and non-compliant EW under-powered, so though we did not find a difference there, it may have been due to a small sample of smoking SCL wearers in the study.

4.7. Gender

Male wearers were significantly more likely to report EW, but usually were doing so with lenses that were approved for EW. This suggests that eye care practitioners prescribe EW to males at a higher rate than females. The higher prevalence of EW use in males could be due to lack of ability or confidence in handling lenses every day or it may be purely a matter of preference.

4.8. College

Over 40% of college students wore SCLs EW. College status was significant in the univariate model but not when controlling for other factors in the multivariate model for EW or non-compliant EW. The high proportion of EW among college students is fuelled by the irregular college lifestyle; EW maximizes convenience for patients who live in close living quarters, are deprived of sleep, and may have poor hygiene habits. But, apparently eye care practitioners are tuned to this desire for EW among college students, as they were typically wearing lenses designed for EW use in a compliant schedule.

4.9. Lens power

Myopic spherical SCL power was also associated with EW, but not with non-compliant EW use. Wearers of minus power lenses were more likely to wear lenses on an EW basis compared with hyperopes, but there was no linear pattern with increasing minus power. Myopes may have a more difficult time functioning without their prescription and be more reliant on their CLs than hyperopes therefore opting for EW. Disadvantages in plus power lens designs, such as thick centers, may also steer eye care practitioners away from EW for hyperopes.

4.10. Non-compliant EW

The US FDA grants approval for EW SCLs on only a 6 night or a 30 night basis. A few SiHy lenses carry approval for DW only, while most SiHy lenses are approved for 6 or 30 nights of EW. A degree of confusion over which SiHy lenses are approved for EW may have grown in recent years, causing practitioners and patients alike to incorrectly assume that all SiHys are appropriate for EW use. In this dataset, 10.7% of the EW wearers wore 2 brands of DW approved SiHy lenses, compared to 7% who used 13 brands of DW approved hydrogel lenses. It is important to note that many of the non-compliant EW hydrogel lenses were DD lenses, all made of hydrogel materials that were not approved for EW usage. Therefore any DD wearer that reported EW was non-compliant with EW of that lens. Reinforcement of the “single daily use” indication for DD lenses should be mentioned at all visits especially among new DD wearers.

Clearly, the main reason to avoid confusion in EW recommendation focuses on patient safety. Some SCLs are not designed for EW and have not undergone successful testing with an EW schedule. Without proper orientation on whether their SCLs are meant for EW use, the typical SCL patient who is trying to fit lens wear and care into a busy life may mis-use their lenses in this important way. By wearing DW lenses for EW, they may unknowingly increase their risk of corneal inflammation and infection. Also, proper EW instruction for patients should include a discussion of the added risks and how to properly self-manage a problem until the patient can seek professional care. A patient trained only for DW use would not have this knowledge and the safety net that it could provide.

Interestingly, many factors that were associated with a significant increase in the report of EW did not follow the same trends for non-compliant EW use. No significant differences in compliance of EW were seen for patient gender, college status, or smoking. Therefore while patients in these demographic groups may be participating in EW more often, they are not necessarily doing it in a non-compliant manner, which hopefully reduces their risk of CL complications.

It is important to remember that the EW status presented here is based on patient reported. This study used a conservative, evidence-based approach to classify EW, and it is entirely possible that many more wearers are actually wearing SCLs in an EW schedule than the number who admitted it to their eye care practitioner in this study. In that case, these results may underestimate the prevalence of both EW and non-compliant EW alike. Also, this study could not determine whether the patient was wearing a lens “unintentionally” non-compliant with respect to the FDA, but in compliance with respect to their practitioners prescribed wearing modality.

When investigating patient reported wear schedules, clear classifications were made. The wearer was classified as EW if they ever reported wearing their lenses overnight at any visit. This included those who reported occasional EW (e.g.: 1 time a month) to those who reported nightly EW. This conservative approach was taken in order to see use patterns that may put the patient at risk periodically.

Similarly to the distinct classification needed to distinguish DW and EW, each brand/type of lens was clearly classified as EW or non-compliant EW. Precision in data on the SCL brand and power is one main advantage of a retrospective clinical chart review compared to other epidemiology survey methods. Patients may not know exactly what lens they have been prescribed, but since the device is a controlled medical device, the eye care practitioner is the gate-keeper for changes in lens type and power. This study was conducted in North America and the study team acknowledged that SCLs can be prescribed or marketed in different ways around the world. We selected to use the US FDA approval for material to determine indication though it may not apply globally.

This observational post-market study found that approximately one-quarter of patients reporting for eye care wore their SCLs on an EW basis at least on an occasional basis, a proportion much higher than that reported in practitioner based surveys, which range from Morgan's 2 to 5% in North America [17]. A higher rate of EW could be influenced by our study population's age, which was limited from 8 to 33 yrs. In addition, our data included many newly launched SiHy CL brands with EW approvals. In today's fast paced world, an increasing number of CL wearers have a strong desire for a “permanent” vision correction. Past studies have shown that 97% of wearers express a desire to be able to continuously wear contact lenses for at least six nights [21]. Knowing the patient profile of those more likely to participate in an EW modality will allow clinicians a method of targeting this population with additional information during patient history or follow-up care, along with

consideration to prescribe this patient population an EW approved lens type.

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Appendix A. Members of the CLAY Study Group as of August 13, 2010

A.1. Clinical sites

Indiana University School of Optometry, Bloomington, IN: Meredith E. Jansen, OD MS (Principal Investigator), Angelina Bonner (Data Entry), Kristen Burkholder (Data Entry), 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), Margi A. Patel (Data Entry).

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

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

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

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

A.2. 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), Lucas Henneman (Data Management).

A.3. 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; Heidi Wagner, OD, MPH.

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

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