Natural course of Lid Wiper Epitheliopathy (LWE) in symptomatic contact lens wearers

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Abstract

Purpose: To establish the time course of lid wiper epitheliopathy (LWE) in established CL wearers after a single day (6-10 h) of daily disposable contact lens (CL) wear, the following day post-CL removal and 1-week after CL discontinuation.

Methods: Twenty-one symptomatic (CLDEQ-8 score ≥ 12) habitual wearers of MyDay® silicone hydrogel daily disposable were included. LWE staining was assessed prior to CL wear (Visit 1, V1) using semi-automated analysis after instillation of two drops of 1% lissamine green (10 μL) that were applied to the superior bulbar conjunctiva. LWE measurements were repeated after 6-10 hours of continuous CL wear (Visit 2, V2), post-CL removal the following day (Visit 3, V3) and after 1-week CL discontinuation (Visit 4, V4). At each visit, ocular symptoms were evaluated using the SPEED-8 questionnaire and set of 0-100 visual analogue scales (VAS).

Results: LWE showed no significant changes after 6-10 hours of continuous CL wear ($p=0.536$), post-CL removal the following day ($p=0.677$) or following 1-week of CL discontinuation ($p=0.478$). Analysis revealed a significant improvement in symptomatology between V1 and V2 (SPEED-8, $p<0.01$) and also improvements in the 0-100 VAS scores between V2 and V4 for average daily dryness ($p<0.01$), end-of-day dryness ($p<0.01$) and frequency of end-of-day dryness ($p<0.05$).

Conclusion: The present data suggest that the etiology of LWE is multifactorial and the sole intervention of temporarily discontinuing CL wear does not lead to resolution of these clinical signs.

Key words: Lid Wiper Epitheliopathy; Dry Eye; Lissamine Green; Soft Contact Lens

1. Introduction

Lid wiper epitheliopathy (LWE) has been established as a diagnostic sign of dry eye disease and may contribute to contact lens (CL) dropout [1,2]. LWE is thought to reflect micro-trauma caused by inadequate ocular lubrication and/or excessive friction between the eye and eyelids [3,4]. Reported prevalence of LWE in symptomatic CL wearers is high (67-85%), while a lower prevalence has been described in asymptomatic CL wearers (13-32%) [1,5–9]. Based on these data, Pult et al. [10] proposed a link between CL symptomatology and LWE but other studies have been unable to show a relation between LWE and subjective discomfort/dryness in CL wearers [3,9,11–14].

A limited number of prospective longitudinal studies have evaluated the progression of LWE over time [11,13,15,16]. One study was a four-week crossover study that examined neophyte CL wearers with two reusable lenses and found that LWE significantly increased with CL wear [15]. Similarly, another study with neophyte CL wearers, also found that lid wiper damage increased following six months of monthly reusable silicone hydrogel CL wear [11]. Stahl et al (2018) evaluated two reusable silicone hydrogel lenses in a cross-over study with existing wearers and also reported increased upper lid wiper staining following 10-days of wear [13]. Yet, there is no evidence of the effect of daily disposable lenses on LWE and/or a link between CL coefficient of friction and LWE.

The time course of LWE resolution is also currently unknown. Despite this, proposed management strategies include reducing CL wearing time or discontinuing CL wear altogether [3]. It has been speculated that a reduction in LWE might take place overnight (post-CL wear) [3]. A close observation over a period of days has been recommended to determine the diurnal course of LWE as well as the impact and effect of ceasing CL wear altogether [3]. For this reason, the aim of this study was to examine the natural course of LWE in symptomatic CL-wearing participants during CL wear and post CL-cessation using a semi-objective technique. Specifically, the intentions were to determine: (1) if LWE increases with daily disposable CL wear, (2) if LWE resolves overnight (after a short break in wear once lenses are removed in established CL wearers), and (3) the pattern of LWE

changes after CL discontinuation (one week of no CL wear). Parallel to the monitoring of the LWE changes, participant symptomatology was measured using the 8-item Standard Patient Evaluation of Eye Dryness (SPEED-8) score [17] and visual analogue scale (VAS) questions exploring dryness symptoms as they have previously been associated between LWE length/width in symptomatic CL wearers.[7]

2. Material and Methods

Participants and experimental protocol

Participants were recruited from the Southern College Optometry (SCO; Memphis, TN, USA) patient base. The study was approved by the Institutional Review Board of SCO and conformed to the tenets of the Declaration of Helsinki. Ethical approval was additionally obtained from Anglia Ruskin University (Cambridge, United Kingdom). Written informed consent was obtained after explanation of the study and possible consequences of participation.

Study inclusion criteria included age 18-50 years, and the presence of LWE in both eyes. LWE determination was made by visual inspection of the lid wiper region 3 minutes after two drops of lissamine green (LG) were instilled [18,19]. Positive LWE was defined as at least Grade 1.0 on the Korb protocol B scale [18]. All participants were habitual wearers of CooperVision MyDay® silicone hydrogel daily disposable CLs (Stenfilcon A 5B, base curve 8.4mm, total diameter 14.2mm, 54% water content, 60 ISO units oxygen permeability, manufacturer available back vertex power range of +8.00D to -12.00D) [20]. Participants were defined as symptomatic if they had a CL Dry Eye Questionanire-8 (CLDEQ-8) score $\geq$ 12) [17].

Participants who were habitual wearers of any CL other than CooperVision MyDay® were excluded, as were participants who reported wearing CLs in an extended wear modality (routinely sleeping in CLs overnight for 1 or more nights per week). Candidates with any anterior segment infection, inflammation, disease, or abnormality (within the previous 7 days) and/or those currently using systemic or ocular medications that would typically

contraindicate CL wear were also excluded. The use of rewetting drops or any other dry eye management was prohibited during the study. CL wear exceeding 12 hours on the day prior to Enrolment Visit was not allowed to limit the number of confounding variables in the study. Participants were required to wear spectacles prior to arrival on the day of V1. Habitual brand of CLs were confirmed to have an optimal fit on V1 as was determined by the CL movement in up-gaze, CL push-up test, and a CL horizontal lag assessment [21]. There was an upper age limit of 50 years as it has been reported that LWE prevalence decreases by 16% in patients >50 years old [7]. Finally, candidates who were monocular or had known allergies to LG were excluded.

To evaluate the cumulative changes that may occur after a day of CL wear and a week of CL discontinuation, the present study evaluated participants at four time points (Figure 1). On enrolment day participants were assessed prior to CL wear (V1) and after 6-10 hours of CL wear before CL removal (V2). Participants were asked to discontinue CL wear and the lid wiper and symptomatology were re-assessed the next day (V3) and a week later (V4) to monitor short-term LWE changes with no CL wear.

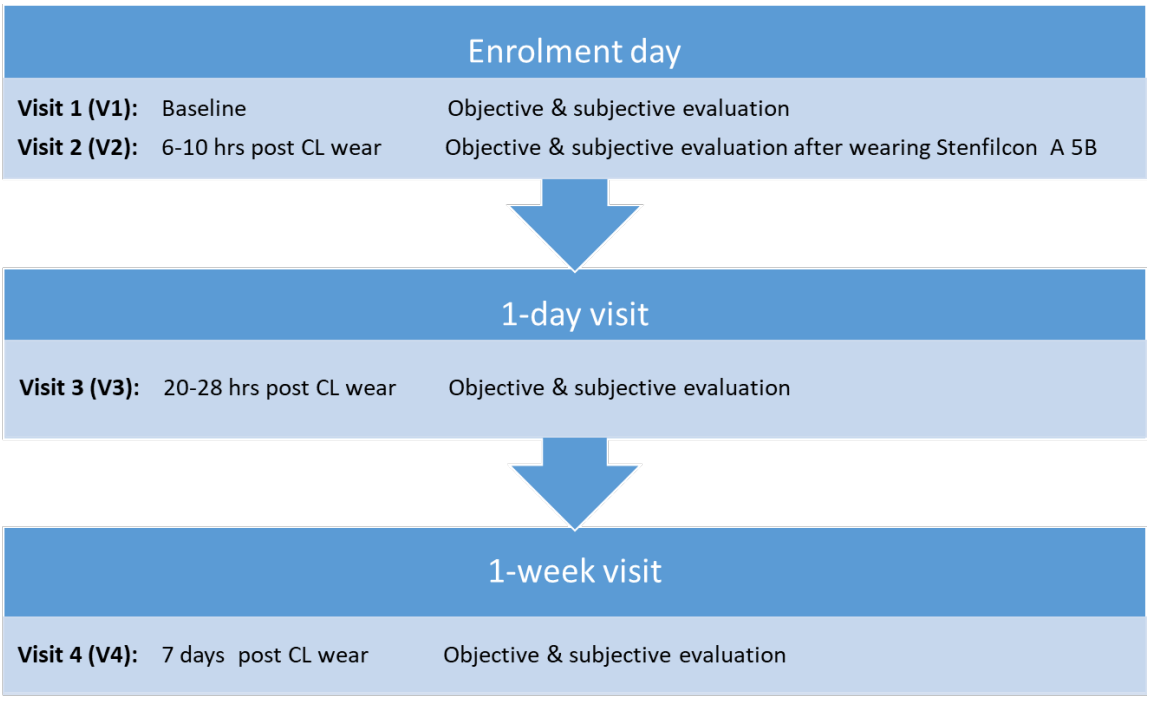

Figure 1. Summary of study visits

The order of clinical tests at each visit is outlined in Table 1. Baseline slit lamp biomicroscopy and digital photography were performed using the same unit (BI900 LED Slit Lamp, with EyeSuite Imaging [Haag-Streit, Bern, SUI]). Baseline assessments of the cornea, bulbar conjunctiva, palpebral conjunctiva, and upper eyelid margin were made for each eye. The Brien Holden Vision Institute Grading Scale was used to assess clinical findings for the anterior eye segment. Symptomatology was assessed using the SPEED-8 and the VAS scales as shown in Table 1. The VAS questions used were average daily dryness at all visits (V1, V2, V3, V4) and end-of-day dryness and frequency of end-of-day dryness on visits 3 and 4 (V3, V4).

Visit	**Visual Correction**	Clinical Tests (Right Eye)				
V1	Spectacles	SPEED-8 questionnaire	VAS: average daily dryness*	Examine lid wiper	Applied CLs	CL Evaluation
V2	CLs	SPEED-8 questionnaire	VAS: average daily dryness*, end-of-day dryness‡ and frequency of end-of-day dryness‡*	Examine lid wiper	Removed CLs	
V3	Spectacles	SPEED-8 questionnaire	VAS: average daily dryness*	Examine lid wiper		
V4	Spectacles	SPEED-8 questionnaire	VAS: average daily dryness*, end-of-day dryness‡ and frequency of end-of-day dryness‡*	Examine lid wiper		

Table 1. Summary of experimental protocol. CL, contact lens; LG, lissamine green; SPEED-8, 8-item Standard Patient Evaluation of Eye Dryness; VAS, visual analogue scale; * where 0=no sensation of dryness whatsoever and 100=extremely dry/intolerable; ‡ where

0=no sensation of dryness whatsoever and 100=extremely dry/intolerable; ** where 0=never and 100=all the time.

Only the right eye was evaluated. Dye was instilled via a MicroPette Plus Single-Channel Variable Volume Pipettor, 2-20 µL volume (Scilogex, Rocky Hill, CT, USA) to ensure exact dose. Two drops of 1% LG (10 µL) were applied, one minute apart to the superior bulbar conjunctiva in the RE [2,22]. Based on the optimal methodology described by Lievens et al. [2021], the 2-drop, 3-minute condition was used to confirm the presence of LWE with LG [19,23]. The eyelid was carefully everted using a cotton-tipped applicator before photography. Care was taken to not applanate the lid margin, causing iatrogenic staining.

The sample size was calculated using power analysis calculations (G*Power). A sample size of 16 participants would give 95% power at an alpha of 0.05 for difference between two dependent means based on previous work (mean ± SD, 5.28 ± 2.13) [19]. Thus, a sample size of 21 participants will allow for potential discontinuation across study visits.

Image Analysis

This study used ADCIS (Advanced Concepts in Imaging Software, Saint Contest, FR) as described by Varikooty et al. and Lievens et al. to evaluate LWE [19,23,24]. Images of the everted lid (resolution of 2000*1000 digitized on 8 bits, 12x magnification, Haag-Streit BI900 LED Slit Lamp system and Canon EOS 60D digital camera) were captured in raw mode, and then converted into tiff-format images. The software is designed to automatically detect LWE when using LG dye. Once this dyed area is detected, the software automatically segments the area and processes a series of computed functions to identify the complete shape and colored intensity of the automatically detected regions of LWE. The ADCIS image processing algorithm carries multiple steps to deliver image optimization and analysis including image transformation, top-hat transformation and Otsu thresholding [24]. As LWE may have different presentations (continuous and non-continuous staining), the calculated area of lid wiper staining (mm^2) used for analysis includes all stained regions as well as the Line of Marx. This approach is consistent with

previous studies using alternative semi-automated methodologies [19,23,25,26]. LWE area was calculated with the ADCIS software and the Korb score calculated using Protocol B [18].

Data Analysis

Statistical analyses were performed using SAS software v9.4 (Cary, NC, USA) and Analyse-it for Microsoft Excel 5.68 build 7620.32918. Differences between LWE on visits were analysed using a one-way repeated measure analysis of variance (ANOVA). Planned analyses were to compare diurnal change associated with CL wear (V1 to V2), the following day (V2 to V3) and one-week after CL discontinuation (V2 to V4). A mixed model with fixed effect of time and a random effect for individual was run on results for SPEED-8, average dryness, end of day dryness, and frequency of dryness.

3. Results

Twenty-one (21) symptomatic CL wearers completed the study; 71% were female (n=15). Enrolled subjects had a spherical power range of +0.25D to -8.00D. Table 2 shows that at the enrolment visit all participants presented with CL related dryness as measured using CLDEQ-8 and SPEED-8 (mean ± SD; 20.04 ± 4.06 and 12.54 ± 2.95 respectively). In addition, all participants showed a positive LWE ranging from 1.0 to 3.0 (mean ± SD, 1.96 ± 0.87) using Korb protocol B score [18].

Test	Mean ± SD
CLDEQ-8	20.04 ± 4.06
SPEED-8	12.54 ± 2.95
LWE Area (mm^2)	3.31 ± 1.42
Korb score	1.96 ± 0.87

Table 2. Clinical signs and questionnaire symptomatology recorded at baseline visit. CLDEQ-8 = CL Dry Eye Questionnaire-8; SPEED-8 = Standardized Patient Evaluation of Eye Dryness-8.

215

216 **Change in LWE area across study visits**

217 Repeated measures analysis of variance (ANOVA) was used to explore changes in LWE
218 area over time (Table 3). Assumptions of normality and homogeneity of variances in the
219 residuals were examined and not violated. No statistically significant changes were found
220 after a day of CL wear (from V1 to V2, $p=0.535$), the following day (from V2 to V3,
221 $p=0.677$) and following a week of CL discontinuation (from V2 to V4, $p=0.478$).

222

223 **Change in patient-reported symptomatology**

224 Patient-reported symptomatology was assessed using SPEED-8 and VAS as shown in
225 Table 3. Assumptions of normality and homogeneity of variances in the residuals were
226 examined and not violated. Planned contrasts revealed significant differences in
227 symptomatology using the SPEED-8 questionnaire from V1 to V2 ($p<0.01$) but the
228 remaining planned contrasts were not statistically significantly different ($p>0.05$ for V2 to
229 V3 and V2 to V4). Similarly, average dryness VAS score showed a significant time effect
230 ($p<0.01$) (Table 3). Planned contrasts showed a significant improvement in average
231 dryness VAS score from V2 to V4 ($p<0.01$) whilst the remaining planned contrast were not
232 statistically significantly different (all $p>0.05$). A significant improvement in
233 symptomatology was also found between V2 and V4 visits for end-of-day dryness score
234 ($p<0.01$) and frequency of end-of-day dryness score ($p<0.05$) (Table 3).

235

	V1	V2	V3	V4
LWE area staining (mm2)	3.31 ± 1.42	3.53 ± 1.45	3.68 ± 1.31	3.27 ± 1.13
SPEED-8	13.00 ± 2.05	9.62 ± 4.64	9.24 ± 5.07	7.62 ± 5.09
VAS average daily dryness	54.24 ± 17.92	47.38 ± 21.85	41.90 ± 22.49	34.19 ± 21.44

VAS end-of-day dryness		63.00 ± 24.33		43.67 ± 24.33
VAS frequency end-of-day dryness		56.52 ± 27.21		40.00 ± 28.21

Table 3. Mean (±1 SD) Lid Wiper Epitheliopathy (LWE) area of staining (mm2) by study visit measured with ADCIS; Mean (±1 SD) SPEED-8, average daily dryness VAS, end-of-day dryness VAS, frequency of end-of-day dryness VAS results by study visit.

4. Discussion

This study focused on diurnal LWE change following soft CL wear as well as overnight and the following day after CL discontinuation. The present results showed that semi-objective measurements of LWE did not significantly change after 6-10 hours wear of a modern daily disposable soft CL, the following day (without CL) or after one-week cessation from habitual CL wear in symptomatic CL wearers. This contradicts the clinical wisdom that: i) friction is likely to increase cumulatively during the day resulting in increased staining and symptoms and ii) overnight CL cessation is likely to repair any damage to the lid wiper on the following day with the associated improvement in symptomology [3]. In agreement with the current work, Navascues-Cornago et al (2015) also noticed that upper lid margin staining did not show a significant diurnal change following 12 hours of CL wear in 10 symptomatic soft CL wearers [12].

LWE staining did not fully or partially resolve after CL cessation, despite the improvements in symptomatology. It is unknown if a longer period of CL cessation would have a greater impact on reducing LWE staining. Subjective symptomatology improved following 1-week CL discontinuation. Since LWE did not show a parallel effect, no connection between LWE and symptoms can be reported. Similarly, no correlation

between lid margin staining and CLDEQ-8 was found by Navascues-Cornago and colleagues and earlier work in this area has also reported contradictory results between LWE and symptomatology [1,6,12,27].

When designing repeated measures in clinical studies, investigators need to decide the best scale or questionnaire [2,28]. Li et al (2018) showed an association between grade of LWE width and length and the three VAS questions included in this study (average daily dryness, end-of-day dryness and frequency of end-of-day dryness) whilst SPEED score was associated with LWE width only [7]. In addition, Stahl et al (2018) suggested that future studies investigating the role of friction and LWE should specifically include questions on end-of-day dryness symptoms given their proposed link [13,29]. In line with this, in this study symptomatology was recorded using both SPEED-8 and with the use of three VAS questions that have previously been associated with LWE and symptomatic CL wear [7]. Unexpectedly, symptomatology as recorded using SPEED-8 significantly improved between V1 and V2 visits (enrolment and after a minimum of 6 hours of CL wear) since end-of-day comfort typically gets worse. Symptomatology did not significantly change following overnight CL discontinuation (V3) but a significant improvement in dryness-related symptoms was noted after discontinuation of CLs using VAS between visits V2 and V4 (i.e. 1-week CL discontinuation) for average daily dryness, end-of-day dryness and frequency of end-of-day dryness.

It is worth noting that all participants wore a highly lubricious silicone hydrogel CL (MyDay®) and it is theorized that CLs with lower lubricity may induce greater amounts of LWE in the region that interacts with the CL [30]. The MyDay® CL was chosen as it is commonly prescribed to symptomatic lens wearers. Due to the nature of the study, it was critical to avoid introducing any confounding factors such as symptomatology when adapting to a new CL and/or linkage to LWE. For this reason, all participants enrolled in the present work were habitual MyDay® CL wearers. Additionally, MyDay® has been shown to have a low water breakup time (5.0 ± 2.6 sec) when tested in vitro and in comparison to two other lenses, with the Interfacial Dewetting and Drainage Optical

289 Platform (iDDrop) instrument and method [31]. Further work should evaluate the potential
290 for LWE symptomatology with other commonly prescribed hydrogel and silicone hydrogel
291 CLs for symptomatic CL wearers and in CL neophytes. In addition, as LWE presents
292 differently with race and age, different populations should also be investigated [9]. Asian
293 patients tend to have a tighter eye lid tension and older patients have greater skin laxity;
294 each of which would correspond to potentially significant differences in eye lid pressure
295 [30,32]. The present study did not enroll enough racial groups to report differences and
296 should be a future investigation. It is plausible that a greater understanding of what causes
297 and exacerbates LWE may enable targeted intervention for specific patient groups.
298
299 Presently, therapeutic approaches are largely hypothetical and lack thorough investigation.
300 There are multiple reasons why management strategies remain varied. There has been a
301 repeated link of LWE to ocular surface disease and patient symptoms have occasionally
302 been connected to CL wear [1,3]. Because of this, most of the proposed treatment
303 strategies have been mimicked after treatments for dry eye and CL intolerance including
304 the use of lubricant eye drops, altering CL type and wearing modalities and improving
305 blinking behavior [3,33]. This study demonstrated that the sole intervention of temporarily
306 discontinuing CL wear did not lead to resolution of the LWE staining, thus reducing CL
307 wearing time in symptomatic CL wearers may not alleviate clinical findings [3].
308
309 When interpreting the findings of the present study in the context of previous longitudinal
310 LWE changes, it is important to note that this study is one of the first to specifically
311 monitor patients wearing daily disposable soft lenses. CL surface characteristics are
312 different among brands and modalities of lenses (i.e. reusable and daily disposable) and
313 might incur differing interactions with the lid wiper. Previous work focused on the effects
314 of reusable lenses (together with a variety of CL care products) [11,13,15]. However,
315 existing work in this area is incomplete, as the potential LWE friction effects that may
316 result from a combination of lens care products and CLs has not been explored. For this
317 reason, this study focused on the natural course of LWE in the absence of care products.
318 The present study focused on existing wearers presenting with symptomatology, but

previous longitudinal studies have focused on neophytes [11,15]. The longest longitudinal study reporting LWE changes is 6 months after commencing CL wear. However, as suggested by Efron, further longitudinal research in this area should also aim to establish when LWE first manifests in neophyte lens wearers.[3] Finally, there is inconsistency in the grading used to establish LWE (simplified 3-point scale [13] vs Korb scale [11,15]). A strength of this study was the use of a semi-automated software to detect and measure dye stained-eye images offers superior guidance when compared to subjective evaluations of LWE. As a result, caution is needed when comparing findings between studies.

In conclusion, this work has shown for the first time that in soft CL wearers using a highly lubricious CL, there was no evidence that LWE changes the following day and one-week CL discontinuation. Yet, as symptomatology improved no connection between LWE and symptoms can be reported. At present, therapeutic management strategies for LWE are largely hypothetical and these findings are important in the clinical management of this condition as the sole intervention of reducing CL wearing time and/or short-term discontinuation of CL wear will not alleviate the presence of LWE.

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