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ORIGINAL ARTICLE

Assessing neophyte response to daily disposable silicone hydrogel contact lenses: A randomised clinical trial investigation over one month

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Abstract

Objective: This randomised clinical trial assessed the impact on symptoms, tear film dynamics and ocular surface integrity of daily disposable silicone-hydrogel contact lenses (CLs) over a month, paying special attention to lid wiper epitheliopathy (LWE) and its implications for CL discomfort.

Methods: Neophyte CL wearers ($n = 44$, 21.09 ± 5.00 years old) were randomly assigned to either the experimental ($n = 24$) or control group ($n = 20$). Participants assigned to the experimental group were required to wear daily disposable CLs for 1 month for at least 8 h/day and 6 days/week. All participants were healthy subjects (no history of ocular surgery or active ocular disease) with spherical refractive errors between −8.00 and +5.00 D and cylindrical power <0.75 D. At the baseline and 1-month sessions, the Dry Eye Questionnaire 5 (DEQ-5) was completed, together with the measurement of tear film osmolarity with the TearLab osmometer, tear meniscus height (TMH) and lipid layer pattern (LLP) using a slit-lamp with Tearscope Plus attached, fluorescein break-up time (FBUT), maximum blink interval (MBI), corneal staining with fluorescein under cobalt blue light and LWE with lissamine green under slit lamp and halogen white light.

Results: At the baseline session, LWE showed a negative correlation with DEQ-5 ($r = -0.37$, $p = 0.02$). Significant differences in FBUT and LWE ($p = 0.04$) and a positive correlation between LWE and DEQ-5 ($r = 0.49$, $p = 0.007$) were observed at 1 month. Intrasession analysis at 1 month showed significant differences between the experimental and control groups in DEQ-5, FBUT and LWE (all $p \leq 0.02$). Intersession analysis in the experimental group showed variations in DEQ-5, FBUT and LWE (all $p \leq 0.02$) but no significant variation in the control group (all $p \geq 0.11$).

Conclusion: The presence of LWE was significantly correlated with higher symptom values in the DEQ-5. Also, participants in the experimental group presented higher values of LWE after 1 month of CL wear, in comparison with the control group.

KEYWORDS
contact lenses, daily disposable lenses, intersession, lid wiper epitheliopathy, randomised clinical trial

INTRODUCTION

Over the past few decades, there has been a consistent increase in the use of contact lenses (CLs) to correct refractive errors.[1,2] Despite the availability of new CL materials, many wearers frequently experience issues that may cause them to discontinue lens wear altogether.[3–5] Contact lens discomfort (CLD) is a common issue that often results in reduced wearing time, a shorter interval before a lens change is required or even dropping out of lenses altogether.[3–5] The Tear Film and Ocular Surface Society (TFOS) proposed a definition of this condition after an extensive literature review as follows: 'Contact lens discomfort is a condition characterised by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear'.[6–8]

Changes in the ocular surface can impact the lens wearer's comfort. A healthy surface microbiota is important for proper interaction between the CL and the ocular surface, as well as to reduce the potential occurrence of serious issues during CL wear.[9–11] One factor that affects ocular discomfort is lid wiper epitheliopathy (LWE), whose prevalence ranges from 67% to 80% in symptomatic CL wearers, but is less than 32% in asymptomatic wearers.[12] LWE results from the friction of the eyelid over the ocular surface when the tear film thins.[13] The use of CLs also alters tear film stability and tear volume, with decreased values being observed after CL removal.[14–16]

Following the suggestion made by the TFOS CLD workshop, this randomised clinical trial aimed to assess the impact of a daily disposable silicone-hydrogel CL (somofilcon A) on symptoms, tear film dynamics and ocular surface integrity, when compared with non-CL wearers over the course of a month, paying special attention to changes in LWE and its potential implications for CLD.

Key points

- After 1 month, neophyte contact lens wearers demonstrated increased ocular discomfort and lid wiper epitheliopathy, as well as decreased tear film break-up time compared with the control group.
- The presence of lid wiper epitheliopathy was correlated with greater symptomatology, highlighting its relevance in contact lens discomfort.
- The findings underscore the importance of monitoring lid wiper epitheliopathy in daily disposable contact lens wearers to mitigate potential discomfort and improve overall satisfaction with lens wear.

MATERIALS AND METHODS

Sample

A sample size calculation was performed using PS Power and Sample Size Calculations Software Version 3.1.2 (biostat.app.vumc.org/wiki/Main/PowerSampleSize). This study involved continuous response variables being obtained from paired sessions to examine the ability to detect variations in LWE.[12,17] A literature review of LWE suggested that the mean standard deviation (SD) of repeated measures followed a normal distribution with a value of 0.7 points, while the minimal clinically significant difference was half a grade point.[17] Therefore, to achieve a statistical power of 0.80 for rejecting the null hypothesis with a Type I error probability of 0.05, a minimum of 17 participants was required. Allowing for a 20% potential loss to follow-up, the total sample size needed was 21 participants.

A total of 44 Caucasian neophyte CL participants (70.45% women) were recruited, having a mean age (±SD) of 21.09 ± 5.00 years. All participants had not worn CL previously, were required to have a spherical refractive error between −8.00 to +5.00 D, <0.75 D of cylindrical error and have best-corrected visual acuity of at least 0.9 decimal acuity (6/6.67) in their worse eye.[18] In addition, participants had to present with healthy eyes and no systemic disease that might affect CL wear (e.g., allergies, diabetes mellitus, rheumatoid arthritis or thyroid disease) in order to participate. All subjects provided written informed consent and the protocol adhered to the tenets of the Declaration of Helsinki, it was approved by the Bioethics Committee of the Universidade de Santiago de Compostela.

Study design

All participants were scheduled for three sessions, namely the inclusion, baseline and 1-month sessions. Subjective refraction, keratometry, horizontal visible iris diameter and best-corrected visual acuity were assessed during the inclusion session. Participants were then randomly assigned to either the experimental ($n = 24$) or control group ($n = 20$). Those assigned to the experimental group were required to wear daily disposable CL for 1 month, whereas the control group did not use any type of CL during the study. At the baseline and 1-month sessions, the Dry Eye Questionnaire 5 (DEQ-5),[19] tear osmolarity, tear meniscus height (TMH), lipid layer pattern (LLP), fluorescein break-up time (FBUT), maximum blink interval (MBI), corneal staining and LWE were measured. Participants in the experimental group also completed the Contact Lens Dry Eye Questionnaire 8 (CLDEQ-8) after 1 month.[20,21] The same examiner performed the

measurements on both eyes of each participant, while a second masked observer analysed the collected data. The first examiner assigned an alphanumeric code to each video for the second masked examiner to analyse. This examiner did not know whether the participants belonged to the experimental or control group, as the procedures were performed and recorded without CL in place.

Contact lens material and wearing instructions

Daily disposable spherical silicone-hydrogel CL were fitted to all participants in the experimental group. These CL were composed of somofilcon A (coopervision.com) that incorporates silicone monomers, N-vinylpyrrolidone and trimethylsiloxane, and were approved for distribution by the United States Food and Drug Administration (FDA).[14,22] The properties of these CLs were 56% water content, 8.6-mm base curve, 14.1 mm diameter, Dk/t 86 · 10^{-9} cm/s · mL O_2/mL · mmHg and modulus of 0.5 MPa. These lenses were selected for the current investigation because they are available worldwide and represent a cost-effective daily disposable silicone-hydrogel CL option. All participants were instructed to apply the CL directly from the original solution, to wear the CL for at least 6 days per week and 8 h per day.

Dry eye symptomatology and CLD

Ocular symptoms relating to dry eye were assessed with the DEQ-5 questionnaire in all participants during each session.[19] The DEQ-5 is a simple form that addresses the most common symptoms related to ocular complaints: eye discomfort, dryness and excessive watering. Additionally, the CLDEQ-8 questionnaire was completed by participants in the experimental group after 1 month of CL wear.[20,21] The CLEDQ-8 is a questionnaire developed specifically to assess the symptomatology of CL wearers. It includes three additional questions compared with the DEQ-5 related to CL wear (frequency of changeable or blurry vision, closing eyes and removing lenses). This addition was made due to the similarity in symptoms between CL wearers and individuals with dry eye disease. DEQ-5 and CLDEQ-8 scores were calculated as the sum of the values for each response.[19–21]

Tear film and ocular surface parameters

Procedures were performed from least to most invasive in order to avoid alterations due to the measurements. Tear film osmolarity was measured with the TearLab (Turkera Medical, trukera.com/tearlab/) by determining the electrical impedance. The same TearLab card lot numbers were used to avoid possible variation.[23] TMH images were captured using a Topcon DC-4 camera (Topcon Healthcare, topconhealthcare.eu/en_EU/products/dc-4) attached to a Topcon SL-D4 slit lamp (topconhealthcare.eu/en_EU/products/sl-d4) using illumination from a Keeler Tearscope Plus (keeler.co.uk) interferometer.[24,25] These images were measured with the open source ImageJ software (National Institutes of Health, imagej.net/ij/).[25] While the Tearscope was configured on the SL-D4, the LLP was video captured and classified using the Guillon scheme.[26] Subsequently, fluorescein was instilled onto the ocular surface with a hydrated fluorescein strip (Contacare Ophthalmics and Diagnostics, caregroupiol.com/products/ophthalmic-solutions/diagnostic-strips/fluo-strips/). After the application of fluorescein, FBUT and MBI were determined with the slit lamp and video captured three times. The two closest measures of the FBUT and MBI were used to obtain the mean value, as done previously.[27] Corneal staining was also video captured with the slit lamp and DC-4 camera, with the participants looking in the five gaze positions. Videos of corneal staining were graded following the Oxford scheme.[28] Finally, a hydrated lissamine green strip was applied to the ocular surface for LWE evaluation. Participants were instructed to close and move their eyes to distribute the lissamine green dye. Only the upper eyelid staining was evaluated and graded following the recommendations of Korb et al.,[29,30] which quantifies the horizontal length and the sagittal height of the staining. LWE horizontal length was graded in four levels as follows: grade 0 (<2 mm), grade 1 (2–4 mm), grade 2 (5–9 mm) and grade 3 (>10 mm). The sagittal height of the LWE was also graded in four levels: grade 0 (<25%), grade 1 (25%–50%), grade 2 (50%–<75%) and grade 3 (>75%). This grading was used for the statistical analysis, taking the average of the two measurements: grade 1 (0.25–1), grade 2 (1.25–2) and grade 3 (2.25–3).[30]

Statistical analysis

SPSS statistical software v.25.0 for Windows (ibm.com/products/spss-statistics) was used for data analysis. Significance was set at $p \leq 0.05$ for all analyses. Initially, the normal distribution of the different parameters was checked using the Shapiro–Wilk test for each eye separately.[31] Parametric analyses were performed on osmolarity and TMH (Shapiro–Wilk, $p \geq 0.07$), while non-parametric analyses were assigned to DEQ-5, CLDEQ-8, LLP, FBUT, MBI, corneal staining and LWE (Shapiro–Wilk, all $p \leq 0.01$). Continuous variables were analysed using a paired *t*-test, unpaired *t*-test or ANOVA when they followed a normal distribution, whereas non-normal distributed variables were analysed with the Kruskal–Wallis test, the Mann–Whitney *U* test or Spearman correlations. Additionally, categorical variables were analysed using cross tables and Fisher's exact test. First, differences between the right and left

eyes were measured for both parametric (unpaired *t*-test, all $p \geq 0.37$) and non-parametric variables (Mann–Whitney *U* test and Fisher's exact test, all $p \geq 0.25$) (Table 1). Due to the absence of statistically significant differences, only the right eye data were analysed to mitigate statistical overestimation.[31,32] Subsequently, the association between the LWE grades and the other parameters was analysed for both the baseline and 1-month sessions. Finally, the comparison of each parameter was assessed between the two groups in session-by-session pairs (intrasession analysis). Pairwise differences between the two groups were assessed using the unpaired *t*-test for parametric parameters and the Mann–Whitney *U* test for non-parametric parameters.[31] In a subsequent analysis, comparison of all parameter values between sessions in both groups was carried out (intersession analysis). Differences in results obtained at the baseline and the 1-month sessions were evaluated using the paired *t*-test (parametric parameters) or the Wilcoxon test (non-parametric parameters) for repeated measurements.[31]

RESULTS

Descriptive statistics for right and left eye data are shown in Table 1. Due to the parametric or non-parametric nature of the data, all tables show either the mean ± SD or the median and interquartile range (IQR).

Association between LWE and the parameters studied

At the baseline session, no significant differences were found for any of the parameters studied when grouped by the severity of LWE (ANOVA, the Kruskal–Wallis test or Fisher's exact test, all $p \geq 0.11$). Spearman correlations showed no significant correlations between any of the parameters and the LWE severity (Spearman correlation, all $p \geq 0.26$). However, DEQ-5 values were negatively correlated with the LWE grades (Spearman correlation, $r = -0.37$, $p = 0.02$). At the 1-month session, significant differences were found for FBUT as a function of the LWE grades (Kruskal–Wallis test, $p = 0.04$). No other parameters showed significant differences between the LWE severity grades at the 1-month session (ANOVA test, the Kruskal–Wallis test or Fisher's exact test, all $p \geq 0.07$). A significant positive correlation at the 1-month session (Spearman correlation) was found between the LWE severity and DEQ-5 values (Spearman correlation, $r = 0.49$, $p = 0.007$). No other parameter showed a significant correlation with the LWE grades (Spearman correlation, all $p \geq 0.21$).

Intrasession analysis

No significant differences were observed between the experimental and control groups at the baseline session for any of the measured parameters (unpaired *t*-test, or Mann–Whitney *U* test, all $p \geq 0.09$; see Table 2). At the 1-month session, pairwise analysis between the groups showed significant differences in DEQ-5, FBUT and LWE (Mann–Whitney *U* test, or Fisher's exact test, all $p \leq 0.03$; Table 3). No other significant differences between the experimental and control groups were noted at the 1-month session (Mann–Whitney *U* test, Fisher's exact test or unpaired *t*-test, all $p \geq 0.12$; Table 3).

Intersession analysis

The intersession analysis performed in the control group between the baseline and the 1-month session showed no significant differences in the studied parameters (Wilcoxon test or paired *t*-test, all $p \geq 0.11$). In the experimental group, the comparison of the baseline and 1-month sessions showed statistically significant differences in DEQ-5, TMH, FBUT and LWE (Wilcoxon test or paired *t*-test, all $p \leq 0.03$). No

TABLE 1 Descriptive statistics and analysis of differences between the right and left eyes of the sample.

	Right eye		Left eye		
	n	**Mean ± SD or median (IQR)**	***n***	**Mean ± SD or median (IQR)**	***p***
Osmolarity (mOsm/L)	44	313.52 ± 11.70	43	311.23 ± 11.94	0.37[a]
TMH (mm)	43	0.13 ± 0.04	43	0.13 ± 0.04	0.69[a]
LLP (Guillon scheme)	44	2 (2–2)	43	2 (2–3)	0.97[c]
FBUT (s)	43	9.96 (5.33–14.67)	40	8.17 (5.08–12.92)	0.25[b]
MBI (s)	43	14 (11–19.67)	40	13.50 (10.67–20)	0.95[b]
Corneal staining (Oxford scheme)	39	0 (0–1)	39	0 (0–1)	0.19[c]
LWE grade (Korb Scheme)	44	0 (0–1)	43	0 (0–1)	>0.99[c]

Abbreviations: DEQ-5, Dry Eye Questionnaire 5; FBUT, fluorescein break-up time; IQR, interquartile range; LLP, lipid layer pattern; LWE, lid wiper epitheliopathy; MBI, maximum blink interval; SD, standard deviation; TMH, tear meniscus height.

[a]Unpaired *t*-test.

[b]Mann–Whitney *U* test.

[c]Fisher's exact test.

TABLE 2 Descriptive statistics and analysis of differences between the experimental and control groups at the baseline session.

	Experimental group		Control group		
	n	**Mean ± SD or median (IQR)**	***n***	**Mean ± SD or median (IQR)**	***p***
DEQ-5	24	2 (0–5)	20	4 (0.50–7.75)	0.24[b]
Osmolarity (mOsm/L)	24	316.29 ± 12.59	20	310.20 ± 9.84	0.09[a]
TMH (mm)	24	0.14 ± 0.04	19	0.12 ± 0.03	0.09[a]
LLP (Guillon scheme)	24	2 (2–2)	20	2 (2–2)	0.97[c]
FBUT (s)	24	8.59 (5.33–12.58)	19	12.33 (5.33–15.67)	0.26[b]
MBI (s)	24	13.33 (10.75–21.12)	19	15.33 (11.33–18)	0.58[b]
Corneal staining (Oxford scheme)	21	0 (0–1)	18	0 (0–0.25)	0.22[c]
LWE grade (Korb Scheme)	24	0 (0–0)	20	0 (0–0)	0.09[c]

Abbreviations: DEQ-5, Dry Eye Questionnaire 5; FBUT, fluorescein break-up time; IQR, interquartile range; LLP, lipid layer pattern; LWE, lid wiper epitheliopathy; MBI, maximum blink interval; SD, standard deviation; TMH, tear meniscus height.

[a]Unpaired *t*-test.

[b]Mann–Whitney *U* test.

[c]Fisher's exact test.

TABLE 3 Descriptive statistics and analysis of differences between the experimental and control groups at the 1-month session.

	Experimental group		Control group		
	n	**Mean ± SD or median (IQR)**	***n***	**Mean ± SD or median (IQR)**	***p***
DEQ-5	24	4.50 (3–6)	20	2 (0–6)	**0.02***[b]
Osmolarity (mOsm/L)	24	313.04 ± 10.97	20	309.35 ± 14.25	0.34[a]
TMH (mm)	24	0.12 ± 0.04	19	0.11 ± 0.02	0.45[a]
LLP (Guillon scheme)	23	2 (2–3)	19	2 (2–3)	0.98[c]
FBUT (s)	24	5.67 (3.84–7.25)	17	9.67 (6.67–22)	**0.003***[b]
MBI (s)	24	11.34 (10.08–16.25)	17	14.67 (10.67–31.33)	0.12[b]
Corneal staining (Oxford scheme)	23	0 (0–1)	17	0 (0–1)	>0.99[c]
LWE grade (Korb Scheme)	11	3 (2–3)	18	0 (0–1)	**<0.001***[c]

Abbreviations: DEQ-5, Dry Eye Questionnaire 5; FBUT, fluorescein break-up time; IQR, interquartile range; LLP, lipid layer pattern; LWE, lid wiper epitheliopathy; MBI, maximum blink interval; SD, standard deviation; TMH, tear meniscus height.

*Bold values indicate significance set of $p \leq 0.05$ for all tests.

[a]Unpaired *t*-test.

[b]Mann–Whitney *U* test.

[c]Fisher's exact test.

other parameter showed significant differences between the two sessions in the experimental group (Wilcoxon test, or paired *t*-test, all ≥0.25).

DISCUSSION

The use of CLs is highly prevalent, with a variety of materials and replacement options being available. CL practitioners are always trying to prescribe the best solution based on the patient's visual demands and lifestyle.[33] The choice of CL material may significantly impact the fitting process and potentially influence the wearer's comfort.[14,34] Even though new materials are available to practitioners promising few CL-related complications, prolonged CL wear is leading to an increasing number of patients with complaints of lens-related discomfort. This is why practitioners widely prescribe daily disposable CL, which increases ocular comfort throughout the day and reduce possible CLD associated with lens care systems.[35,36] The present randomised clinical trial contributes valuable information by focusing on a specific daily disposable CL material (somofilcon A) and its impact on ocular symptomatology and the alteration of the ocular surface and tear film.

All the participants included in the experimental group were fitted with the same daily disposable CL, showing significant differences compared with the control group in DEQ-5, FBUT and LWE (Table 2) after 1 month of CL use. The initial discomfort experienced by first-time CL wearers is often attributed to the sensation of the lens edges. Daily disposable CLs are often found to have poorly finished edges.[3,37] This may be because the manufacturing process for daily disposable lenses differs significantly from that of monthly disposable CL. Daily disposable CLs are generally moulded, whereas monthly disposable CLs are produced using a lathe cutting method. This

may have been reflected in the DEQ-5 and CLDEQ-8 values obtained at the 1-month session, where new wearers could have misinterpreted the sensation of the lens edges as ocular discomfort and dryness. Alternatively, lens edge sensation as well as ocular discomfort and dryness may actually be taking place.[17,38] In order to make a more accurate assertion, it would have been useful to measure ocular comfort immediately after CL insertion, or alternatively once a week over the first month to determine whether adaptation occurred following the initial discomfort.[3,36,39] Although Pena-Verdeal et al.[14] did not find differences in ocular comfort assessed by the CLDEQ-8 questionnaire in subjects fitted with somofilcon A and omafilcon A CL for 1 week, they performed an intersession analysis and observed a reduction in ocular comfort after CL wear with both lens materials, similar to the current findings.

The use of CL is known to disrupt normal tear film function by altering the layers of the tear film and generating a pre- and post-lens tear film.[40] The interaction of the CL with the ocular surface diminishes the stability of the tear film over the cornea or the CL.[41] Despite the fact that FBUT and non-invasive tear break-up time (NIBUT) are both techniques to measure the stability of the tear film, and their values are not interchangeable, a reduction in both parameters has been found after CL use.[16,41] Additionally, the disruption of the tear film layers did not seem to affect the lipid layer thickness, regardless of the wearing time or CL material, as reported in both the present study and previous investigations.[16] A newly developed contact lens material (verofilcon A), composed of a core of silicone-hydrogel material having a water content of 33% and an outer surface with an 80% water content, showed good pre-CL NIBUT values during lens wear, when compared with other daily disposable silicone-hydrogel and hydrogel CLs.[42–44] The findings suggest that less dehydration may occur on this lens surface than on other materials. Unfortunately, there are no reports of FBUT or NIBUT after this type of CL is removed.

Many authors have indicated that ocular complaints and CLD could be related to the friction of the eyelids over the CL surface during blinking.[13,17,35,38] LWE is an indirect measure as it is caused by the friction, although its presence has been associated with ocular discomfort. The use of rewetting drops that provide lubrication during CL wear diminishes LWE severity for different types of CLs.[45] However, Stahl and Jalbert[17] reported no relationship between LWE severity and osmolarity values. In the present findings, participants in the experimental group showed higher values of LWE but no significant differences in osmolarity compared with the control group. While Efron et al.[13] also did not establish a definitive relationship between CL wear and LWE, they encouraged investigators to conduct well-designed studies to address the potential limitations of previous investigations. With regard to the physical properties of the CLs, several investigators have associated the presence of LWE with the modulus of the CL material and the edge profile, since both factors alter the interaction between the CL surface and the eyelids during blinking.[46–48] On the other hand, the water content of the CL may play a role in LWE, as dehydration of the CL will lead to greater friction, and lower values of LWE are found in silicone-hydrogel CL wearers.[45] While Morgan et al.[46] stated that no studies have clearly linked the coefficient of friction with LWE, the current findings could support the proposal that the presence of LWE is due to the modulus of the CL material and edge profile rather than the water content, since silicone-hydrogel materials exhibit less dehydration during CL wear.[45]

The main strength of the present study is that a control group was examined at the same time and during the same sessions as the experimental group. Both groups were randomly assigned from a pool of CL neophytes. Further, we followed the TFOS recommendations for CL research.[49] All measurements were recorded by a second masked observer who was unaware of whether the images were from the experimental or control group, thus reducing potential bias. Furthermore, although it may appear as a limitation to have used only one type of CL, this also enhances the results, as it eliminates factors related to the use of different materials, as well as the maintenance products required for monthly CLs, whose physical properties could have influenced the outcomes.[50] All these aspects reinforce the link between CL wear and the presence of LWE. Further, by using new, daily disposable CL, the possibility of deposits affecting the lens surface was minimised.[51,52] In addition, the present study evaluated symptoms using standardised questionnaires, while the signs of ocular surface changes related to CL wear were assessed following the TFOS recommendations.[6–8]

This study does have some limitations. First, it could have been performed using daily disposable CLs composed of different materials to investigate whether LWE can be attributed to material factors such as water content, modulus, edge profile or surface treatments to enhance CL comfort, because to date the origins of LWE are unclear. While the results obtained here provide valuable information regarding the short-term effects of daily disposable silicone-hydrogel CL on the ocular surface, it would be of interest to add a second experimental group wearing daily or monthly disposable hydrogel CL. In addition, despite avoiding chronic exposure to lens care solutions by using daily disposable lenses, wearers were still exposed to lens packaging solutions.[53] Second, as LWE could be multifactorial, it could be useful to perform the study on a more heterogeneous sample, including subjects with a broader range of races and different ages. Third, while the sample incorporated strict inclusion criteria, the heterogeneity of the demographics and ocular characteristics (e.g., no astigmatism, only young Caucasians) may also generate a lack of diversity that limits the applicability of the results to other populations, including older individuals or those of different ethnic backgrounds. Finally, it should be noted that the longitudinal duration of the current investigation was only

1 month, thus showing only short-term effects; a longer follow-up period could add valuable information on the ocular surface status of these new CL wearers.

In conclusion, the presence of LWE was correlated with greater symptomatology on the DEQ-5 questionnaire. Additionally, participants in the experimental group exhibited greater LWE after 1 month of CL wear, compared with the control group.

AUTHOR CONTRIBUTIONS

Jacobo Garcia-Queiruga: Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); visualization (lead); writing – original draft (equal); writing – review and editing (equal). **Hugo Pena-Verdeal:** Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); visualization (equal); writing – original draft (equal); writing – review and editing (equal). **Dolores Ferreiro-Figueiras:** Data curation (equal); formal analysis (equal); investigation (equal); writing – original draft (equal); writing – review and editing (equal). **Veronica Noya-Padin:** Formal analysis (equal); visualization (supporting); writing – original draft (equal); writing – review and editing (equal). **Maria J. Giraldez:** Conceptualization (equal); methodology (equal); project administration (equal); resources (equal); supervision (equal); writing – original draft (supporting); writing – review and editing (supporting). **Eva Yebra-Pimentel:** Conceptualization (equal); methodology (equal); project administration (equal); resources (equal); supervision (equal); writing – original draft (supporting); writing – review and editing (supporting).

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest in the present study and that they received no specific funding for this study.

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