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The ability of the Contact Lens Dry Eye Questionnaire (CLDEQ)-8 to detect ocular surface alterations in contact lens wearers

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ABSTRACT

Purpose: To study whether some ocular surface alterations could be associated with contact lens (CL) wearers suffering from CL discomfort (CLD) detected using the Contact Lens Dry Eye Questionnaire (CLDEQ)-8.

Methods: Forty-one soft CL wearers further classified into symptomatic CL wearers (SCLW) and asymptomatic CL wearers (ACLW) by the CLDEQ-8, and 20 non CL wearers (NCLW) were included. Tear osmolarity, slit-lamp biomicroscopy findings, tear film break-up time, corneal and conjunctival staining, and Schirmer test were performed 24 h after CL removal. Data were compared among groups using the analysis of variance and the Student *t*-test or the Kruskal-Wallis H and the Mann-Whitney U tests, applying the Bonferroni correction. Correlations between the CLDEQ-8 and the clinical signs were performed using the Spearman correlation coefficient.

Results: Twenty-four SCLW, 17 ACLW and 20 NCLW were recruited. There were significant differences among groups for tear osmolarity ($p < 0.001$), limbal hyperaemia ($p = 0.014$), and tarsal hyperaemia ($p = 0.031$). Pairwise comparisons revealed that SCLW and ACLW had higher tear osmolarity ($p < 0.003$, both comparisons) and limbal hyperaemia ($p = 0.027$ and $p = 0.048$, respectively) than NCLW. Moreover, SCLW had higher tarsal hyperaemia ($p = 0.030$) than NCLW. No significant correlations were found ($p > 0.05$).

Conclusion: The CLDEQ-8 was ineffective to detect clinical alterations between SCLW and ACLW; therefore, the use of questionnaires alone remains being the best approach to detect CLD. The role of the tarsal conjunctiva in the development of CLD should be analyzed in future studies.

1. Introduction

Contact lens (CL) wear is an extended method for correcting the refractive error around the world. However, a great amount of CL wearers suffer symptoms of dryness, itching, burning or foreign body sensation while wearing their CLs, a condition that the Tear Film and Ocular Surface (TFOS) Society has recently named as CL discomfort (CLD) [1]. The prevalence of CLD is estimated to be between 35% and 60% and it has become the first cause of cessation of CL wear [2–4]. As a consequence, this condition has a considerable impact over the CL wearers, clinicians, and the industry [5,6]. Besides, despite the numerous research efforts in this field, the cause of CLD is still unknown.

In the scientific literature, several methods have been applied for detecting CLD. Some authors have used the comfortable CL wearing time [7,8]. For example, Korb et al. [7] considered symptomatic those CL wearers whose CL wearing period without symptoms was lower than 12 h, whereas Glasson et al. [8] considered as intolerant CL wearers those who were unable to wear CLs regularly during 9 h or longer. However, the most extended method is the administration of validated questionnaires. The Ocular Surface Disease Index (OSDI) questionnaire [9] has been previously used [10,11] despite it has a great inconvenience: it was not designed for evaluating CL wearers, but for dry eye patients. On the other side, the Contact Lens Dry Eye Questionnaire (CLDEQ) [12] as well as its short forms, the CLDEQ-short form [13] and the CLDEQ-8 [14,15], were designed for assessing CLD. The three forms of the CLDEQ have been widely used [3,16–18]. Despite all the alternatives available, the TFOS Society stated that no specific instrument can be recommended for detecting CLD, although the CLDEQ-8 was

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Table 1
Contact lens (CL) wearing characteristics of the symptomatic (SCLW) and asymptomatic (ACLW) CL wearers.

	SCLW	ACLW	p-value
CL type (hydrogel / silicone hydrogel)	10 / 14	4 / 13	0.228
Replacement schedule (daily / bi-weekly / monthly)	4 / 4 / 16	2 / 1 / 14	0.530*
CL experience (years)	7.0 (5.3-9.8)	8.0 (5.0-11.0)	0.989
Weekly frequency of CL wear (days/week)	6.0 (5.0-7.0)	7.0 (5.0-7.0)	0.244
Daily frequency of CL wear (hours/day)	8.0 (7.0-10.0)	9.0 (8.0-12.0)	0.396

Qualitative data are presented as frequency and were analyzed using the Chi-square test or the Fisher exact test (*). Non-normal distributed quantitative data are presented as median (interquartile range) and were analyzed using the Mann-Whitney *U* test.

Table 2
Clinical signs evaluated in the three study groups: symptomatic (SCLW) and asymptomatic (ACLW) contact lens wearers, and non contact lens wearers (NCLW).

	SCLW	ACLW	NCLW	p-value
Tear osmolarity (mOsms/L)	336.5 (328.5-347.9)	337.0 (324.5–344.0)	303.5 (298.8–315.8)	***< 0.001***
Bulbar hyperaemia (Efron scale)	1.0 (1.0–1.0)	1.0 (0.5–1.0)	1.0 (0.3–1.0)	0.802
Limbal hyperaemia (Efron scale)	1.0 (0.3–1.0)	1.0 (0.5–1.0)	0.0 (0.0–1.0)	***0.014***
Tarsal hyperaemia (CCLRU scale)	1.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	***0.031***
Lid roughness (CCLRU scale)	1.0 (0.3–1.0)	1.0 (0.0–1.0)	0.0 (0.0–1.0)	0.148
Tear film break-up time (s)	9.6 ± 6.0	10.4 ± 4.9	9.4 ± 8.0	0.363
Total corneal staining (0-20 scale)	0.0 (0.0–2.5)	0.0 (0.0–0.0)	0.0 (0.0–1.0)	0.160
Conjunctival staining (CCLRU scale)	0.0 (0.0–0.0)	0.0 (0.0–1.0)	0.0 (0.0–0.0)	0.784
Schirmer test without anaesthesia (mm)	20.0 (10.3–35.0)	22.0 (14.5–35.0)	18.0 (9.3–35.0)	0.749

Normal distributed data are presented as mean ± standard deviation and were analyzed using the analysis of variance. Non-normal distributed data are presented as median (interquartile range) and were analyzed using the Kruskal-Wallis H test.
Significant p-values are denoted in bold, italic font.

considered the best approach [19]. Therefore, since classifying CL wearers properly (as symptomatic or not) is key for any clinical and research purpose, it is necessary to develop new methods or at least, improve the existing ones.

As well as for CLD, the diagnosis of dry eye syndrome (a disease that courses with similar ocular symptoms but without the necessity of wearing CLs [20]), is also commonly performed using validated questionnaires [21], such as the OSDI questionnaire [9]. However, the use of dry eye questionnaires is frequently combined with alterations in clinical signs, such as tear break-up time, corneal staining or Schirmer test [22,23], given that these combinations increase the sensitivity and specificity of the diagnosis [24]. CL wear, indeed, is associated with several alterations of the ocular surface including a decrease of tear stability and volume, and an increase in epithelial damage, among others [24,25]. On the opposite, it is widely recognized that ocular symptoms and clinical signs are not well related in CL wearers [24,25]. Nonetheless, this lack of relationship found up to date could be the result of using diagnosing methods not accurate enough for properly classifying CL wearers as having CLD or not.

Therefore, the aim of this work was to study whether classifying CL wearers into symptomatic and asymptomatic by means of the CLDEQ-8 questionnaire is able to identify differences in the clinical signs of the ocular surface that could help to understand and detect CLD.

2. Materials and methods

This study was approved by the Hospital Clínico Universitario Ethics Committee (Valladolid, Spain) and complied with the Tenets of the Declaration of Helsinki. The nature of the research and protocols were explained to the subjects before written consent was obtained.

2.1. Sample

Sixty-one subjects were included in the study, 41 soft CL wearers and 20 non CL wearers. The CLDEQ-8 questionnaire [14] was administered to further divide CL wearers into symptomatic (SCLW) and asymptomatic CL wearers (ACLW). Inclusion criteria were age between 18 and 40 years, astigmatism ≤ 0.75 D, and visual acuity ≤ 0.0 LogMAR. CL wearers had to be CL users for at least 6 months before being included in the study and had to wear their CLs at least 5 days per week and 6 h per day. Exclusion criteria were extended or continuous CL wear (overnight use), and dry eye syndrome defined as an Ocular Surface Disease Index [9] (OSDI) score ≥ 13 and at least two of the following tests altered (in at least one eye): tear film break-up time ≤ 7 s, corneal staining extension with fluorescein ≥ grade 2 (CCLRU scale [26]) in any of the corneal areas, and Schirmer test without anaesthesia ≤ 5 mm. Those volunteers who had any other active ocular disease, ocular allergy, history of anterior ocular surgery, any systemic disease that contraindicates CL wear, and use of any topical medication other than artificial tears were also excluded.

The study protocol consisted of one visit scheduled between 9 a.m. and 6 p.m. All subjects were instructed to not wear their CLs for at least 24 h before the visit to minimize the possible influence of the diverse CL materials, care solutions or replacement schedules. Clinical evaluation was performed in both eyes. However, only one eye per subject was randomly selected for statistical analysis, except for tear osmolarity where the mean of both eyes was considered.

2.2. Experimental procedure

2.2.1. Contact Lens Dry Eye Questionnaire-8

CL wearers were classified as symptomatic or asymptomatic by administering the CLDEQ-8 questionnaire [14]. CL wearers were instructed to complete the questionnaire taking into account the symptoms they commonly suffer while wearing their CLs. The CLDEQ-8 questionnaire consists of 8 questions which evaluate discomfort, dryness, blurred vision, and the desire of removing the CLs from the eyes; giving a total score up to 37 points. CL wearers were classified as symptomatic if the total score was equal or higher than 12 points and asymptomatic if the total score was lower than 12 points [15].

2.2.2. Tear osmolarity

Tear osmolarity was assessed once for each eye using the TearLab system (TearLab Corporation, San Diego, CA, EE.UU). This device provides the tear osmolarity value (mOsms/L) after taking a 50 nl tear sample from the temporal canthus of the lower eyelid. The mean

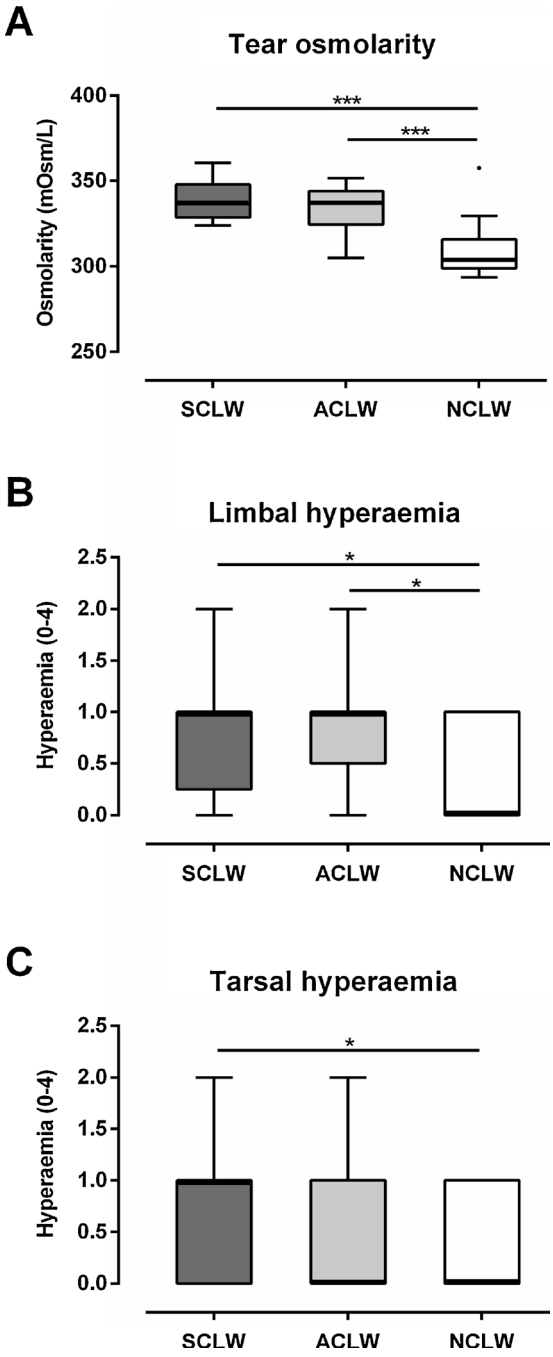

Fig. 1. Pairwise comparisons among the three study groups of the variables with significant differences: tear osmolarity (A), limbal hyperaemia (B), and tarsal hyperaemia (C). The box represents percentiles 25 through 75 with the median as a bold line, the whiskers represent range within 1.5 times the interquartile range, and outliers are shown as points. ACLW: asymptomatic contact lens wearers; NCLW: non contact lens wearers; SCLW: symptomatic contact lens wearers. Differences among groups were analyzed using the Mann-Whitney U test applying the Bonferroni correction. *P < 0.05, ***P < 0.003.

osmolarity value of both eyes was considered.

2.2.3. Biomicroscopy findings

The ocular surface was examined with a slit lamp (SL-D7; Topcon Corporation). Bulbar and limbal hyperaemia were graded using the Efron grading scale (0–4) [27], while tarsal hyperaemia and lid roughness (papillae formation) were graded using the CCLRU grading scale (0–4) [26].

Table 3
Correlations between the CLDEQ-8 questionnaire and the clinical signs.

	rho	p-value
Tear osmolarity	−0.052	0.747
Bulbar hyperaemia	−0.030	0.855
Limbal hyperaemia	−0.089	0.579
Tarsal hyperaemia	0.105	0.515
Lid roughness	0.196	0.220
Tear film break-up time	−0.165	0.303
Total corneal staining	0.267	0.091
Conjunctival staining	−0.061	0.706
Schirmer test without anaesthesia	−0.021	0.896

Data were analyzed using the Spearman correlation coefficient (rho).

2.2.4. Tear film break-up time

Tear film break-up time measurement was performed after instillation of 5 µL of 2% sodium fluorescein (Bausch and Lomb, Rochester, NY, USA). The corneal surface was observed with the slit lamp using a cobalt blue filter over the slit-lamp and a Wratten #12 yellow filter. After 3 complete blinks, tear film break-up time was established as the interval (in seconds) between the last blink and the appearance of the first dry spot; this procedure was repeated 3 times and the mean value was recorded.

2.2.5. Corneal and conjunctival staining

Corneal and conjunctival staining were evaluated 2 min after the instillation of 5 µL of 2% sodium fluorescein using the cobalt blue and the Wratten #12 yellow filters. Extent corneal staining (within each of five zones: superior, inferior, nasal, temporal, and central) was assessed using the CCLRU grading scale (0–4) [26], and a total corneal staining score was generated by adding up the 5 areas scores (0–20). Conjunctival staining was also assessed using the CCLRU grading scale (0–4) [26].

2.2.6. Schirmer test without anaesthesia

Schirmer test was performed inserting a Schirmer sterile strip (Tearflo; Alcon Laboratories, Inc., Fort Worth, Texas, USA) into the external canthus of the eyelid margin without topical anaesthesia. Five minutes later, the length (mm) of the strip that had been moistened by the tear was measured and recorded.

2.3. Statistical analysis

The sample size was estimated to find a difference between two groups of 15 mOsm/L in the tear osmolarity considering a standard deviation of 13.65 mOsm/L [28]. Then, to reach a statistical power of 80% with a level of signification of 5%, the sample size should be of at least 17 subjects per group.

The inferential analysis was performed using SPSS Statistics 23 for Windows (IBM, Chicago, IL, USA). Qualitative parameters are presented as frequencies and were analyzed using either the Chi-square test or the Fisher's exact test when expected frequencies were too small to perform the Chi-square test. Categorical variables are presented as median (interquartile range) and were analyzed using the Kruskal-Wallis H test and the Mann-Whitney U for pairwise comparisons. Quantitative variables were tested for normality (Shapiro-Wilk test) and equality of variances (Levene test). If normality or log normality could be assumed, quantitative data are presented as mean ± standard deviation and were analyzed using the analysis of variance (ANOVA) and the Student T test for pairwise comparisons. However, if normality could not be assumed, quantitative parameters are presented and were analyzed as categorical variables. Bonferroni correction was applied in pairwise comparisons. In addition, correlations between the CLDEQ-8 questionnaire and the clinical signs were also performed using the Spearman correlation coefficient. P values ≤ 0.05 were considered statistically

significant.

3. Results

3.1. Sample

A total of 22 males and 39 females, with a mean age of 26.3 ± 5.3 years were recruited. Twenty-four out of the 41 CL wearers reached a CLDEQ-8 score of 12 points or higher [16.5 (14.0–20.0)], so they were classified as symptomatic, while 17 CL wearers obtained a score lower than 12 points [9.0 (6.5–10.5)], so they were classified as asymptomatic. The SCLW group was composed of 5 males and 19 females aged 26.4 ± 5.4 years, the ACLW group included 8 males and 9 females aged 25.5 ± 5.7 years, and the NCLW group was composed by 9 males and 11 females aged 27.0 ± 5.2 years. No significant differences were found in the subject gender ($p = 0.135$) and age ($p = 0.706$) among the three groups. The CL wearing characteristics of the two CL wearers groups are described in Table 1.

3.2. Clinical evaluation

The comparison of the clinical variables among the three groups is presented in Table 2. Significant results were found for tear osmolarity ($p < 0.001$), limbal hyperaemia ($p = 0.014$), and tarsal hyperaemia ($p = 0.031$). Tear osmolarity was significantly increased ($p < 0.003$, in both cases) in the SCLW and ACLW groups regarding the NCLW group (Fig. 1A). Limbal hyperaemia was significantly increased ($p = 0.027$ and $p = 0.048$, respectively) in the SCLW and ACLW groups comparing with the NCLW group (Fig. 1B). Tarsal hyperaemia was significantly increased ($p = 0.030$) in the SCLW group in comparison with the NCLW group (Fig. 1C). No significant correlations were found between the CLDEQ-8 and the clinical signs (Table 3).

4. Discussion

Several instruments have been used for detecting CLD; however, according to the TFOS Society, no specific one can be recommended [19]. Given that the CLDEQ-8 was considered the best approach [19], combining this instrument with some clinical signs could help to detect CLD. The current study analyses the differences in the clinical signs of the ocular surface among symptomatic and asymptomatic CL wearers, classified by means of the CLDEQ-8 questionnaire, and non CL wearers. The results indicate that, in comparison with non CL wearers, tear osmolarity and limbal hyperaemia are increased in both CL wearers groups, whereas tarsal hyperaemia is increased only in CL wearers who suffer from CLD.

Several studies have reported, as well as in the present work, that CL wear increases tear osmolarity [28–31]. In addition, the current study found no difference between the SCLW and ACLW groups. In concordance with these results, Sarac et al. [28] and Stahl et al. [32] found no relationship between the levels of tear osmolarity and ocular comfort. Besides, Glasson et al. [8] found no significant difference between intolerant and asymptomatic CL wearers, although their outcomes almost reached statistical significance. In contrast, Nichols et al. [3] reported an increased tear osmolarity in symptomatic CL wearers, although they took the measurement immediately after CL removal and admitted that reflex tears could have interfered in their results. Therefore, despite an increase in tear osmolarity is strongly related to CL wear, this parameter appears not to be associated with CLD.

Another parameter found altered in this study was the limbal hyperaemia. It was increased in both CL wearers groups in comparison with the NCLW group, but again, no difference was found between the SCLW and ACLW groups. Limbal hyperaemia is highly known to increase as a response to low oxygen supply to the cornea wearing low oxygen permeability CLs [33,34]. Given that both CL wearers groups were composed by a combination of hydrogel and silicone hydrogel CL wearers, the increase in limbal hyperaemia was expected as a result of the lower oxygen supply to the cornea produced, mainly, by hydrogel CL wear. Thus, although an increase in limbal hyperaemia was related to CL wear, it cannot be associated with CLD.

The tarsal conjunctiva of the SCLW group presented higher hyperaemia in comparison with the NCLW group, but not with the ACLW group. This finding may indicate that friction between the cornea/CL and the upper eyelid is greater in the SCLW group, producing ocular symptoms during CL wear. An increased friction could be the result of a combination of different factors, such as greater lid roughness or poorer tear film stability. However, these parameters were not different among groups in the present study. On the other hand, in agreement with this hypothesis, Young et al. [35] associated lid roughness with a poor comfort in healthy CL wearers, several authors found lower tear film stability in symptomatic CL wearers [8,36,37], and greater staining of the lid wiper area has been related to symptomatic CL wearers [38,39]. Therefore, these results may indicate that tarsal conjunctiva have a role in the development of CLD. Nonetheless, tarsal hyperaemia was not different between the SCLW and ACLW groups; therefore, despite the association found for the symptomatic CL wearers, this parameter appear not to be useful to detect CLD.

It was also found that several clinical signs including bulbar hyperaemia, tear film break-up time, corneal and conjunctival staining, and Schirmer test were not different among groups. Besides, no correlations were found between symptoms and clinical signs. On the contrary, it has been reported numerous times in the scientific literature that CL wear produces a decrease in tear stability and volume [40–42], an increase in bulbar hyperaemia [43], and corneal and conjunctival staining [43–45]. Nonetheless, considering that measurements of this study were taken 24 h after CL removal, these findings may indicate that these clinical signs quickly recover from the alterations produced by CL wear. Besides, the hypothetical recovery would be independent of whether CL wearers are symptomatic or asymptomatic. Therefore, these parameters neither seem to be associated with CL wear nor CLD when measured 24 h after CL removal.

In the present study, the wearing characteristics of the CL wearers were not initially controlled, which could be considered a limitation. However, to minimize the possible influence of the diverse CL materials, care solutions or replacement schedules, CL wearers were instructed to remain at least 24 h before the visit without wearing their CLs. Besides, there were no significant differences between both groups in terms of CL type or replacement schedule (Table 1). The effect of CL type or replacement schedule was not analyzed into each group because sample size would be too small. On the contrary, the exact time that subjects remained without CL wear was not controlled; however, considering the minimum frequency of CL wear (5 days per week), and the median frequency of CL wear (6 and 7 days per week in the SCLW and ACLW groups, respectively), this period of time is expected to be not much longer than 24 h.

In conclusion, an increase in tear osmolarity and limbal hyperaemia can be associated with regular soft CL wear, but not with CLD as measured by means of the CLDEQ-8. Indeed, none of the clinical signs discerned between symptomatic and asymptomatic CL wearers classified by means of the CLDEQ-8 questionnaire. Therefore, the use of questionnaires alone remains being the best approach to detect CLD. On the other hand, the higher tarsal hyperaemia found regarding non CL wearers may indicate that tarsal conjunctiva have a role in the development of CLD. Future studies analysing the role of the tarsal conjunctiva are recommended to elucidate its real implication.

Conflicts of interest

None of the authors have any financial or conflicting interests to disclose.

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