Clinical characterisation of contact lens discomfort progression

Authors

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Abstract

Purpose: This study aimed to assess the subjective and objective differences among the steps of the contact lens discomfort (CLD) progression classification established by the Tear Film and Ocular Surface Society (TFOS) using questionnaires and clinical signs, and to propose a simplified classification.

Methods: Contact lens (CL) wearers were evaluated in a single visit. The Contact Lens Dry Eye Questionnaire (CLDEQ)-8, the Contact Lens Discomfort Index, and visual analog scales for discomfort and dryness were administered. The non-invasive break-up time, the tear film lipid layer thickness, conjunctival hyperemia and papillae, lid-parallel conjunctival folds, the fluorescein tear film break-up time, corneal and conjunctival staining, lid wiper epitheliopathy, and the Schirmer test were assessed. Sign and symptom scores were compared among TFOS CLD progression steps using analysis of variance or the Kruskal-Wallis H test. Steps 1 and 2 (reduced comfort), and steps 3 and 4 (reduced wearing time) of the TFOS classification were combined to obtain a simplified classification, and the same comparison was performed. A p-value ≤0.05 was considered statistically significant.

Results: One hundred-fifty CL wearers (97 women and 53 men) aged 34.4±12.6 years were included. In the TFOS classification, there were significant differences between step 0 (no CLD) and the rest of the severity steps for the scores obtained in all questionnaires ($p \leq 0.015$). All steps were differentiated ($p \leq 0.032$) based on the simplified classification for all questionnaires, except steps 1 and 2 for the CLDEQ-8 and dryness VAS ($p=0.089$ and $p=0.051$, respectively). There were no differences (all $p \geq 0.06$) between the sign scores among the steps of either classification.

Conclusion: CLD management is encouraged from its first appearance. Simplifying the phases of CLD severity may allow a more accurate classification and a better awareness of the problem by clinicians and CL wearers by using more straightforward simple messages.

Keywords

Contact lens, discomfort, classification, questionnaires

Introduction

Contact lens (CL) discomfort (CLD) has been defined as ‘a condition characterized by episodic or persistent adverse ocular sensations related to CL wear, either with or without visual disturbance, resulting from reduced compatibility between the CL and the ocular environment, which can lead to decreased wearing time and discontinuation of CL wear’ [1]. In fact, CLD is one of the main reasons for CL abandonment [2]. Different strategies are commonly performed in daily clinical practice to manage CLD [3–7]. Therefore, precise assessment and/or classification of symptoms is essential for adequate counseling and also to monitor the effectiveness of CLD management. However, measuring CLD is challenging because the condition itself is episodic, variable in degree, and resolves upon CL removal [8].

For research and clinical purposes, CL wearers are usually classified into symptomatic and asymptomatic wearers according to validated questionnaires, such as the Contact Lens Dry Eye Questionnaire (CLDEQ-8) [9]. However, poor relationships have been reported between signs and symptoms in CL wearers [10,11]. After an extensive and deep revision of CLD, the Tear Film and Ocular Surface Society (TFOS) recommends classifying the progression of CLD into five steps: 1) physical awareness of the CL and visual disturbance, 2) reduced comfortable CL wearing time, 3) reduced total CL wearing time, 4) temporary discontinuation of wearing CLs, and 5) permanent discontinuation of wearing CLs (CL dropout) [1]. Therefore, the purposes of this study were: 1) to evaluate whether the different steps of CLD progression established by the TFOS can be differentiated subjectively and objectively using questionnaires and clinical signs, and 2) to propose a simplified classification that might be subjectively and objectively more useful in the clinical setting.

Methods

A prospective, cross-sectional study was conducted to assess the subjective and objective clinical usefulness of the CLD progression steps established by the TFOS. It was approved by the East Valladolid Health Area Ethics Committee (Spain) and followed the tenets of the Declaration of Helsinki. The nature of the study was explained to the volunteers and the informed consent was obtained.

Patient selection

The inclusion criteria were ≥18 years old and CL wear (except ortho-k or scleral CLs). The exclusion criteria were any ocular or systemic disease or allergy contraindicating the use of CLs, any corneal ectasia, any topical treatment other than artificial tears, any anti-inflammatory systemic treatment, any ocular surgery, pregnancy, or breastfeeding.

Clinical evaluation

Clinical evaluation of all CL wearers was performed by the same clinician (L.V.N.) while subjects wore their habitual CLs during a single visit. The order of the examinations was the following:

Measurement of symptoms

Ocular symptoms were evaluated with several instruments. The CLDEQ-8 score ranges from 1 to 37, and its cut-off value for detecting symptomatic CLD is ≥12 [9]. The Contact Lens Discomfort Index (CLDI) score ranges from 0 to 18, with a cut-off value of >8 [12]. Finally, a visual analog scale (VAS) assessed current discomfort and dryness felt by the participants at the beginning of the study visit on a 0–10 scale [13]. In addition, the participants were classified by the evaluator into the CLD progression steps proposed by the TFOS based on the responses each participant provided to the specific questions. The steps were assigned as follows: step 0 if any discomfort symptom was reported; step 1 if they felt a physical awareness; step 2 if they had a reduced comfortable CL wearing time; step 3 if they had a reduced total CL wearing time; and step 4 if they had temporarily discontinued their habitual CL use. Step 5 (CL dropout) was not

addressed, as all participants were currently wearing CLs. Therefore, the present study initially modified the TFOS modes of CLD progression to a 4-step scale.

Measurement of signs

Visual acuity was measured monocularly at 4 m using a logMAR scale with 100% contrast (Topcon Corporation, Tokio, Japan; http://global.topcon.com/). Bailey-Lovie optotypes with a geometrical progression factor in letter size from row to row of x1.26 (0.1 log units) were used [14].

The non-invasive break-up time (NIBUT) was measured using the EASYTEAR®view+ (EASYTEAR s.r.l., Trento, Italy; http://www.easytearviewplus.com/en/). The participants were asked to blink three times before obtaining the measurement. The final value was the average of three measurements.

The tear film lipid layer thickness (LLT) was evaluated with the Lipiview II interferometer (Johnson & Johnson Vision, Santa Ana, CA, USA; https://www.jnjvisionpro.ca/products). The measurement computed for analysis was the mean of the LLT automatically obtained during a 20-s video, which was recorded while CL wearers were blinking normally.

An ocular surface examination was performed using a slit lamp (SL-D7, Topcon Corporation). Bulbar and limbal conjunctival hyperemia were evaluated with the Efron scale (0–4) [15], while tarsal hyperemia and papillae were measured with the Cornea and Contact Lens Research Unit (CCLRU) scale (0–4) [16]. Lid parallel conjunctival folds (LIPCOF) were measured as the average of the nasal and temporal values (a scale from 0 to 3) [17].

The tear film break-up time (TBUT) was measured after instillation of 5 µL of 2% sodium fluorescein into the inferior fornix using a cobalt blue filter (Topcon Corporation) and a yellow Wratten no. 12 filter (Eastman Kodak, Rochester, NY, USA). The participants were asked to blink three times before the measurement. The final value recorded was the average of three measurements.

Corneal fluorescein staining (CFS) was evaluated 2 min after instillation of sodium fluorescein into the inferior fornix using the extension CCLRU scale for each of the five corneal areas [16]. The global punctuation was obtained as the sum of the values obtained for all five corneal areas.

Conjunctival staining was evaluated after the instillation of lissamine green strips (GreenGlo; HUB Pharmaceuticals LLC, Rancho Cucamonga, CA, USA) wetted with 25 µL sodium chloride into the inferior fornix. The Oxford scale was used to grade the staining [18].

Lid wiper epitheliopathy was evaluated after instillation of sodium fluorescein and lissamine green into the inferior fornix. The final value was the mean of the horizontal length (0–3) and the sagittal height (0–3) staining [19].

The Schirmer test was evaluated placing Schirmer sterile strips (Tearflo; HUB Pharmaceuticals LLC, Plymouth, MI, USA) in the external canthus of the inferior lid margins. After 5 min, the wetting length of the strips was recorded.

Statistical analysis

Statistical analysis was performed using R version 4.2.1. Questionnaires, main CL wearing characteristics, and sign scores obtained among the different CLD progression steps proposed by the TFOS were compared using analysis of variance (ANOVA) for parametric variables, the Kruskal-Wallis H test for non-parametric variables, and the chi-squared test for qualitative variables (CL type and replacement). Multiple comparisons were performed after the Kruskal-Wallis H test using Dunn's test with the Bonferroni correction. Then, the TFOS classification was simplified by merging CLD progression steps 1 and 2 (both related to reduced comfort) and steps 3 and 4 (both related to reduced wearing time). The same comparison among questionnaires and sign scores was performed for the steps of the simplified classification. To report the magnitude and uncertainty of the observed effects, the mean rank difference and 95% confidence interval were calculated among all steps for both classifications. Only one eye per subject was randomly selected for the analysis of clinical signs. Quantitative variables are shown as mean ± standard deviation, and ordinal variables are shown as median [interquartile range]. A p-value ≤0.05 was considered statistically significant.

Results

Descriptive data

A total of 150 CL wearers (97 women and 53 men) with a mean age of 34.4±12.6 years (range: 18–67 years) were consecutively recruited. The CL characteristics are shown in Table 1.

Table 1. Contact lens (CL) characteristics of the sample included in the study.

Characteristic	
CL type	
Silicone hydrogel	100
Hydrogel	42
Gas permeable	8
CL replacement	
Frequent	92
Single use	46
Conventional	12
CL wearing time	
Days/week	5.2±2.1 (1–7)
Hours/day	9.0±3.7 (2–17)
Comfortable CL wearing time (hours/day)	7.7±3.8 (0–17)
Spherical CL power (D)	-4.25±3.50 (-16.25 to 5.75)
CL design	
Spherical	115
Toric	35
Cylindrical CL power (D)	-1.50±1.00 (-4.50 to -0.75)
Visual acuity (logMAR scale)	-0.03±0.16 (-0.26 to 0.85)

The data are presented as mean ± standard deviation (range) for quantitative parameters, and frequency for qualitative parameters.

Frequent replacement involves biweekly, monthly, and quarterly replacements.

D, diopters.

TFOS classification for CLD progression

The percentage of CL wearers classified into each of the CLD progression steps proposed by the TFOS is shown in Figure 1A. There were significant differences among CLD progression steps for all the CL questionnaires ($p \leq 0.001$). Specifically, there were differences between step 0 (no CLD) and the rest of the CLD progression steps for the CLDEQ-8 ($p \leq 0.002$), the CLDI ($p \leq 0.015$), and the discomfort and dryness VAS ($p \leq 0.001$) (Figure 1B–E). There were no differences ($p \geq 0.084$) among the other CLD progression steps for any questionnaire. Figure 2 shows the observed effect of the multiple comparisons among the CLD progression steps for the CL questionnaires. There were no differences ($p \geq 0.09$) among the CLD progression steps for the clinical signs and CL wearing characteristics (Table 2), except for the days per week of CL wear ($p < 0.001$). Specifically, there were significant differences between step 4 and steps 0 ($p < 0.001$), 1 ($p < 0.001$), and 2 ($p = 0.003$).

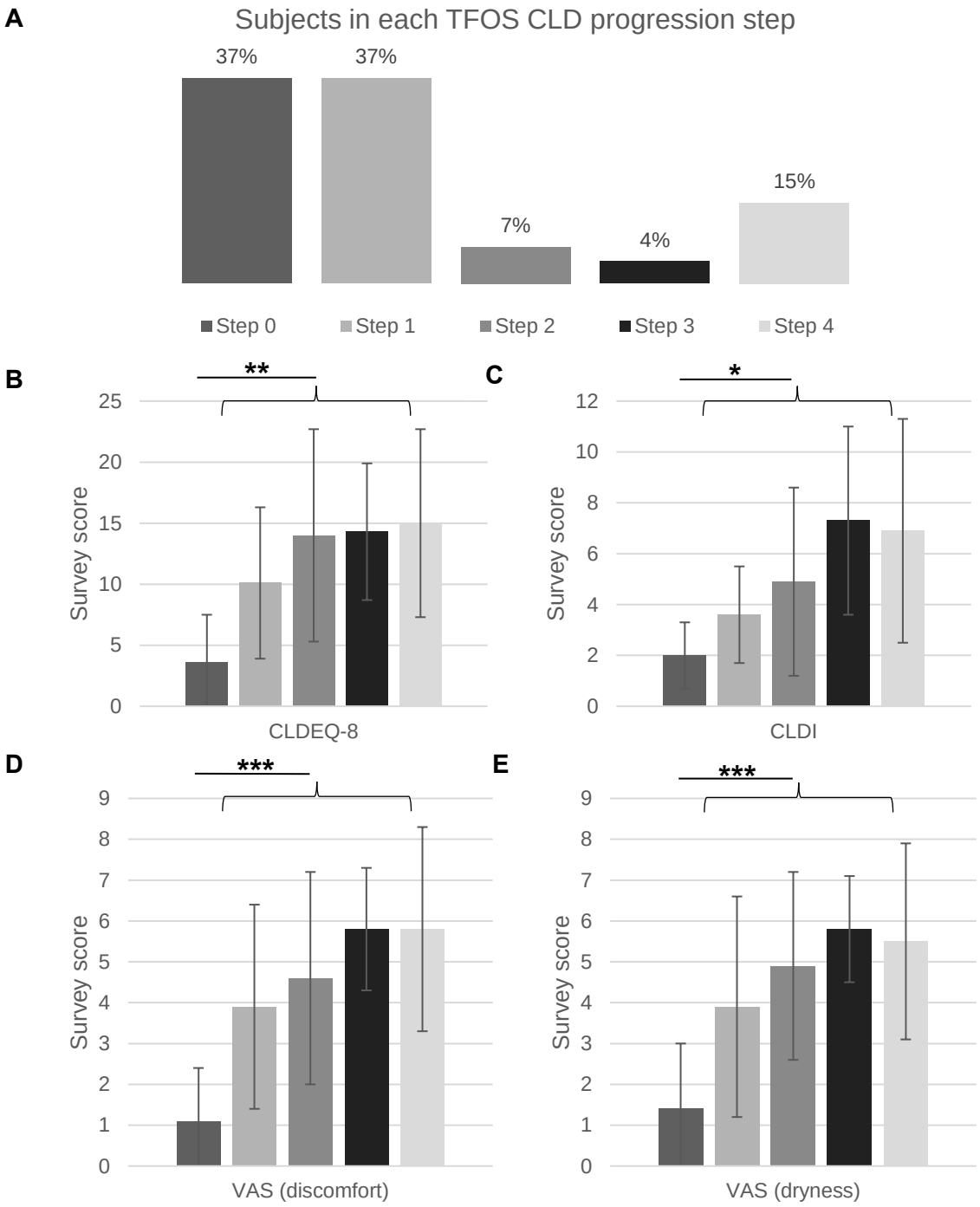

Figure 1. A) Percentage of subjects classified into each step of the contact lens discomfort (CLD) progression classification proposed by the Tear Film and Ocular Surface Society (TFOS). B) Scores obtained for each step of the CLD progression classification proposed by the TFOS in the Contact Lens Dry Eye Questionnaire (CLDEQ)-8, C) the Contact Lens Discomfort Index (CLDI), and the visual analog scales (VAS) for D) discomfort and E) dryness. * p≤0.05; ** p≤0.01; *** p≤0.001.

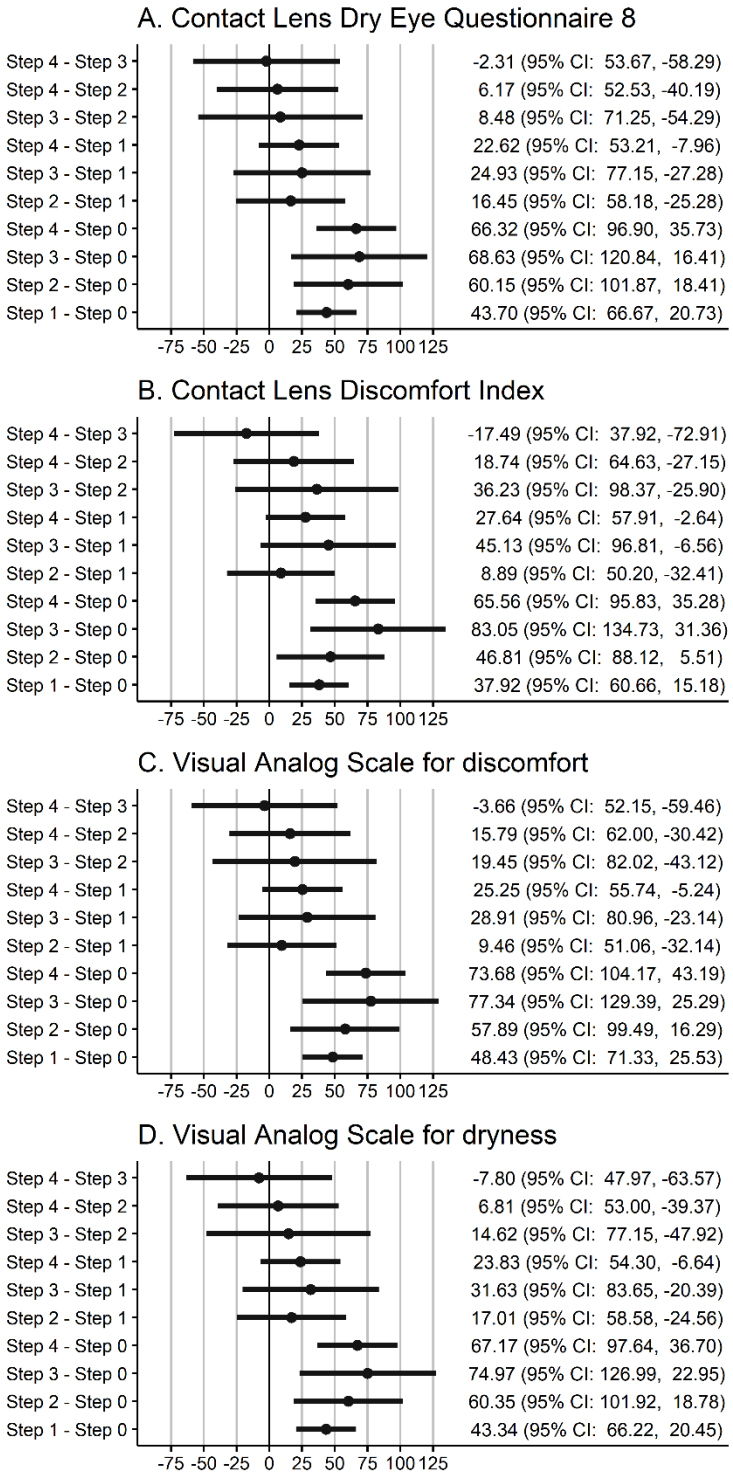

Figure 2. The observed effect of the multiple comparisons between the steps of the contact lens discomfort progression classification proposed by the Tear Film and Ocular Surface Society for A) the Contact Lens Dry Eye Questionnaire-8, B) the Contact Lens Discomfort Index, and the visual analog scale C) for discomfort and D) for dryness. The data are presented as the mean rank difference and 95% confidence interval (CI).

Table 2. Outcomes of the contact lens wearing characteristics and clinical signs obtained for each step of the contact lens discomfort progression classification proposed by the Tear Film and Ocular Surface Society (TFOS).

	TFOS classification					
	Step 0	**Step 1**	**Step 2**	**Step 3**	**Step 4**	**p-value**
Days/week of CL wear	5.6±1.9	5.5±2.1	6.1±1.6	4.7±2.1	3.2±1.9	*<0.001*
Hours/day of CL wear	9.7±3.8	8.9±3.4	9.9±4.7	7.3±4.3	7.4±3.1	0.09
CL type						
Silicone hydrogel	40	35	7	3	15	0.55
Hydrogel	12	18	2	3	7	
CL replacement						
Frequent	37	33	7	5	10	0.10
Single use	12	19	2	1	12	
NIBUT	7.9±3.0	8.6±3.7	7.7±2.6	5.8±1.1	7.1±2.8	0.19
LLT	75.8±14.5	74.3±16.4	67.3±15.0	74.5±14.6	71.9±19.8	0.60
Bulbar hyperemia	1 [2]	1 [1.25]	1 [0]	1 [0.75]	1 [1]	0.45
Limbal hyperemia	1 [1]	1 [1]	1 [0]	1 [0]	1 [1.75]	0.80
Tarsal hyperemia	1 [1]	1 [1]	1 [0]	1 [0]	1 [1]	0.21
Eyelid papillae	1 [1]	1 [1]	1 [0.75]	1 [0]	1 [1]	0.86
LIPCOF	1.75 [1.5]	1.5 [1]	1.25 [1.375]	2 [1.125]	1.5 [1]	0.65
TBUT	7.2±3.6	7.0±3.4	8.3±2.3	6.1±1.8	7.0±3.8	0.33
Corneal staining	2 [2.25]	1 [1]	1 [1.75]	1.5 [1]	2 [2]	0.16
Conjunctival staining	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.81
LWE	0 [0]	0 [0]	0 [0]	0 [0]	0 [0]	0.77
Schirmer test	16.6±9.6	17.2±12.2	14.5±12.2	12.2±6.6	17.0±11.4	0.83

The data are presented as the mean ± standard deviation for quantitative variables or the frequency or median [interquartile range] for qualitative variables.

Frequent replacement involves biweekly, monthly, and quarterly replacements.

CL, contact lens; NIBUT, non-invasive break-up time; LLT, tear film lipid layer thickness; LIPCOF, lid-parallel conjunctival folds; TBUT, fluorescein tear film break-up time; LWE, lid wiper epitheliopathy.

Simplified classification for CLD progression

Steps 1 and 2 and steps 3 and 4 of the CLD progression classification proposed by the TFOS were combined. Thus, the proposed simplified classification of CLD progression comprised only three steps: 0 for no CLD, 1 for a reduction in comfortable CL wearing time, and 2 for a reduction in total CL wearing time.

Figure 3A shows the percentage of CL wearers classified into each step of the simplified classification. There were significant differences among CLD progression steps for all the symptom questionnaires ($p \leq 0.001$). Specifically, there were significant differences between all steps for the CLDI ($p \leq 0.006$), the discomfort and dryness VAS ($p \leq 0.032$), and the CLDEQ-8 ($p \leq 0.001$), except for the difference between steps 1 and 2 for the CLDEQ-8 and dryness VAS ($p=0.089$ and $p=0.051$, respectively) (Figure 3B–E). Figure 4 shows the observed effect of the multiple comparisons among the CLD progression steps for all questionnaires. Regarding the CL wearing characteristics (Table 3), there were significant differences in the CL wearing time ($p \leq 0.02$). Specifically, there were differences for the days per week of CL wear between step 2 and steps 0 and 1 ($p<0.001$ in both cases); and for the daily hours of CL wear, there were differences between step 0 and step 2 ($p=0.020$). There were no differences ($p \geq 0.06$) between the clinical signs among any of the CLD progression steps (Table 3).

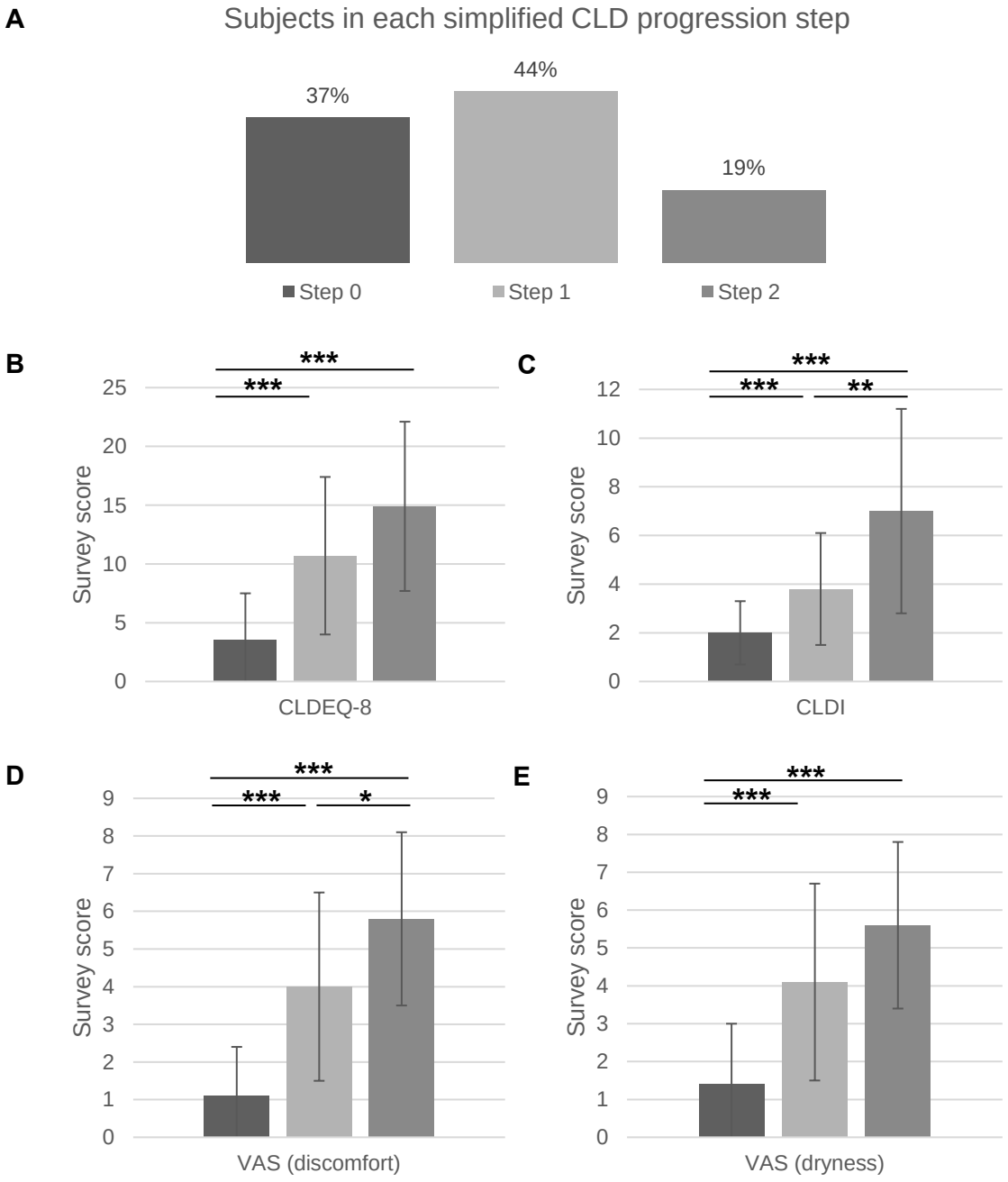

Figure 3. A) The percentage of subjects classified into each step of the simplified contact lens discomfort (CLD) progression classification. B) The scores obtained for each step of the simplified classification for the CLD progression in the Contact Lens Dry Eye Questionnaire (CLDEQ)-8, C) the Contact Lens Discomfort Index (CLDI), and the visual analog scale (VAS) for D) discomfort and (E) dryness. * p≤0.05; ** p≤0.01; *** p≤0.001.

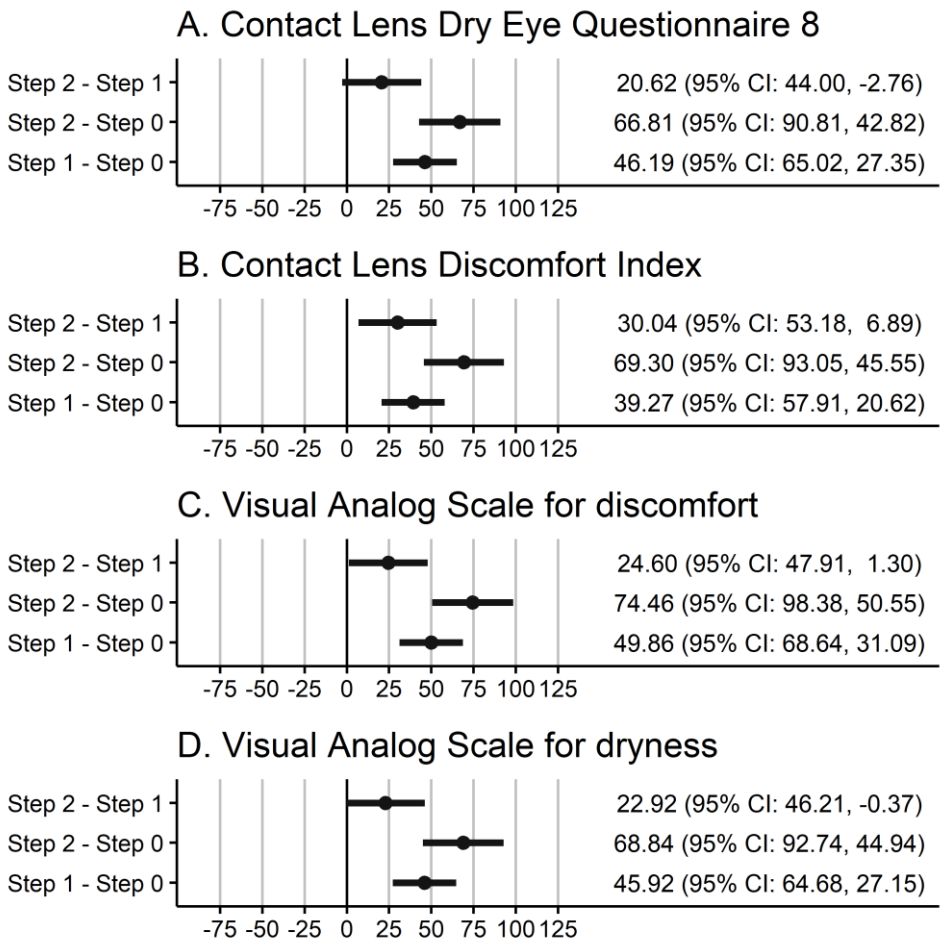

Figure 4. The observed effect of the multiple comparisons among the steps of the simplified contact lens discomfort progression classification for A) the Contact Lens Dry Eye Questionnaire-8, B) the Contact Lens Discomfort Index, and the visual analog scale for C) discomfort and D) dryness. The data are presented as the mean rank difference and 95% confidence interval (CI).

Table 3. Outcomes of the contact lens wearing characteristics and sign scores obtained for each step of the simplified contact lens discomfort progression classification.

	Simplified classification			
	Step 0	**Step 1**	**Step 2**	**p-value**
Days/week of CL wear	5.6±1.9	5.6±2.0	3.5±2.0	*<0.001*
Hours/day of CL wear	9.7±3.8	9.0±3.6	7.4±3.3	*0.02*
CL type				
Silicone hydrogel	40	42	18	0.41
Hydrogel	12	20	10	
CL replacement				
Frequent	37	40	15	0.14
Single use	12	21	13	
NIBUT	7.9±3.0	8.5±3.6	6.8±2.5	0.11
LLT	75.8±14.5	73.2±16.3	72.5±18.5	0.59
Bulbar hyperemia	1 [2]	1 [1]	1 [1]	0.63
Limbal hyperemia	1 [1]	1 [1]	1 [1.25]	0.78
Tarsal hyperemia	1 [1]	1 [1]	1 [1]	0.74
Eyelid papillae	1 [1]	1 [1]	1 [1]	0.83
LIPCOF	1.75 [1.5]	1.5 [1]	1.5 [1]	0.43
TBUT	7.2±3.6	7.2±3.3	6.8±3.5	0.53
Corneal staining	2 [2.25]	1 [1]	2 [2]	0.06
Conjunctival staining	0 [0]	0 [0]	0 [0]	0.58
LWE	0 [0]	0 [0]	0 [0]	0.72
Schirmer test	16.6±9.6	16.8±12.1	16.0±10.6	0.87

The data are presented as the mean ± standard deviation for quantitative variables or the frequency or median [interquartile range] for qualitative variables.

Frequent replacement involves biweekly, monthly, and quarterly replacements.

CL, contact lens; NIBUT, non-invasive break-up time; LLT, tear film lipid layer thickness; LIPCOF, lid-parallel conjunctival folds; TBUT, fluorescein tear film break-up time; LWE, lid wiper epitheliopathy.

Discussion

CLD is a highly prevalent condition. Its incidence is around 40% of CL wearers and discomfort is one of the primary reasons why CL wearers abandon the use of CLs [2,20,21]. Questionnaires designed to assess CLD, such as the CLDEQ-8 and the recent CLDI [9,11], are being used with increasing frequency in the clinical setting. However, signs and symptoms have not yet been well associated [10,11]. Hence, one of the aims of this study was to assess the usefulness of the CLD progression steps proposed by the TFOS to differentiate CLD severity using habitual questionnaires and clinical signs. In addition, with the objective of making the CLD classification even more useful for clinical and research purposes, a simplification of this CLD progression scale was also proposed.

The sample included in this study is intended to be representative of the general population of CL wearers. For this reason, all CL types were included, except ortho-k and scleral CL wearers. The percentage of women (64.7%), the mean age (34.4±12.6 years), and the percentage of rigid corneal CL wearers (5.3%) of the sample are very similar to those reported worldwide (65%, 33.7±15.9 years, and 12%, respectively) [22].

Regarding the CLD progression classification proposed by the TFOS, the distribution of the sample among the steps was quite heterogeneous. The number of CL wearers classified into the intermediate steps –2 (reduced comfortable CL wearing time) and 3 (reduced total CL wearing time)– was much lower than that of those classified into steps 0, 1, and 4. This finding might suggest that the transition from initial to severe CLD stages could occur rapidly. Therefore, it is encouraged to manage CLD acting on its potential causes. Sometimes, it has been demonstrated useful to switch to frequent CL replacements, to eliminate CL care systems, or to use lubricating agents such as artificial tears [3–7]. In addition, it was only possible to subjectively differentiate step 0 (non-CLD) from the rest of the CLD steps according to the scores obtained for all the administered questionnaires. The main reason is likely the large confidence intervals of the observed effect sizes (Figure 2), despite the large sample size included in this study. Therefore, the CLD progression classification proposed by the TFOS might make sense to understand progression of the condition from a clinical viewpoint,

but it might not be appropriate to differentiate each step based on CLD signs and symptoms in small- and medium-sized samples.

The impossibility to differentiate most of the steps of CLD progression objectively (clinical signs) or subjectively (questionnaires) led to a simplification of the CLD progression classification. Steps 1 and 2 (both related to reduced comfort) and steps 3 and 4 (both related to reduced wearing time) were combined. Thus, the following CLD grades were proposed: 0 for no CLD, 1 for a reduction in comfortable CL wearing time, and 2 for a reduction in CL wearing time. Using this new CLD progression classification, first, the distribution of the sample was much more homogeneous, and consequently, this classification might better represent the population of current CL wearers. Second, the confidence intervals of the observed effect sizes were much smaller (Figure 4), allowing for subjective differentiation of most CLD progression steps based on the questionnaires administered, except for steps 1 and 2 for the CLDEQ-8 ($p=0.089$) and dryness VAS ($p=0.051$), which remained at the edge of significance. Therefore, this simplification could be beneficial to better differentiate each step and to classify CL wearers properly, not only in research studies with small- and medium-sized samples, but also in the clinical setting. Besides, providing CL wearers with simple information about CLD and its implications would help them to be more aware of the problem. Thus, they would be more likely to seek professional advice regarding CLD management.

No differences were found among TFOS CLD steps for CL types and replacements (Table 2). However, as expected, a trend to reduced CL wearing time was observed in the most severe stages of CLD progression, since the average number of days per week of CL wear decreased in both classifications. The simplification of the TFOS classification that is proposed in this study allowed a better discrimination between steps (Table 3). It showed differences between groups for the daily hours of CL wear that were not observed in the original TFOS CLD classification.

It was not possible to objectively differentiate any of the CLD steps based on the scores obtained in the clinical tests for the TFOS and the new simplified classifications. This outcome was not unexpected, as the association between signs and symptoms of CLD is not frequent [10,11]. On the other hand, some clinical signs have been related to discomfort symptoms while wearing CLs, such

as a reduced NIBUT, an increased LWE and LIPCOF, Meibomian gland dysfunction, or changes in the papillae of the epithelial-lamina propria junctions of the tarsal conjunctiva [19,23–27]. However, none of them have such a strong relationship that they could be established as the gold standard for the diagnosis of CLD [28]. Indeed, the clinical signs that were previously reported to worsen in CLD [19,23–26], did not change with increasing CLD severity in the present study. Moreover, this finding was also reported by other authors such as Young et al. [10], who observed tear film instability, decreased tear film secretion, and Meibomian gland dysfunction only in approximately one quarter or less of their symptomatic CL wearers. Thus, both signs and symptoms may be recommended for the diagnosis and follow-up of CLD [29]. Future studies should address this topic because an ocular surface biomarker that objectively allows CLD detection would help CL practitioners to better manage CLD.

The main limitation of this study was that it was not possible to include a large number of CL wearers into all the CLD progression steps proposed by the TFOS. However, as explained previously, this fact may also mean that CLD could progress rapidly from mild to severe stages. Additional studies confirming this hypothesis are required. Besides, step 5 of CLD progression (CL dropout), which is intrinsically difficult to study, was not addressed. Second, the participants were not evaluated under the same CL wearing time or time of day [30]. Thus, future works should consider these aspects during the study design to confirm the results found in the present study. Finally, the evaluator who performed the assessment of the clinical signs was not masked to the CLD classification. The absence of masking might have slightly biased some clinical findings; however, questionnaire outcomes should have not been affected.

In conclusion, managing CLD from its first appearance may prevent CL dropout. Simplifying the steps of CLD severity may allow for a more accurate subjective classification of CL wearers. In addition, CL wearers might be more aware of the problem by receiving more straightforward and simpler information. Additional studies regarding the objective assessment of CLD are warranted.

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