Title:

Italian translation and validation of the Contact Lens Dry Eye Questionnaire-8

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Declarations of interest:

Robin Chalmers is a co-holder of the copyright of the original English language CLDEQ-8. The remaining authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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Abstract

Purpose: To translate and validate an Italian version of the CLDEQ-8 (CLDEQ-8_IT). **Methods:** The study was carried out in two phases. In the first phase, a cross-cultural adaptation of CLDEQ-8 to Italian was performed by forward and backward translation in sequence. In the second phase, a multi-centre study was conducted for the validation of the questionnaire. Validity CLDEQ-8_IT was evaluated against three gestalt questions: overall opinion of soft contact lenses (SCLs), global self-assessments of eye sensitivity and eye dryness. Reliability was evaluated by test-retest assessment in a subgroup of subjects. Finally, the psychometric properties of CLDEQ-8_IT were explored by Rasch analysis. **Results:** Two hundred and forty soft contact lens wearers, fluent Italian speakers (73 males and 167 females), between 18-70 years of age were enrolled. A significant correlation was found between CLDEQ-8_IT and each of the three Gestalt questions. The cutoff score of 12 points demonstrated the best balance between sensitivity and specificity in differentiating wearers grading their CLs as “Excellent/Very good” from those reporting their overall opinion as “Good/Fair/Poor”. The Intraclass Correlation Coefficient between test and retest was 0.88 (95% CI: 0.81-0.92). Finally, infit and outfit statistics using Rasch analysis for the 8 items were in a good range, however Principal Components Analysis revealed a certain degree of multi-dimensionality of the instrument. Also, item 8 analysis could be computed after merging the last two response categories. **Conclusion:** The CLDEQ-8_IT showed very good validity and reliability in measuring symptoms of contact lens wearers, comparable to the original English language version. A cut-off of 12 was confirmed as yielding the best balance between sensitivity and specificity in detecting CL wearers who could benefit from clinical management of their CL-related symptoms. Collapsing of the response options 5 and 6 in the last item of questionnaire could optimise its functioning.

Key words: Contact lens discomfort; questionnaire; CLDEQ-8_IT, symptoms

Introduction

Following the 2013 Tear Film Ocular Society (TFOS) International Workshop on Contact Lens Discomfort (CLD), CLD is described as "….*a condition characterized 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"*.[1] CLD prevalence varies from 31 to 58% among contact lens (CL) wearers and up to 88% while wearing the lenses. [2–5] Yet, despite the advances in the field of CL technology (materials and surface treatment for example), [6] CLD is still responsible for over a third of dropouts of new CL wearers.[7] A proactive approach against CLD is to utilize a validated symptom questionnaire and/or patient-reported outcomes measure (PROM) to assess and quantify patients' symptomatology. Several PROMs can be considered in dry eye and ocular surface disease,[8] although they might not be specifically designed for CLs wearers. In a review from Jalbert et al,[9] seven different questionnaires were considered: the ocular surface disease index (OSDI), the contact lens dry eye questionnaire (CLDEQ) and its shortened version (the CLDEQ-8), ocular comfort index (OCI), the subjective evaluation of symptoms of dryness (SeSoD), the standard patient evaluation of eye dryness (SPEED) and the McMonnies dry eye index. While this review remarked the need of context specific validation for these PROMs, CLDEQ-8 appears to be the best-validated instruments available for CLs practitioners interested to track their patients' symptoms. In fact, the validation process detailed by Chalmers et al. [10] noted as "*excellent dose–response relationship to the subjects' overall opinion of Soft CLs (SCL)*" showed agreement between the eight items considered and was suggested as a valid PROM tool for SCL clinical trials. The best cut-off score to identify highly symptomatic SCL wearers and the clinically important difference in the CLDEQ-8 score resulted ≥12 and 3 points, respectively.[10,11]

A well-developed translation and validation of the CLDEQ-8 in Italian could support the assessment and continuous follow-up of Italian-speaking CL wearers' symptomatology. To date, beyond the original English version, CLDEQ-8 is available in the Japanese, Spanish, Portuguese, Canadian French and Turkish languages [12–16]. These translated versions were framed in the new cultural and linguistic context and validated in a population that spoke those languages to guarantee the equivalence to the original [8]. A version of the CLDEQ-8 that followed this process is not available

in Italian. The aim of this study is to translate and validate an Italian version of the CLDEQ-8 among wearers in Italy, by evaluating its reliability and repeatability.

Methods

Cross-cultural adaptation

The cross-cultural adaptation of CLDEQ-8 to Italian (CLDEQ-8_IT) was performed in sequential and independent steps by experienced eye care professionals and researchers, following the guidelines for adaptation methodology for self-reported measures in healthcare.[17,18] The forward translation was conducted by two CL researchers, who are native Italian speakers but also fluent in English, prioritising the equivalence in significance of the items. The backward translation was completed by two different CL researchers, who are also native Italian speakers and fluent in English and living in the UK. The translated and the original versions of the questionnaire were compared to highlight any discrepancies by a native English speaker, CL researcher, in the UK. The correspondence of the backward translation to the forward translation and the variations needed for a satisfactory cross-cultural adaptation of the questionnaire were supervised and advised by an autonomous panel of two native Italian speaking researchers with established English proficiency and experience of living and working in the UK.

Participants

A multi-centre study was designed for the validation of the CLDEQ-8_IT questionnaire. Eligible subjects (n= 240) were fluent Italian speakers between 18-70 years of age and in good general and eye health. Subject were enrolled if they had been wearing spherical disposable SCLs in both eyes for at least 6 months and if they were not familiar with the CLDEQ-8 questionnaire. Any self-reported history of systemic disease contraindicating SCL wear, ocular surgery (including refractive surgery), ocular pathology, or any significant anterior segment abnormality were exclusion criteria. In addition, subjects using toric, multifocal, monovision, extended wear, CL that were not SCL, pregnant or breastfeeding were excluded (see Table 1).

Table 1: Inclusion and exclusion criteria for subjects enrolled in the study.

Inclusion criteria
Aged 18-70 years
Contact Lens wearers for at least 6 months
No history of strabismus, intraocular or refractive surgery
Absence of ocular pathologies
Able and willing to adhere to any study instructions and complete all specified evaluation
Read, indicate understanding of, and sign informed consent
Be native Italian speakers
Exclusion criteria
Pregnancy or breastfeeding
Systemic disease contraindicating soft contact lens wear
Toric and/or multifocal SCL, monovision
Extended and/or continuous wear
RGP, orthokeratology or scleral lenses

Procedure

The study was approved by the Board of Optics and Optometry of the University of Milano-Bicocca (April 9, 2020) and performed in agreement with the tenets of the Declaration of Helsinki. Participants were recruited in five CL clinics across Italy (north, centre and south, to cover any potential cultural differences within the country) according to the inclusion and exclusion criteria presented in Table 1. The majority of participants were enrolled in conjunction with a standard CL follow up visit. All participants enrolled provided signed informed consent after receiving an explanation of the nature of the study. The questionnaire was self-administered at the site of recruitment, while retests were taken online. All eligible subjects were first asked to complete the CLDEQ-8_IT, followed by a set of questions to assess demographics and CL history, and then the responders were administered three gestalt questions to be used as stratifying variables. The first (Gestalt 1) was about the overall opinions of their CLs: "*Which statement best describes your overall opinion of your current contact lenses?*". The response was recorded with a 5-point Likert scale ranging from excellent to poor. The second (Gestalt 2) and third (Gestalt 3) concerned about eye sensitivity ("*How do you evaluate eye sensitivity while wearing contact lenses*?") and dryness

("*How do you evaluate eye dryness while wearing contact lenses*?") with options of response varying on a 4-point Likert scale for from Normal to Very sensitive/dry.[12] CLDEQ-8_IT test-retest repeatability was evaluated in a subgroup of 82 participants. Participants in the subgroup were asked to complete the CLDEQ-8_IT a second time after 15 days. All questionnaires were univocally coded, allowing people to be contacted for the online retest whilst respecting and maintaining questionnaire anonymity.

Data analysis

The distribution of the CLDEQ-8_IT scores were assessed and possible correlations with age, CL power, years of CL use, number of wearing days per week, or average wearing time per day were evaluated.

Performance of the CLDEQ-8_IT instrument, in terms of **validity** (the extent to which an instrument measures the underlying concept it is supposed to measure), **reliability** (the consistency of the instrument in measuring the same construct over different administrations), and **psychometric properties** (such as dimensionality, targeting, and Item Fit statistics), was explored in the following ways. Convergent validity (the amount of correlation with a related measure) was determined by measuring the correlation between CLDEQ-8_IT with the overall opinion of SCLs (Gestalt 1), the global self-assessments of eye sensitivity (Gestalt 2), and global self-assessments of eye dryness (Gestalt 3), as performed by previous researchers [10, 12].

Predictive validity (whether the instrument can make accurate predictions of future outcomes) of the CLDEQ-8_IT to detect CL wearers with "excellent/very good" experience from those who consider having "good/poor/bad" experience with their lenses was determined calculating sensitivity, specificity, accuracy, and inter-rater reliability (Kappa statistic) for different cutoff values [19] (according the work of Chalmers [11] and Koh [12]).

Test-retest reliability of the CLDEQ_IT was assessed using Intraclass Correlation Coefficient (ICC,) calculated with two-way mixed effects model, consistency, single measures [20] and the 95% limits of agreement [21]. A Bland-Altman plot was used to assess the difference in measurements in the two sessions (test-retest) as a function of the mean between them.

A Cronbach's alpha coefficient was calculated using the inter-item correlations to assess the cohesiveness, i.e. the internal consistency of the eight items which form

the questionnaire. Cronbach's alpha was also used to evaluate the cohesiveness of three pairs of items which investigate three sub-dimensions: eye discomfort (items 1a and 1b), eye dryness (items 2a and 2b), and changeable/blurry vision (items 3a and 3b).

To further evaluate the psychometric properties of CLDEQ-8_IT, a Rasch analysis was also conducted to assess targeting, Item fit statistics and dimensionality of the questionnaire. For parameter estimation, the joint maximum likelihood estimation method was used [22]. The fit of the model was estimated by the unweighted (outfit) mean square of standardized residuals (UMS) and the weighted (infit) mean square of standardized residuals (WMS). The Rasch principal component analysis (PCA) of standardized residuals was used to assess dimensionality. The statistical analyses were performed with IBM© SPSS© Statistics v28.0 (SPSS Inc., Chicago, IL, USA). Rasch analysis was run by the jMetrik™ (Psychomeasurement Systems, LLC).

Results

Two hundred and forty subjects completed the CLDEQ-8_IT. All subjects were Italian speakers, and their demographics are reported in Table 2.

Across all sites, completion of the questionnaire took less than 3 minutes per participant, in line with what was previously reported. [12]. The frequency distribution of the CLDEQ-8_IT score is shown in Figure 1. The mean, median, standard deviation, skewness, and kurtosis of distribution resulted 11.2, 11.0, 6.1, 0.4, and 0.1, respectively. The data was not normally distributed (Kolmogorov-Smirnov, p=0.049). CLDEQ-8_IT scores were significantly different between female (11.9 ± 6.1) and male (9.4 ± 5.8) subjects (Mann-Whitney Test; p=0.003). Age (Spearman Rho=-0.18; p=0.006) was negatively correlated with CLDEQ-8_IT score. No correlations were found between CL powers and CLDEQ-8_IT score for either eye (Spearman Rho=0.054; p=0.41 and Rho=0.048; p=0.46). CLDEQ-8_IT scores were not dependent on CL Replacement Schedule (Mann-Whitney Test; p=0.31), or material type (Median 12.0 vs 11.0, Mann-Whitney Test; p=0.44).

A significant negative correlation was found between years of CL wear and CLDEQ-8_IT score (Spearman Rho=-0.14; p=0.04) but days per week of CL wear or average wearing time a day did not correlate with CLDEQ-8_IT scores (Spearman R=-0.10; p=0.12 and Spearman Rho=-0.11; p=0.10 respectively).

A significant correlation was found for each Gestalt variable: CLDEQ-8_IT score and the Overall Opinion of SCLs (Gestalt 1) (Spearman Rho=0.49; p<0.001), between the

CLDEQ-8_IT score and the global self-assessments of Eye Sensitivity (Gestalt 2) (Spearman Rho=0.49; p<0.001), and between the CLDEQ-8_IT score and the global self-assessments of Eye Dryness (Gestalt 3) (Spearman Rho=0.58; p<0.001).

The frequency distribution of the Gestalt questions responses is reported in Figure 2 and Figure 3.

Convergent validity (the amount of correlation with a related measure) was explored in box and whisker plots in which is shown the relationship between the CLDEQ-8_IT score and the Overall Opinion of SCLs (Figure 4) and global self-assessments of Eye Sensitivity and Eye Dryness (Figure 5). A significant correlation was found for each comparison: between the CLDEQ-8_IT score and the Overall Opinion of SCLs (Gestalt 1) (Spearman Rho=0.49; p<0.001), between the CLDEQ-8_IT score and the global self-assessments of Eye Sensitivity (Gestalt 2) (Spearman Rho=0.49; p<0.001), and between the CLDEQ-8_IT score and the global self-assessments of Eye Dryness (Gestalt 3) (Spearman Rho=0.58; p<0.001).

Predictive validity of the CLDEQ-8_IT was assessed for different cutoff values (Table 3). The cut-off score of 12 points demonstrated the best balance (lowest difference) between sensitivity and specificity in differentiating wearers grading their CLs as "Excellent/Very good" from those reporting their overall opinion as "Good/Fair/Poor".

Table 2: Demographic and study characteristics of the whole sample considered (n=240). *For these cases it was not possible to identify the category of materials (Hydrogels vs Silicone Hydrogels) from the commercial name of the CL.

	Whole sample (n=240)
Gender	
Men (N, %)	73 (30.4 %)
Women (N, %)	167 (69.6%)

Age (years) Mean ± SD (min;max)	32.5 ± 11.9 (16;68)
Age distribution Age group (Number; %)	Up to 25 years (92; 38.3%) 25.1-35 years (64; 26.7%) 35.1-45 years (42; 17.5%) 45.1-55 years (30; 12.5%) >55 years (12; 5.0%)
CL Power (D)	
OD Mean ± SD (min;max)	-3.32 ± 2.89 (-6.00;-14.50)
OS Mean ± SD (min;max)	-3.32 ± 2.91 (-6.00;-17.00)
Lens Replacement Schedule (N, %)	
Daily	141 (58.8 %)
Bi-weekly	18 (7.5 %)
Monthly	80 (33.3 %)
Longer than a month	1 (0.4 %)
Manufacturer (N, %)	
Alcon	78 (32.5 %)
Baush & Lomb	39 (16.3 %)
Cooper Vision	54 (22.5 %)
Johnson & Johnson	45 (18.7 %)
Others	24 (10.0 %)
Material (N, %)	
Hydrogel	127 (52.9 %)
Silicone Hydrogel	99 (41.3 %)
N/A*	14 (5.8 %)
Year of wear Mean ± SD (min;max)	10.8 ± 7.9 (0.5;36.0)
Day a week of wear Mean ± SD (min;max)	4.8 ± 2.1 (1.0;7.0)
Average Wearing time a day (hours) Mean ± SD (min;max)	9.1 ± 3,6 (1;18)

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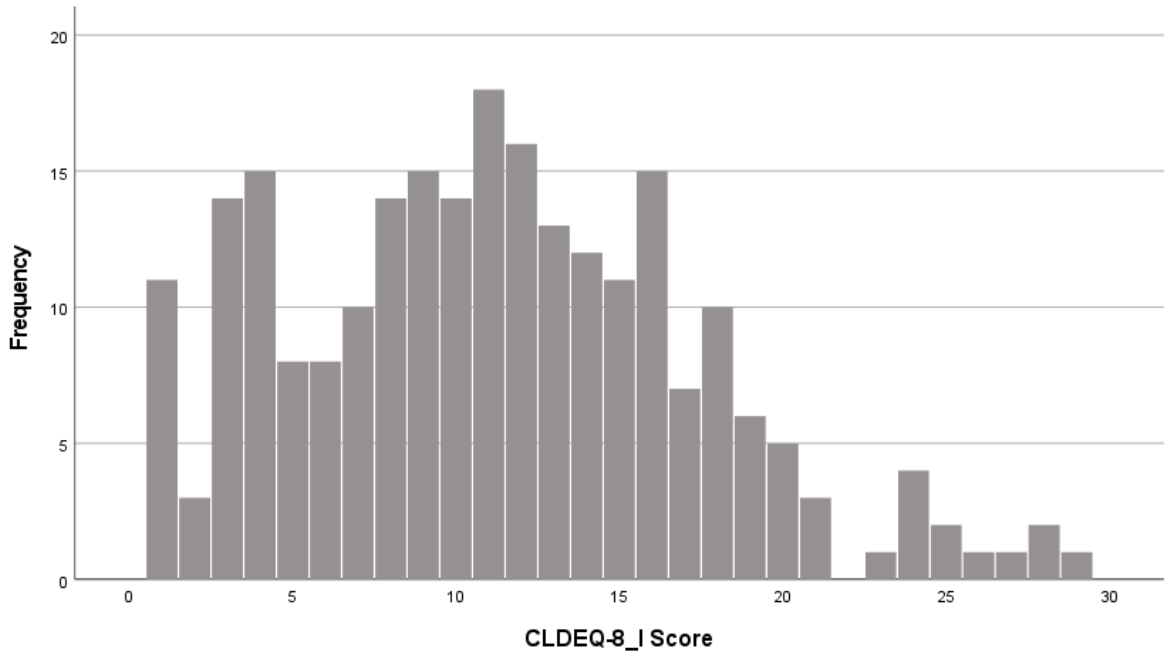

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Figure 1: Frequency distribution of the CLDEQ-8_IT score.

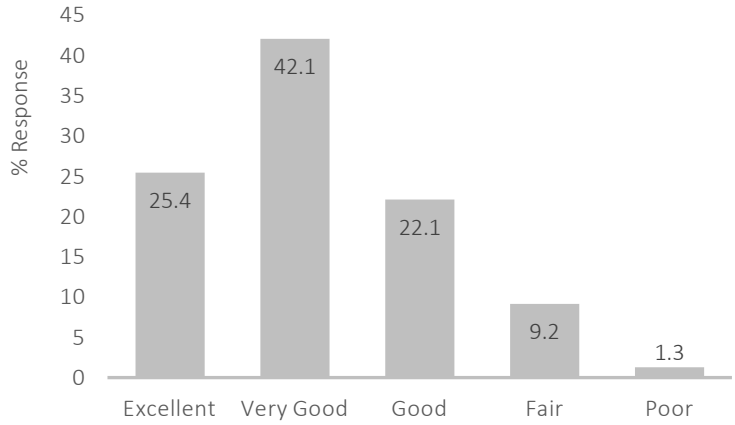


Figure 2: Frequency distribution of the Gestalt 1 Question scores: "*Which statement best describes your overall opinion of your current contact lenses?*"

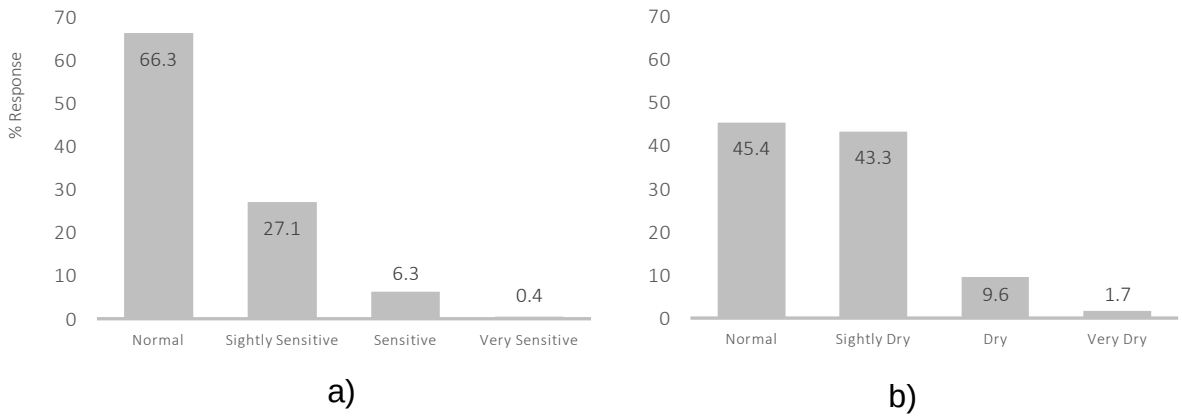


Figure 3: Frequency distribution of (a) Gestalt 2 ("*How do you evaluate eye sensitivity with the wearing of contact lenses?*") and (b) Gestalt 3 ("*How do you evaluate eye dryness with the wearing of contact lenses?*") questions.

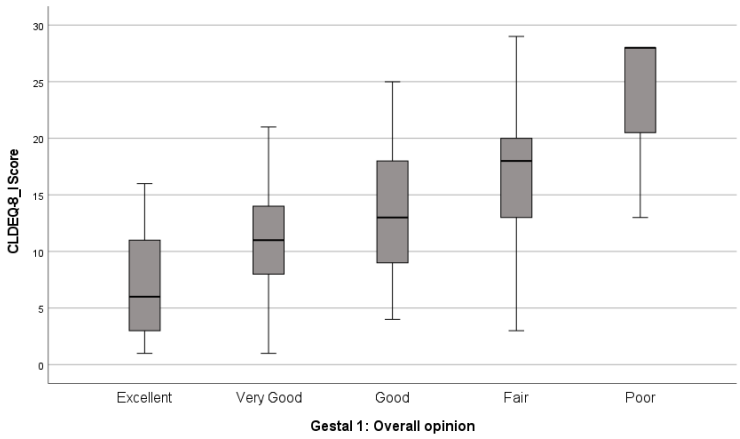
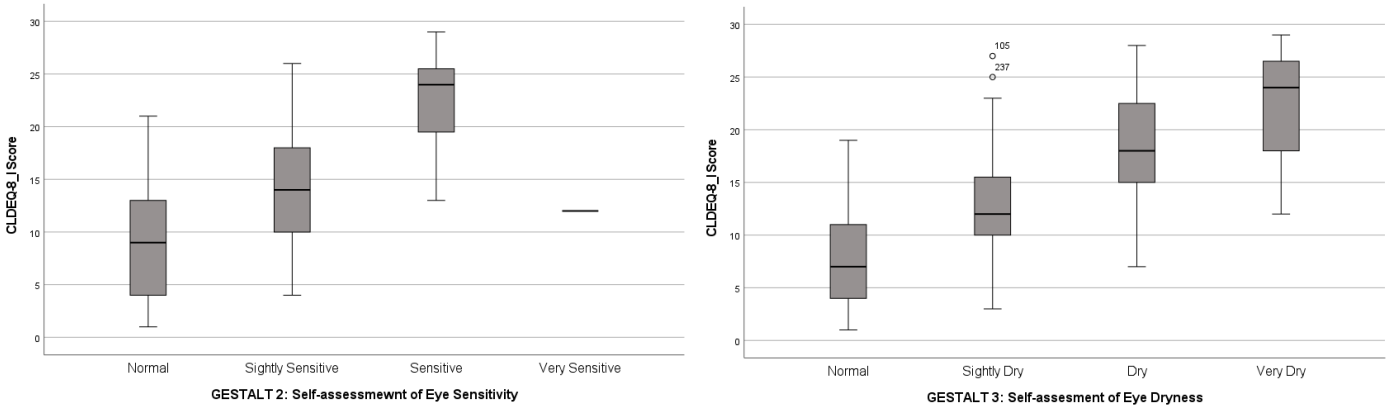


Figure 4: Distribution of CLDEQ-8_IT score by Overall Opinion of Contact Lenses.



a) b)

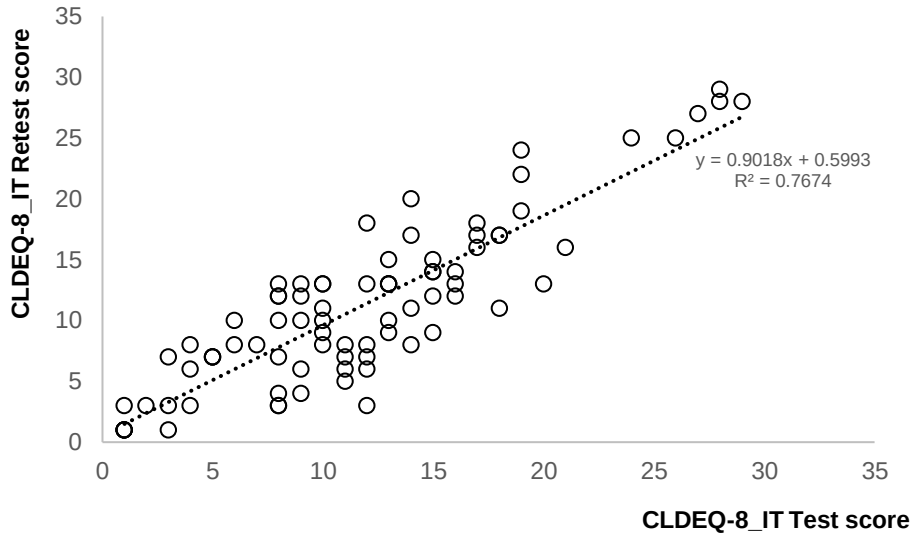
Figure 5: Distribution of CLDEQ-8_IT score by Self-assessed Eye Sensitivity and Eye Dryness.

Table 3: Predictive validity of the CLDEQ-8_IT.

Cutoff Value	Sensitivity	Specificity	Accuracy	Cohen's Kappa
<10	0.77 (0.73-0.81)	0.49 (0.47-0.52)	0.58 (0.55-0.61)	0.22 (0.16-0.27)
<11	0.73 (0.69-0.77)	0.56 (0.53-0.59)	0.62 (0.59-0.65)	0.25 (0.19-0.31)
<12	**0.69 (0.66-0.73)**	**0.65 (0.62-0.69)**	**0.67 (0.63-0.70)**	**0.31 (0.25-0.37)**
<13	0.64 (0.61-0.67)	0.73 (0.69-0.76)	0.70 (0.67-0.74)	0.35 (0.29-0.41)
<14	0.56 (0.54-0.59)	0.77 (0.73-0.81)	0.70 (0.67-0.74)	0.33 (0.27-0.40)

For test-retest reliability, 82 (34.2%) returned their second questionnaire. The mean CLDEQ-8_IT score of these 82 responds was (mean ± SD) 11.8 ± 6.6 (range 1-29) for the first response and 11.3 ± 6.8 (range 1-29) for the retest. The ICC was 0.88 (95% CI: 0.81-0.92). The scatterplot between CLDEQ-8_IT score achieve during the test and retest is reported in Figure 6. **Error! Reference source not found.**Figure 7 shows the Bland-Altman plot of the correlation between the average of the two measures; the difference between test and retest score was not significant, which was 0.56 with a SD of 3.3 (95% LoA: -5.99-7.12).

The internal consistency (Cronbach's alpha) for the overall items was 0.86. The Cronbach's alpha values calculated for the two items investigating the subdimensions of the eye discomfort, eye dryness and changing/blurry vision were 0.80, 0.88 and 0.84 respectively.



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300 Figure 6: Scatter plot of test-retest repeatability of the CLDEQ-8_IT (N=82).

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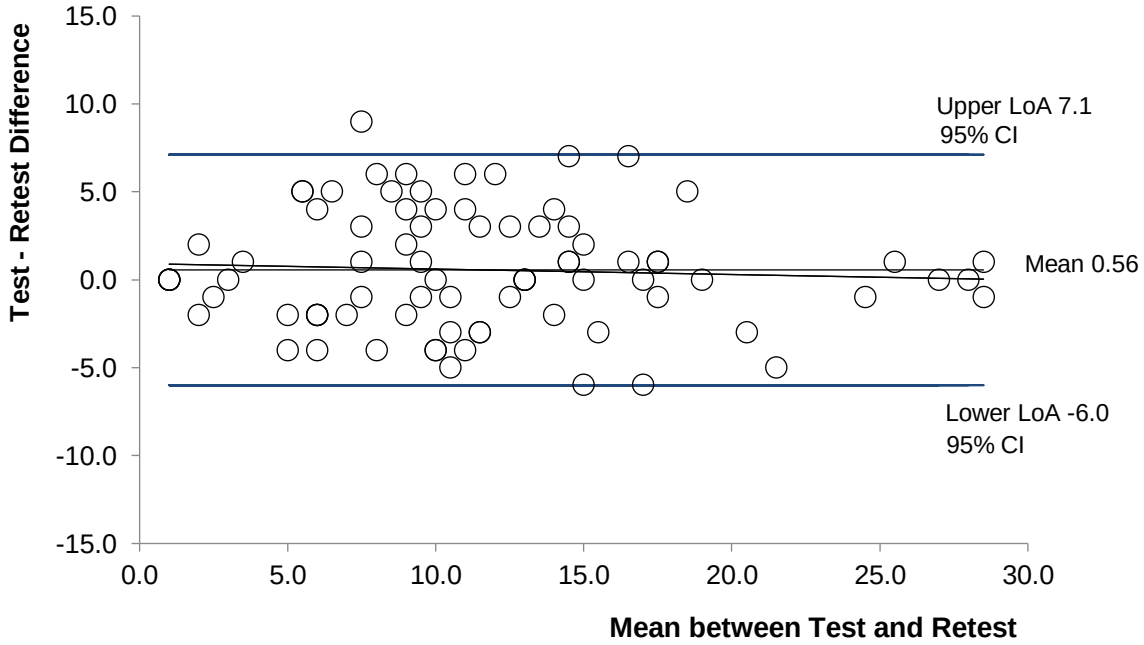

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305 Figure 7: Bland-Altman plot of the differences between the CLDEQ-8_IT achieved in
306 the test and re-test against the mean of the two scores. Limits of Agreement are
307 calculated as mean difference ± 1.96 SD of differences, CI at 95%. The Bland-Altman
308 plot indicates a good agreement between the first and second measurement with no
309 bias.

Rasch Analysis

Item measures (difficulty, in logits) and Item Fit statistics (WMS and UMS) for the CLDEQ-8_IT are provided in **Error! Reference source not found.**Table 4. Item difficulty ranges from -0.49 (Item n. 2b of the original questionnaire: "*When your eyes felt dry, how intense was this feeling of dryness at the end of your wearing time*?) to 0.66 logits (Item n.4 of the original questionnaire: "*How often did your eyes bother you so much that you wanted to close them*?"). Therefore, the distance between the minimum and maximum level of difficulty was 1.15 logits. It should be noted that for item number 5 of the original questionnaire (8th question, "*How often during the past two weeks, did your eyes bother you so much while wearing your contact lenses that you felt as you needed to stop whatever you were doing and take out your contact lenses?"*), the sixth response option was never selected by responders. For this reason, category 5 and 6 have been collapsed together to avoid the software JMetrik would drop the item 8.

Item No. (Original number in the CLDEQ-8)	Measure (logits)	Weighted Mean Square (infits)	Unweighted Mean Square (outfits)
1 (1a)	-0.11	0.87	0.86
2 (1b)	-0.42	0.99	0,98
3 (2a)	-0.27	0.94	0.92
4 (2b)	-0.49	1.06	1.05
5 (3a)	0.19	1.18	1.15
6 (3b)	0.03	1.11	1.10
7 (4)	0.66	0.97	0.96
8 (5)	0.40	0.76	0.85

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Table 4: Rasch Fit Statistics and Item Measure for CLDEQ-8_IT. WMS weighted (infit) mean square of standardized residuals. UMS: unweighted (outfit) mean square of standardized residuals.

The Person Separation Index for CLDEQ-8_IT was 2.32, indicating a reliability of 0.84 and meaning that the CLDEQ-8_IT was able to distinguish 3-42 strata of scores. Using the Wright method (a sample-independent method suitable for clinical samples) to determine the number of performance levels across the CLDEQ-8_IT score range, it was found that the CLDEQ-8_IT could distinguish 5.8 levels of symptoms. In terms of dimensionality, the Principal Components Analysis of the CLDEQ-8_IT revealed an eigenvalue of the first contrast is 2.50 and a raw variance explained <50%. The targeting is the extent to which item difficulty matches with the level of participants' symptoms. It is the difference between item and person means (difference of >1 logit indicates significant mistargeting). In this analysis the targeting value was –1,6 logits (> 1)**Error! Reference source not found.**.

Discussion

This study first developed a translation of the CLDEQ-8 into Italian and then validated it through a multicentre cross-sectional study. Validated translations of this questionnaire are important because it has been demonstrated that unvalidated versions can affect the ability of the questionnaire to identify individuals with increased symptoms associated with soft CL wear [23]. The characteristics of the cohort of Italian responders in terms of gender (70% females) were found comparable to the data reported for the validation of the same questionnaire in other studies including those for other languages,[11,12,24], and also comparable to the responders involved in several Italian surveys on CL wearers.[25–28] Female wearers reported a higher CLDEQ-8_IT score than males, though lower than the cut-off of ± 3 points considered as the minimum clinically important difference by Chalmers et al.[11] The average age of the Italian respondents was similar to the US and Japanese[11,12] cohorts, and slightly higher than the Spanish one.[14] Albeit the relationship between age and symptoms may be a point of contention, the results of

the present study were in alignment with what was reported in the validation of the original CLDEQ-8 questionnaire, indicating a negative correlation between Italian CLDEQ-8 score and age.[10,29] This, together with the negative correlation found between CLDEQ-8_IT score and year of CL wear, can be explained by a “survival of the fittest” effect, by which wearers having an unsatisfactory experience in their SCL may be more likely to drop out. In the same view, it can be interpreted that the higher average CLDEQ-8 score recorded in the Spanish group,[14] could be associated with the younger age of the responders and their reduced length of CL wear.

An important feature of the Italian cohort is the higher prevalence of wearers using hydrogel CL compared to the primary US cohort,[10], possibly due to the massive presence of private label daily disposable (DD) hydrogels CLs in the Italian CL market where there is a majority of DD CL users.

The CLDEQ-8_IT instrument showed a good overall performance in terms of **validity.** The significant correlation found between the CLDEQ-8_IT score and the Overall Opinion of SCLs (Gestalt 1), the global self-assessments of Eye Sensitivity (Gestalt 2), and the global self-assessments of Eye Dryness (Gestalt 3) showed a good convergent validity of the CLDEQ-8_IT (Fig.4 and Figure 5). These results were in accordance with what was observed for the original English questionnaire,[11] as well as with its Japanese version.[12] Concerning the predictive validity, a cut-off score of 12 was identified focusing on the best balance between sensitivity and specificity (Table 3). The value overlapped with the cut-off found for the English version of the questionnaire, holding similar outcomes of sensitivity, specificity, accuracy, and inter-rater reliability to the baseline results found for the US cohort.[11] Also, in terms of **reliability**, the CLDQ-8_IT showed good performances with an ICC of 0.88 (Figure 6). This outcome resembles the good test-retest repeatability found in the Japanese version with cross-sectional validation of CLDQ-8, although the retest delay was shorter than the one used in the present study [12]. Moreover, the differences between test and retest scores were not affected by the amplitude of the CLDEQ_8_IT score as shown by the Bland-Altman plot (Figure 7). Furthermore, the value of Cronbach’s Alpha for the overall items was 0.86 which means good internal consistency,[30] very close to the values of 0.89 and 0.87, which were achieved in the Spanish,[14] and Turkish versions,[13] respectively.

Finally, the **psychometric properties** analysis performed by the Rach analysis showed strong properties of the CLDEQ-8_IT questionnaire but also some elements of weakness. Infit and outfit statistics for the 8 items were within the accepted range (0.7–1.3) proposed in previous studies [31][32] However, the Principal Components Analysis of the questionnaire revealed an eigenvalue of the first contrast of 2.50 and a raw variance explained <50% which, may indicate a certain degree of multidimensionality of the instrument. [32] The last outcome of the Rasch analysis showed a targeting value of –1,6 logits suggesting that item difficulty does not match the level of the participants' symptoms**Error! Reference source not found.**. It should be noted that in performing the Rasch analysis the response categories 5 and 6 ("Daily" and "Several times a day", respectively) for item 8 (which correspond to item number 5 in the original questionnaire, "Question about removing your lenses") were collapsed. In the analysis of the English version of the CLDEQ-8, Puker et al. found that response category probability curves for this item were disordered, and combining categories 3-4 could optimise its functioning. [24] Similarly, Dogan et al. found that it was needed to merge categories 2-3 and 5-6 to obtain a correct order in item characteristic curves plot for the same item.[13] Also, as recently suggested that in order to preserve the psychometric properties of clinical instruments, it is crucial to achieve a proper cross-cultural adaptation, and the latter should be validated by specific psychometric analyses.[33] Hence, it could be assumed that whereas a combination of consecutive response categories may be beneficial for the CLDEQ-8 *per se*, the use of Rasch analysis to optimise the response category structure for translated versions of the questionnaire could provide a more effective strategy in the cross-cultural adaptation of the items of the CLDEQ-8.

To conclude, the CLDEQ-8_IT showed very good validity and reliability in measuring symptoms of contact lens wearers and is comparable to the original English language version of the CLDEQ-8 in. A cut-off of 12 was identified, focusing on the best balance between sensitivity and specificity in detecting CL wearers who could benefit from clinical management of their CL-related symptoms. Finally, a combination of response options 5 and 6 in the last item of questionnaire could optimise its functioning.

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Supporting information

S1 Figure CLDEQ-8_IT questionnaire.

Paziente/Soggetto #:

Data: _____/_____/_____ Ora:_____

Questionario sulle lenti a contatto -8 (CLDEQ-8)

1. Domande sul **FASTIDIO OCULARE**:

a. Durante una giornata tipo nelle ultime 2 settimane, **quanto spesso** hai provato fastidio agli occhi mentre usavi le lenti a contatto?

0 Mai
1 Raramente
2 Qualche volta
3 Frequentemente
4 Costantemente

Quando hai provato fastidio agli occhi mentre usavi le tue lenti a contatto, **quanto intensa era questa sensazione di fastidio...**

b. Alla fine del loro tempo d'uso?

Mai avuta	Per niente intensa				Molto intensa
0	**1**	**2**	**3**	**4**	**5**

2. Domande sulla **SECCHEZZA OCULARE**:

a. Durante una giornata tipo nelle ultime 2 settimane, **quanto spesso** hai provato secchezza agli occhi?

0 Mai
1 Raramente
2 Qualche volta
3 Frequentemente
4 Costantemente

Quando hai provato secchezza agli occhi, **quanto intensa era questa sensazione di secchezza**...

b. Alla fine del loro tempo d'uso?

Mai avuta	Per niente intensa				Molto intensa
0	**1**	**2**	**3**	**4**	**5**

3. Domande su visione **SFOCATA, INSTABILE**:

a. Durante una giornata tipo nelle ultime 2 settimane, **quanto spesso** la tua visione è cambiata da nitida a sfocata, o annebbiata, mentre indossavi le lenti a contatto?

0 Mai
1 Raramente
2 Qualche volta
3 Frequentemente
4 Costantemente

Quando la tua visione era sfocata, **quanto evidente è stata la sensazione di visione instabile, sfocata o annebbiata**...

b. Alla fine del tempo d'uso?

Mai avuta	Per niente intensa				Molto intensa
0	**1**	**2**	**3**	**4**	**5**

4. Domanda sul **CHIUDERE I TUOI OCCHI:**

Durante una giornata tipo nelle ultime 2 settimane, **quanto spesso** i tuoi occhi **ti hanno dato così tanto fastidio da volerli chiudere?**

0 Mai
1 Raramente
2 Qualche volta
3 Frequentemente
4 Costantemente

5. Domanda sulla **RIMOZIONE DELLE LENTI A CONTATTO**:

Quanto spesso durante le ultime 2 settimane, hai provato un fastidio tale agli occhi, mentre indossavi le lenti a contatto, da sentire l'esigenza di interrompere quello che stavi facendo e **rimuovere le lenti a contatto**?

1 Mai
2 Meno di una volta a settimana
3 Una volta alla settimana
4 Diverse volte alla settimana
5 Quotidianamente
6 Diverse volte al giorno

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