



Translation and validation of the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) among Japanese soft contact lens wearers: The J-CLDEQ-8



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ABSTRACT

Purpose: To translate and validate a Japanese version of the 8-item Contact

Lens Dry Eye Questionnaire (CLDEQ-8) among a multicenter sample of Japanese-speaking soft contact lens (SCL) wearers in Japan.

Methods: The study comprised two phases, 1) forward and backward translation of the CLDEQ-8 into Japanese, 2) cross-sectional validation of Japanese CLDEQ-8 (J-CLDEQ-8) among Japanese spherical disposable SCL wearers (daily disposable, 2 week, or monthly disposable) against their Overall Opinion of SCLs, and 3) repeatability testing in a subset of subjects.

Results: 300 subjects (118 males and 182 females) completed the J-CLDEQ-8 and anchoring Gestalt SCL questions. The J-CLDEQ-8 had a strong significant linear relationship to Overall Opinion of SCLs and the Self-Assessment of Eye Dryness. The Gestalt Eye Sensitivity question did not translate well in Japanese and the relationship between it and the J-CLDEQ-8 was not linear. A cutoff score of < 11 points with the J-CLDEQ-8 related best to patients who reported “Excellent” or “Very Good” Overall Opinion of their SCLs, differing slightly from the North American CLDEQ-8 cutoff of < 12 points. This < 11 points cutoff yielded accuracy of 0.66, and a sensitivity of 0.67 and specificity of 0.66, very similar to the values for the original CLDEQ-8.

Conclusions: The J-CLDEQ-8 was capable of differentiating SCL wearers with different Overall Opinions of their SCLs, comparable to the original CLDEQ-8 in English.

1. Introduction

Once a contact lens is placed on the ocular surface, multiple biophysical changes can occur in the tear film that are associated with contact lens wear. According to the Contact Lens Discomfort (CLD) report by The 2013 Tear Film Ocular Surface Society (TFOS) Workshop on CLD, the hallmark of CLD is ocular surface symptoms, but tear film stability, tear volume, prelens lipid layer thickness, and changes in the tear composition are also associated with CLD [1]. CLD is defined 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” [2]. Symptoms of discomfort and dryness are more frequent and intense in soft contact lens (SCL) wearers and show a greater increase in intensity during the wearing day than in non-wearers [3,4].

The prevalence of CLD and dryness symptoms in SCL wearers is reported to be around 50% [5]. According to the TFOS CLD report [1], the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) [7] represents the

most validated measure of these symptoms [6]. The CLDEQ-8 is the result of item reduction from the much longer CLDEQ in which items were selected that related best to the Overall Opinion of the wearers’ contact lenses, Gestalt Eye Dryness and Eye Sensitivity. It is an 8-item self-administered questionnaire that queries the frequency and late-day intensity of Discomfort, Dryness and Changeable, blurry vision and the frequency of closing eyes for relief while wearing contact lenses and removal of lenses earlier than planned for relief of symptoms. Recently, the diagnostic cutoff criteria of < 12 points and clinically important difference of 3 points for the CLDEQ-8 were established among English-speaking North American SCL wearers [8].

Previous population-based CLD studies conducted among the Japanese population found that contact lens wear was associated with a high prevalence of severe dryness symptoms [9–11]. A study among Japanese office workers using visual display terminals showed that 50.4% of contact lens wearers reported severe symptoms of both ocular dryness and irritation [9]. In a study conducted among Japanese high school students, 37% of SCL wearers reported severe symptoms of both ocular dryness and irritation [10]. According to a study in a rural setting in Japan, severe symptoms of both ocular dryness and irritation in

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contact lens wearers was found in 28% of males and 35% of females [11]. Thus, CLD is as an important clinical issue and hurdle to expanding the number of contact lens wearers in Japan.

More than 10 years ago, Japanese researchers performed a prevalence study of contact lens induced "dryness" and its symptoms, and reported that approximately 80% of the contact lens wearers complained of "dryness" [12]. However, many of the subjects in that study wore rigid gas permeable lenses and the work was not continued through validation steps. Since then, in Japan, the number of SCL wearers has been increasing annually. During the past decade, with new materials entering the market, several options, such as lenses with internal lubricating agents, silicone hydrogel lenses and daily disposable replacement schedules have become available for SCL wearers in Japan. Moreover, in Japan, there have been remarkable changes in the definition, diagnosis and treatment of dry eye [13] which is one of the important risk factors for unsuccessful contact lens wear. Despite its clinical importance to date, there is no validated questionnaire for SCL wearers in Japanese. Studies using the CLDEQ-8 were conducted in North America among English speaking SCL wearers [7,8]. It is unknown whether the discriminative ability of a Japanese translation of the CLDEQ-8 will effectively differentiate across opinions of contact lenses.

The purpose of this study is to translate and validate a Japanese version of the CLDEQ-8 among a multi-center sample of Japanese-speaking SCL wearers in Japan.

2. Methods

This prospective study was reviewed and approved by the institutional review board of Osaka University Hospital, and the study adhered to the tenets of the Declaration of Helsinki. All participants provided informed consent after receiving an explanation of the nature and possible consequences of the study.

This study took place in three phases, 1) forward and backward translation of CLDEQ-8 into Japanese and 2) cross-sectional validation of Japanese CLDEQ-8 (J-CLDEQ-8) among Japanese SCL wearers against the Overall Opinion of their SCLs, and 3) repeatability testing in a subset of subjects.

2.1. Study procedure

2.1.1. Translation of CLDEQ-8 to Japanese and development of J-CLDEQ-8

The CLDEQ-8 was translated forward from English to Japanese through independent translation by 3 Japanese eye care professionals who were familiar with dry eye and symptoms relating to SCL wear (2 had received advanced education in the United States and the other was a fluent English speaker without extensive residence in an English speaking country). After consensus on the wording of the translation to Japanese, the instrument was translated back to English by 3 bilingual (Japanese/American English) SCL wearers who were not eye care professionals and were unfamiliar with the original English version of the CLDEQ-8. When the back-translation in English did not match the CLDEQ-8, one-on-one interviews with the bilingual SCL wearers were conducted to discuss the changes necessary to make the proper Japanese version to reflect the concepts in the original CLDEQ-8. In this manner, the J-CLDEQ-8 was developed. (Fig. 1) The original CLDEQ-8 [7] is shown as a reference in Supplementary Figure S1.

2.1.2. Validation of the J-CLDEQ-8 among Japanese SCL wearers

The J-CLDEQ-8 was validated in the same process described by Chalmers and co-workers for the CLDEQ-8 [8]. To accomplish this, a cross-sectional, multi-center, prospective study in 5 clinical sites fielded the survey to SCL wearers who were presenting for eye care by collecting self-administered responses to the J-CLDEQ-8 on paper before their eye examinations. Five study sites were selected based on diverse geographic locations in Japan.

Eligible subjects were experienced SCL wearers between 20–60 years of age who had been wearing spherical disposable SCLs (daily disposable, 2 week, or monthly disposable) in both eyes. Exclusion criteria were any extended wear of SCLs, wear of toric or multi-focal SCL, use of monovision correction, having clinically significant anterior segment abnormalities (iritis or infection of the eye, lids, or adnexa), or having ocular or systemic disease that would preclude SCL wear, habitual Snellen visual acuity of less than 20/30 in either eye, and being pregnant or lactating.

2.1.3. Repeatability of the J-CLDEQ-8

To evaluate test-retest repeatability of the J-CLDEQ-8, a subgroup of 50 participants from one site were asked to complete J-CLDEQ-8 twice, at the check-in time point of the clinic and the check-out of the clinic after the examination on the same day of visit. This was deemed appropriate due to the 2-week recall period of the instrument.

2.2. Data handling

A paper version of the J-CLDEQ-8 was self-administered by each participant before the clinic appointment. Demographics, SCL history, and anchoring Gestalt questions on Overall Opinions of SCLs and global self-assessments of Eye Sensitivity and Eye Dryness were also obtained in the same fashion. Questionnaires from each site were stored in the Research Electronic Data Capture (REDCap) database after double data entry by two staff members.

2.3. Statistical analyses

In order to examine an association between the J-CLDEQ-8 score (possible 1–37) and Overall Opinion of SCLs, Eye Sensitivity and Eye Dryness, a mixed-effect model with sites as a random effect was utilized. This model included the J-CLDEQ-8 score as a dependent variable and each factor described above separately as an independent variable. Furthermore, the predictive ability of the J-CLDEQ-8 score for positive Overall Opinion (Excellent/Very good) was assessed using the proportion of agreement, kappa statistics, sensitivity and specificity for all possible cut-off values of the J-CLDEQ-8 score. Then, the Youden-index method was used to determine the cutoff value of the J-CLDEQ-8 score that maximized sensitivity + specificity -1. The repeatability of the J-CLDEQ-8 score was assessed using the mean and standard deviation of the difference of the J-CLDEQ-8 scores repeatedly measured within single subjects. All statistical analyses were performed 2-sided at the 5% significance level using R software version 3.5.0 (<https://www.r-project.org/foundation/>) using the "rms", "epiR" packages.

3. Results

A total of 300 subjects completed the J-CLDEQ-8 (Fig. 1) and anchoring Gestalt SCL questions. All subjects were Japanese and completed the questionnaire in the range of 1–3 minutes (by report of the site investigators). The demographics of the subjects are shown in Table 1 for the entire cohort.

3.1. Validation of the J-CLDEQ-8

The frequency distribution of the J-CLDEQ-8 scores are shown in Fig. 2. Frequency distributions of responses for each question of the J-CLDEQ-8 are shown in Supplementary Fig S2. The median and frequency distributions of Overall Opinion of SCLs and global self-assessments of Eye Sensitivity and Eye Dryness are shown in Fig. 3. Previously reported data from the most recent US validation study [8] are shown for comparison.

Construct validity of the J-CLDEQ-8 scores are presented in Fig. 4 showing the J-CLDEQ-8 scores by Overall Opinion of SCLs, and global self-assessments of Eye Sensitivity and Eye Dryness. The relationship

コンタクトレンズ問診票

各質問であてはまる番号に○をつけてください。

1. 目の不快感 についての質問:

- a. この2週間の典型的な1日のなかで、コンタクトレンズをつけているときに目の不快感を感じるものがどのくらいありましたか?
- 0 なかった
 - 1 ほとんどなかった
 - 2 時々あった
 - 3 よくあった
 - 4 いつもあった

目の不快感を感じたときの、その不快感の程度についておたずねします…

- b. コンタクトレンズを外す直前にはどのくらいひどいものでしたか?

感じたこと	全くひどく				とても
はない	なかった				ひどかった
0	1	2	3	4	5

2. 目の乾燥感 についての質問:

- a. この2週間の典型的な1日のなかで、コンタクトレンズをつけているときに目の乾燥感を感じるものがどのくらいありましたか?
- 0 なかった
 - 1 ほとんどなかった
 - 2 時々あった
 - 3 よくあった
 - 4 いつもあった

目の乾燥感を感じたときの、その乾燥感の程度についておたずねします…

- b. コンタクトレンズを外す直前にはどのくらいひどいものでしたか?

感じたこと	全くひどく				とても
はない	なかった				ひどかった
0	1	2	3	4	5

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Fig. 1. The Japanese 8-Item Contact Lens Dry Eye Questionnaire (J-CLDEQ-8).

Table 1
The demographics of the overall subjects.

		Overall
Number		N = 300
Gender	Male	118 (39.3)
	Female	182 (60.7)
Age (year) Mean		32.00
[IQR]		[25.00, 42.00]
Age Distribution	Age group	
	20–29	118 (39.3)
	30–39	88 (29.3)
	40–49	64 (21.3)
	50–59	29 (9.7)
	60	1 (0.3)
Lens Replacement Schedule	Daily	144 (48.0)
	2 week	149 (49.7)
	Monthly	7 (2.3)

施設番号 _____	管理番号 _____
質問日 ____/____/____	時間: _____

3. 見え方が変わる、ぼやけて見えることについての質問:

- a. この2週間の典型的な1日のなかで、コンタクトレンズをつけているときに、きれいに見えたりぼやけたりかすんで見えたりするといった見え方が変わることがどのくらいありましたか?

- 0 なかった
- 1 ほとんどなかった
- 2 時々あった
- 3 よくあった
- 4 いつもあった

ぼやけて見えたときの、見え方が変わる、ぼやけて見えるという程度についておたずねします…

- b. コンタクトレンズを外す直前にはどのくらいひどいものでしたか?

感じたこと	全くひどく				とても
はない	なかった				ひどかった
0	1	2	3	4	5

4. 目を閉じたいくなるかどうかについての質問:

この2週間の典型的な1日のなかで、コンタクトレンズをつけていると目がとてもつらくて目を閉じたいくなるものがどのくらいありましたか?

- 0 なかった
- 1 ほとんどなかった
- 2 時々あった
- 3 よくあった
- 4 いつもあった

5. コンタクトレンズを外したくなるかどうかについての質問:

この2週間の間に、コンタクトレンズをつけていると目がとてもつらくて、やっていることを中断してでもコンタクトレンズを外したくなるものがどのくらいありましたか?

- 1 全くなかった
- 2 1週間に1回未満
- 3 1週間に1回
- 4 1週間に何回か
- 5 毎日1回
- 6 毎日

between J-CLDEQ-8 scores and Overall Opinion of SCL, and between J-CLDEQ-8 scores and the Gestalt Eye Dryness responses were linear and significant ($P < 0.001$, each). Although there was a significant relationship between the J-CLDEQ-8 scores and the Gestalt Eye Sensitivity responses, the relationship was not linear.

The J-CLDEQ-8 cutoff score to best differentiate SCL wearers who rated their SCLs were “Excellent” or “Very Good” compared to those who thought their Overall Opinion as “Good”, “Fair” or “Poor” was 11 points. Cutoff score for the J-CLDEQ-8 with sensitivity and specificity are shown in Table 2.

3.2. Repeatability of J-CLDEQ-8

All 50 participants from one site (20 males and 30 females) repeated the J-CLDEQ-8 at the same visit. The result for the total J-CLDEQ-8 score was a difference of 0.34 ± 1.59 . The results for all 8 questions of

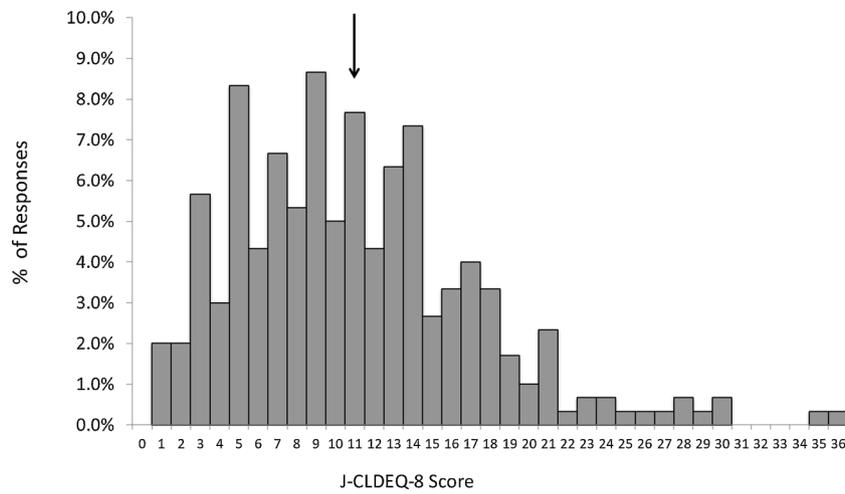


Fig. 2. The frequency distribution of J-CLDEQ-8 scores. Arrow indicates median score.

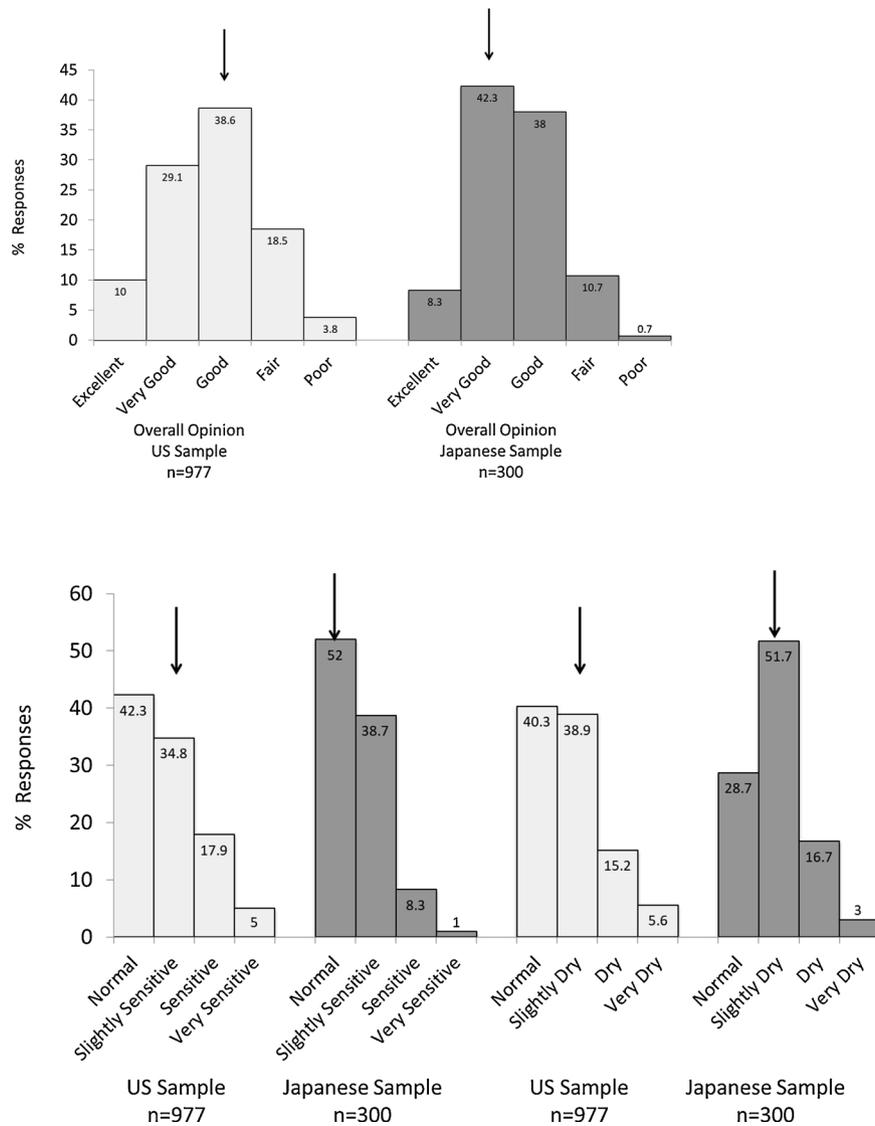


Fig. 3. The distribution of Overall Opinion of SCLs and global self-assessments of Eye Sensitivity and Eye Dryness. Darker gray is n = 300 Japanese sample in this study and light gray is previously reported US reference sample.⁸ Median response is shown by arrows.

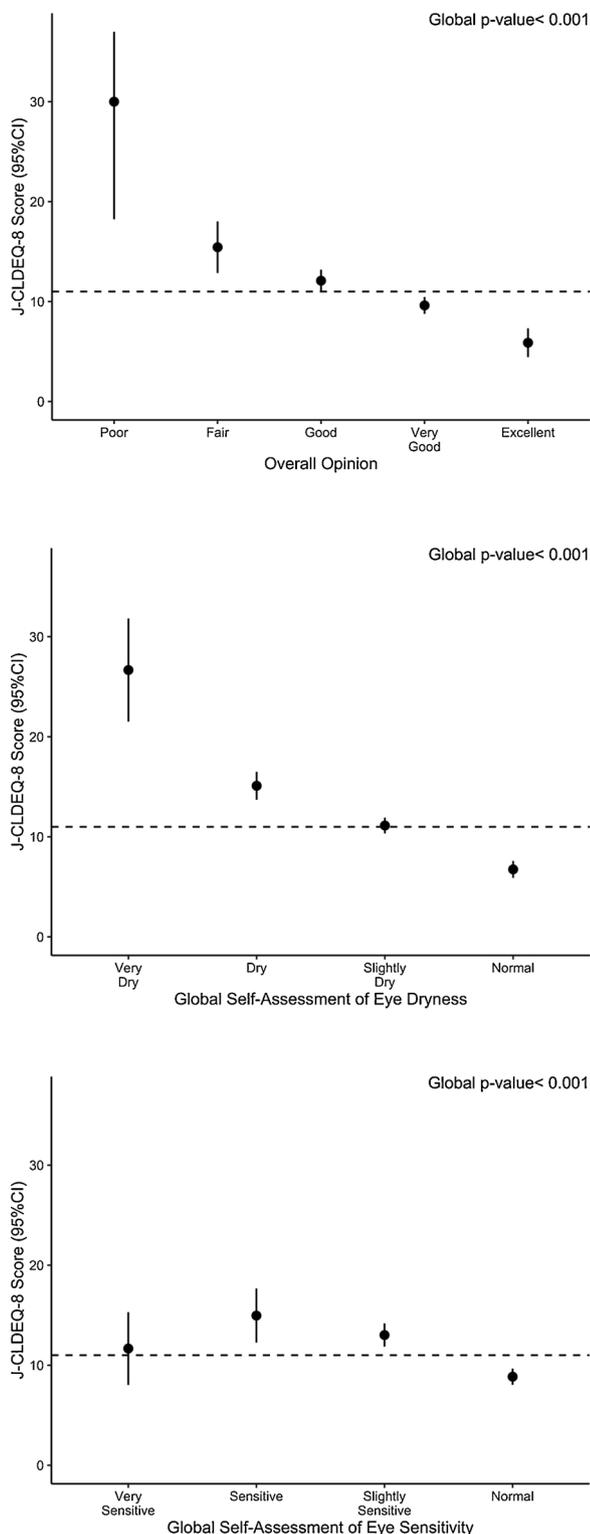


Fig. 4. The J-CLDEQ-8 scores by Overall Opinion of SCLs, and global self-assessments of Eye Sensitivity and Eye Dryness. (Mean and 95% CI).

J-CLDEQ-8 are shown in Table 3. A scatter plot of test-retest scores is shown in Fig. 5.

4. Discussion

This study first developed a proper Japanese translation of the CLDEQ-8, termed the J-CLDEQ-8. It was then validated in a cross-

sectional multi-center study. The J-CLDEQ-8 was comparable with the English CLDEQ-8 in distinguishing between SCL wearers with positive and neutral or negative Overall Opinion of their SCLs. Even though some clinical signs are associated with CLD, it is necessary to compare J-CLDEQ-8 scores to a concept like Overall Opinion because there is no gold standard of clinical signs that are diagnostic for CLD, as it is not a disease condition, per se.

In this study, the prevalence for reporting the following symptoms in the past 2 weeks was high; eye discomfort: 75.7%, eye dryness: 88.3%, and changeable, blurry vision: 74.7%. This was consistent with a previous Japanese study [12] in which eye dryness was reported from 82.6% of Japanese SCL wearers. That team analyzed the subjective symptoms of CLD in detail, and also reported that changeable, blurry vision was observed with high frequency related with eye dryness. In the Gestalt questions of degree of Eye Dryness in this study, 71.3% of the subjects reported this symptom. It is noted that more than 70% of the SCL wearers reported Eye Dryness both “in the past 2 weeks” in the CLDEQ-8 item and a separate Gestalt question.

The cutoff score for the J-CLDEQ-8 was 11, very similar to the score for the English CLDEQ-8 cutoff score of 12 [8]. Although, only 2 subjects reported a “poor” Overall Opinion and, not ignoring the effect of small number, the distribution of Overall Opinion was comparable to the previous US study [8]. However, when the distribution of Overall Opinion of SCLs was compared to the original data conducted in the US [8], several interesting differences were found. (Fig. 3) The rate of positive Overall Opinion (“Very Good/Excellent”) of their SCLs was 50.6% in Japan (current study) compared with 39.1% in the US cohort. Japanese SCL wearers may be more likely to be satisfied with the habitual SCL compared with US SCL wearers, although the distribution of lens type was also different between two studies; the prevalence of daily disposable SCL wearers was 20–25% in the previous US study [5], and 48.0% in this study. According to the recent report about contact lens prescribing trends in Japan [14], the prescription of daily disposable SCL was 46% in 2016 and the current study population was similar to this. The differences in race, culture, and several background factors may also have influence on the difference in reported satisfaction as well.

The J-CLDEQ-8 scores were also compared to two other global assessments, Eye Sensitivity and Eye Dryness. While there was a linear and significant relationship between the J-CLDEQ-8 score and Eye Dryness, the distribution of Eye Sensitivity did not correlate well with the J-CLDEQ-8 score. For example, in the Japanese study, three people answered “Very sensitive” in the Gestalt questions of degree of Eye Sensitivity. Interestingly, all 3 of these “Very sensitive” subjects rated their Overall Opinion as “Very Good“. Among the 25 subjects with the response of “Sensitive” in the Gestalt questions, eleven out of these 25 subjects (44.0%) responded lower Overall Opinion (“Good/Fair”) and 14 subjects (56.0%) rated their Overall Opinion as positive (“Very Good/Excellent “). The assumption is that Eye Sensitivity was difficult to interpret as an eye symptom in the Japanese population. One possible reason for this is that “Eye Sensitivity” is unlikely to be used for expressing ocular symptoms in general, while “sensitive skin” is generally used in Japanese. The recently developed Dry Eye-Related Quality-of-Life Score (DEQS) [15] (which has been reported to be valid and reliable among non lens wearers in Japan) does not include “Eye Sensitivity” as a bothersome ocular symptom, although “dry sensation in eyes” is included. A study from Chao, et al. [16] a study to develop and validate a Chinese version of the ocular comfort index (OCI) [17] also reported that “grittiness” and “stinging” in the original OCI were difficult to interpret in Chinese. It was fortunate that all of the terms in the J-CLDEQ-8 did translate well.

While the question about Eye Sensitivity may not be translated or understood well in Japanese, distribution of Gestalt Eye Dryness correlated with the J-CLDEQ-8 score in the Japanese SCL population, comparable to the previous US study [8]. The Gestalt questions in this study showed that 48.0% and 71.3% of the subjects reported Eye

Table 2
Cutoff score for J-CLDEQ-8 to predict “Excellent/Very Good” overall of SCLs.

Cut point J-CLDEQ-8	Accuracy (95%CI)	Kappa statistic (95%CI)	Sensitivity (95%CI)	Specificity (95%CI)
< 9	0.63 (0.57–0.68)	0.26 (0.15–0.36)	0.60 (0.52–0.67)	0.68 (0.58–0.76)
< 10	0.65 (0.59–0.70)	0.29 (0.18–0.41)	0.63 (0.55–0.70)	0.67 (0.58–0.74)
< 11	0.66 (0.61–0.72)	0.33 (0.21–0.44)	0.66 (0.58–0.74)	0.67 (0.59–0.74)
< 12	0.65 (0.60–0.71)	0.31 (0.19–0.42)	0.68 (0.59–0.76)	0.64 (0.56–0.71)
< 13	0.64 (0.59–0.70)	0.28 (0.17–0.39)	0.68 (0.59–0.77)	0.62 (0.55–0.69)

Bold values indicates line showing < 11 is the most important data.

Table 3
The repeatability of the J-CLDEQ-8.

Question	Time 2 - Time 1 difference Mean (SD)
Eye discomfort: frequency	0 (0.40)
Eye discomfort: intensity	0.02 (0.47)
Eye dryness: frequency	0.08 (0.40)
Eye dryness: intensity	0.1 (0.46)
Changeable, blurry vision: frequency	0.06 (0.31)
Changeable, blurry vision: intensity	0 (0.40)
The need for closing the eyes	0 (0.50)
The need for removing the lenses earlier	0.08 (0.49)
Total J-CLDEQ-8 score	0.34 (1.59)

Note: Positive difference scores indicate worse symptoms at Time 2.

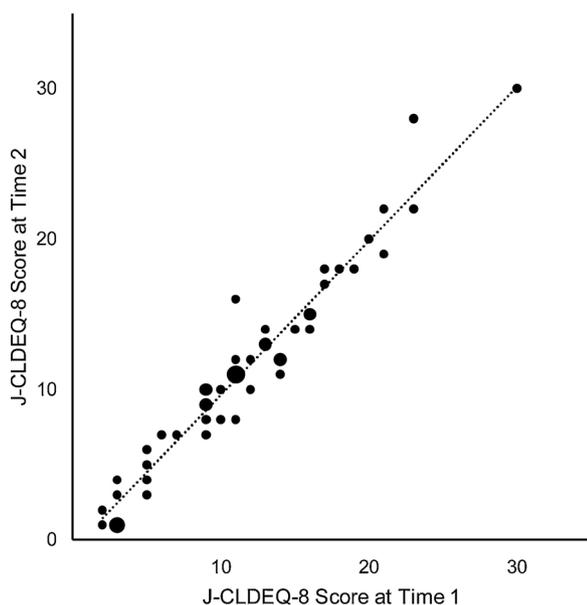


Fig. 5. A scatter plot of test-retest repeatability of the J-CLDEQ-8 obtained from 50 participants.

Sensitivity and Eye Dryness respectively, while previous US data reported that 57.7% and 59.7% of the subjects reported Eye Sensitivity and Eye Dryness. It seems like that Japanese SCL wearers were more likely to have “Eye Dryness” symptom compared with US SCL wearers. These results agree with previous studies which reported that Asian ethnicity is associated with discomfort and dryness with contact lens wear [18,19]. Among the 9 subjects who answered “Very dry” in the Gestalt questions, seven out of these 9 subjects (77.8%) responded negative Overall Opinion (“Good/Fair/Poor”) and only 2 subjects (22.2%) rated their Overall Opinion as positive, “Very Good”.

The Japanese study from Hanamo et al. [12] investigated what kind of subjective symptoms were recognized as “Eye Dryness”, and found that there were approximately 120 terms and most of them were imitative words or words that sound like what they are describing. Regardless of some linguistic feature, “Eye Dryness” can be translated and understood well in the Japanese population. The current study results

suggest that a Gestalt estimate of “Eye Dryness” would be useful as an anchoring question for Japanese SCL wearers.

The repeatability of the J-CLDEQ-8 was investigated in the current study, though it was not established in the original English CLDEQ-8 studies [7,8]. The J-CLDEQ-8 scores had good test-retest repeatability, though the population mean got slightly worse at the time of the second J-CLDEQ-8. Therefore, the J-CLDEQ-8 appears to be a suitable and reliable tool for assessing Overall Opinion of SCLs in a Japanese population over time.

Regarding the two coping questions in the J-CLDEQ-8, the need for closing the eyes or removing the lenses earlier, both of the 2 subjects with lowest Overall Opinion of SCLs (Poor) reported a frequent need for these actions. These questions represent methods to cope with a higher degree of struggle with SCLs and should be retained in the instrument even they are not frequently cited in order to capture extra steps taken to maintain SCL wear. Conversely, there was a tendency that subjects with highest Overall Opinion of SCLs (Excellent) were less likely to report use of the coping activities. Despite the few subjects with the poorest Overall Opinion of SCLs, the results of the current study are consistent to those of the previous study [7]; patients can simply quit wearing their SCLs if they become too bothersome.

Although statistically adequate, compared to the previous CLDEQ-8 study in the US [8], the current sample size is relatively small. A further investigation in a larger population based on factors such as lens type, replacement frequency, age or the geographical location could inform other questions. As previous studies showed that the CLDEQ-8 is capable of reflecting improvement and worsening of Overall Opinion after refitting new SCLs [7,8], investigation of the change in J-CLDEQ-8 scores in those who are unsatisfied with their habitual SCLs and refitted with new SCLs in Japanese population could establish the clinically important difference in the Japanese population.

In conclusion, the properly translated J-CLDEQ-8 was capable of differentiating SCL wearers across a range of Overall Opinions of their SCLs, comparable to the original CLDEQ-8 in English. A cutoff of 11 points was established as a good screening criteria for patients who may benefit from treatment such as a change in lens material or replacement schedule. The correlation between Gestalt self-assessment of global questions of degree of Eye Sensitivity and Eye Dryness showed that Eye Dryness was useful to capture the symptoms, but not Eye Sensitivity in the Japanese populations.

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Conflicts of interest

Dr. Koh received fees from Johnson & Johnson K.K. Vision Care Company for a sponsored seminar not related to this article. Dr. Chalmers has had research supported in the past by Johnson & Johnson Vision Care, Inc. None of the other authors or their family members have any proprietary or financial interests in any of the material or instruments mentioned in this article.

Clinical sites included (Site Principal Investigator (Sub-

investigators)): Hisayo Higashihara, MD, Yasushi Inoue, MD, Akiko Matsuzawa, MD (Masayuki Kudo, MD), Sayuri Ninomiya, MD, Takashi Suzuki, MD.

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