

Validity of the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and its comprehensiveness in assessing disease impact after the widespread adoption of digital media in patients with Contact Lens Discomfort (CLD) and concomitant Meibomian Gland Dysfunction (MGD)

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PURPOSE

- Contact lens discomfort (CLD) is defined by episodic or continuous adverse ocular reactions resulting from an incompatibility between the contact lens (CL) and the ocular environment.¹
 - People with CLD experience a variety of signs, symptoms, and impacts from CL wear.²
- The CLDEQ was developed to measure ocular surface symptoms among soft CL wearers, from which an 8-item short form (CLDEQ-8) was developed via item reduction and known groups validity.³
 - The CLDEQ-8 was developed in 2012, at the onset of the modern digital device era, thus there is limited evidence on whether it fully captures the impact of CL wear in the modern digital device era and whether additional items are needed. In addition, this instrument has not been tested among people with CLD and concomitant meibomian gland dysfunction (MGD).
- The purpose of this study is to understand symptoms and impacts associated with CLD in patients with MGD, assess the content validity of the CLDEQ-8 in this population, and determine whether the CLDEQ-8 fully captures disease impact in the modern digital device era.

DEMOGRAPHICS

- In Stage 1, 12 participants were screened and all completed the interviews before randomization (Table 1).

TABLE 1. STAGE 1 DEMOGRAPHIC CHARACTERISTICS

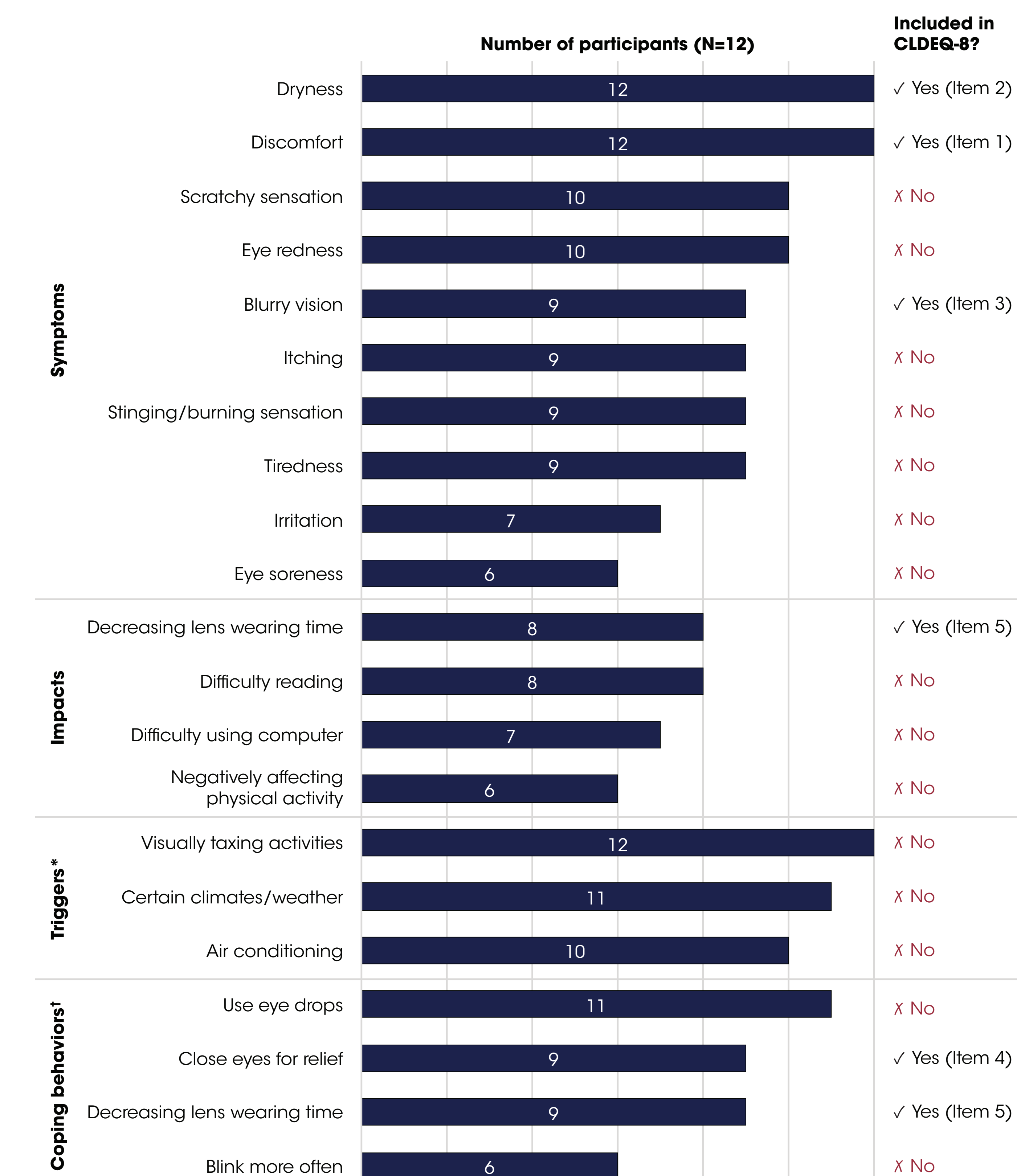
		PARTICIPANTS (N=12)
Age (years)	Mean (SD)	37.2 (14.1)
	Median (min, max)	30.5 (19.0, 58.0)
Sex, n (%)	Female	9 (75)
	Male	3 (25)
Race, n (%)	Asian	6 (50)
	White	6 (50)
OSDI total score	Mean (SD)	28.1 (10.9)
	Median (min, max)	25.0 (13.9, 45.8)
CLDEQ-8 total score	Mean (SD)	20.2 (5.0)
	Median (min, max)	18.0 (13.0, 29.0)
MGS score	Mean (SD)	8.3 (1.4)
	Median (min, max)	8.5 (5.0, 10.0)

Characteristics captured at the screening visit. CLDEQ-8, 8-item Contact Lens Dry Eye Questionnaire; MGS, meibomian gland secretion; OSDI, Ocular Surface Disease Index; SD, standard deviation.

RESULTS

- From the concept-elicitation exercise, 10 symptoms of CLD were reported by at least half (≥50%) of participants, as well as 4 impacts, 3 triggers, and 4 coping behaviors (Figure 1).
- All CLDEQ-8 items were reported; however, the CLDEQ-8 did not capture many commonly reported symptoms, impacts, triggers, and coping behaviors (Figure 1).

FIGURE 1. CONCEPT ELICITATION: MOST COMMONLY REPORTED (≥50%) CONCEPTS AND PRESENCE IN THE CLDEQ-8



*Participants were asked to share if they avoided certain triggers to prevent or reduce symptoms of contact lens discomfort. †Participants were asked to share how they managed the difficulties they face because of their [participant's term for contact lens discomfort].

- For all CLDEQ-8 items, ≥82% of participants interpreted the item as intended and found the concepts to be relevant (Table 2).
- For response options, ≥80% interpreted the response options as intended and reported that the response scales were clear (except for Item 5) (Table 2).

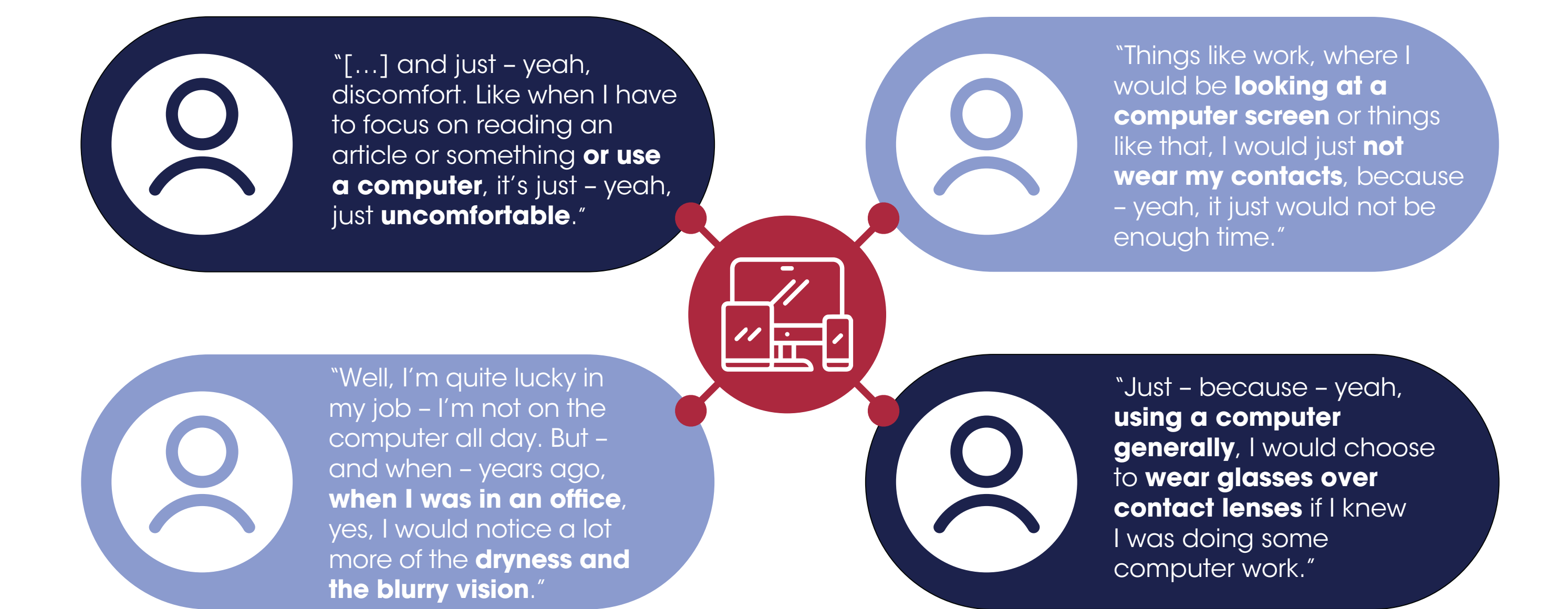
TABLE 2. COGNITIVE DEBRIEFING: INTERPRETATION, CLARITY, AND RELEVANCE OF CLDEQ-8 ITEMS AND RESPONSE OPTIONS

ITEM	CLDEQ-8 ITEM			RESPONSE OPTION	
	INTERPRETATION	CLARITY	RELEVANCE	INTERPRETATION	CLARITY
1a How often did your eyes feel discomfort?	✓	✓	✓	✓	✓
1b How intense was this feeling of discomfort?	✓	✓	✓	✓	✓
2a How often did your eyes feel dry?	✓	✗*	✓	✓	✓
2b How intense was this feeling of dryness?	✓	✓	✓	✓	✓
3a How often did your vision change between clear and blurry or foggy?	✓	✓	✓	✓	✓
3b How noticeable was the changeable, blurry, or foggy vision?	✓	✗†	✓	✓	✓
4 How often did your eyes bother you so much that you wanted to close them?	✓	✗**	✓	✓	✓
5 How often did your eyes bother you so much that you removed your contact lenses?	✓	✓	✓	✓	✗§

✓ Overwhelmingly interpreted as intended (i.e., not misinterpreted), clear, relevant to, and/or acceptable (i.e., not problematic); only misinterpreted by, irrelevant to, or problematic for ≤2 participants (≤17% of the total sample); ✗ Misinterpreted by, irrelevant to, or problematic for 3-5 participants (25%-42% of the total sample). *A few participants reported it was unclear whether the question was exclusive to when they were wearing contact lenses in Items 2a and 4. †Some participants reported the phrase "At the end of your wearing time" as unclear in the context of Item 3b. ‡Some participants reported the phrase "closing your eyes" to be unclear in Item 4. §Some participants reported the response options "2 Less than once a week," "3 Weekly," and "4 Several times a week" in Item 5 to be unclear.

- For recall periods, ≥83% interpreted each recall period ("a typical day in the past 2 weeks"; "at the end of your wearing time"; "during the past 2 weeks") as intended and reported that the recall periods were easy to think back to when considering their experience with CLD.
- Most participants did not have any missing concepts (73% [8/11]) or difficult words (58% [7/12]) to report.
 - Note that the CLDEQ-8 does not probe aspects of CLD that are due to digital device use, though participants did specifically identify difficulties with computer use due to CLD (Figure 2).

FIGURE 2. PARTICIPANT ACCOUNTS OF DIGITAL IMPACT OF CLD



- This study resulted in the development of the Stage 1 novel questionnaire (S1NQ) to capture all frequently reported symptoms, impacts, and coping behaviors of CLD; the S1NQ was fielded in Stage 2 for an exploratory analysis of the relationships between S1NQ scores and other efficacy measures.
 - Please see other posters for results of Stage 2 of this study (6584 - B0271; 2971 - A0130; 2677 - B0513; 2669 - B0505).

CONCLUSIONS

- Stage 1 of this study identified common symptoms, impacts, triggers, and coping behaviors in participants with CLD and signs of MGD.
- The CLDEQ-8 relevance/validity was appropriate in patients with CLD and concomitant MGD.
- Future work should focus on determining the validity of the CLDEQ-8 among CL wearers with MGD, understanding the prevalence of CLD with other conditions, and if additional symptom and/or impact questions about digital device use may account for additional sources of variance.

Contact

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Disclosures

R.L. Chalmers: Consultant: Alcon Research, Azura Ophthalmics, CooperVision, Johnson & Johnson Vision
Y. Alster: Owner, employment, stock options, and patent: Azura Ophthalmics
C. Bosworth: Employment, stock options, and patent: Azura Ophthalmics



METHODS

- Study design:** Two-part qualitative interview comprising (1) content confirmation through a concept-elicitation exercise and (2) cognitive debriefing of the CLDEQ-8 (NCT05548491)
 - The qualitative interview occurred within 14 days of the screening visit by trained personnel, in person or virtually
 - The qualitative interview was based on a hybrid concept elicitation and cognitive debriefing interview guide, which included open-ended questions used to encourage spontaneous responses and good qualitative data
- Objectives:** (1) Understand the symptoms associated with CLD and the impacts these have on the lives of people who experience CLD and concomitant MGD, and (2) assess the content validity of the CLDEQ-8
- Eligibility:** Adults (≥18 years) who had evidence of MGD (based on a meibomian gland secretion score of ≤12 for 15 glands of the lower lid) in both eyes at screening; had a history of wearing soft CL for ≥6 months, including ≥3 weeks before the screening visit, and wore or attempted to wear CL ≥4 times a week before the screening visit; answered "No" to "Are you able to comfortably wear your lenses as long as you want?"; self-reported history of CL dryness/intolerance in the 6 months preceding screening; and had a CLDEQ-8 score of >12 at screening⁴
 - CL could be used during the study.

CLDEQ-8



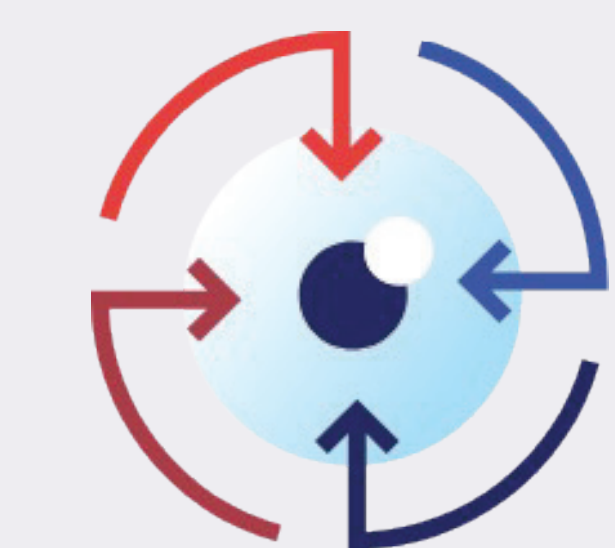
Captures the frequency and late-day intensity of ocular symptoms (eye discomfort, eye dryness, and changeable/blurry vision) and the frequency of coping behaviors (need to close the eyes and early CL removal), using a 2-week recall period⁵

Concept-elicitation exercise



Used to assess saturation and confirm CLDEQ-8 content; includes a general discussion about the participant's experience with CLD, followed by more in-depth discussion about each symptom and impact reported

Cognitive debriefing exercise



Used to evaluate the performance of CLDEQ-8; focused on the participants' perceptions of the CLDEQ-8 content validity, including: each item's clarity, interpretation, understanding, and ease; the appropriateness of the format, response scales, and recall periods; and overall CLDEQ-8 comprehensiveness