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Discrimination of subjective responses between contact lenses with a novel questionnaire

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ABSTRACT

Purpose: To describe a ranked symptoms scale (RSS) discriminating subjective responses in contact lens (CL) wear in various situations.

Method: Forty experienced clinical trial participants were interviewed for their perceptions of ocular comfort scales, resulting in a numerical RSS. For further evaluation, 20 CL wearers enrolled into a prospective, randomised, crossover trial. Two silicone-hydrogel CLs and a lens care solution (LCS) [Combinations A & B] were selected based on prior performance identifying best/worst combinations for end-of-day comfort. The RSS and a numerical rating scale (NRS) were administered at two time-points (insertion/removal) on alternating days for 6 days.

Results: Both NRS and RSS showed acceptable internal consistency for comfort, vision and handling (Cronbach alpha = 0.71 for both scales) and similar repeatability for comfort and handling (coefficients-of-repeatability within 0.1 and 0.2 units, respectively, for each scale). The NRS and RSS discriminated differences between combinations for comfort ($p \leq 0.031$) and vision ($p \leq 0.026$) at both time-points. Additionally, the RSS showed lens/edge awareness influenced discomfort the most, ranking higher at insertion ($p = 0.038$) and higher for Combination-B at both time-points ($p \leq 0.002$). Symptoms of dryness and tired eyes increased for both combinations at removal ($p < 0.02$). The RSS also showed haziness and blurred distance vision influenced vision dissatisfaction with Combination-B at lens removal ($p \leq 0.038$) while eye strain/headache increased for both combinations by time of removal ($p \leq 0.013$).

Conclusions: The RSS is able to discriminate subjective responses between combinations and time-of-day. The RSS's ability to rank symptoms may be a useful tool in understanding perceptions of discomfort or dissatisfaction with CL wear.

1. Introduction

Contact lens discomfort, one of the most common symptoms reported during contact lens wear, is a multifactorial phenomenon elicited by sensations experienced at the ocular surface. Up to 50% of wearers abandoning contact lens wear do so due to symptoms of discomfort. [1–4] Subjectively, these sensations can manifest as dryness, grittiness, contact lens edge awareness, itchiness or other symptoms [5,6] and it is usual for the perceived magnitude to increase towards the end of the wearing period. [7–9] This response is one of the most difficult problems in the contact lens field, especially as there is a lack of correlation between the symptoms experienced and clinical signs observed. Finding a solution is hindered by this inherent subjectivity which necessitates reliance on the subjective input from wearers.

Reliably assessing subjective responses during contact lens wear is critical to understanding the level of problem that exists and how perceived symptoms relate with an individual's satisfaction ratings. Several methods exist to elicit subjective responses with contact lens wear, ranging from informal verbal questioning, which most often is the case in clinical practice, to the use of specially designed questionnaires in research settings. According to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), the quality of a measurement instrument for patient-reported outcomes includes three major domains: reliability, validity and responsiveness; with interpretability of the instrument also considered to be important. [10] Ease of use and time taken to complete the questionnaire by the

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patients should also be taken into account as educating the patient on the use of the questionnaire is time consuming, and there is no guarantee that the concept will be successfully grasped or applied as designed.

Current questionnaires used in contact lens research into discomfort vary among different studies and this presents a challenge when attempting to compare their findings. The various questionnaires used in research each have their advantages and disadvantages. For example, dichotomous scales, indicating only the presence or absence of a symptom, are quick and simple to understand but provide no information about frequency or severity. Visual analogue scales (VAS), verbal rating and numerical rating scales (NRS) are also quick and simple to use and offer detail about the intensity or frequency of symptoms, but only in an overall sense. They lack the ability to distinguish between the various component dimensions of sensation that may exist, such as dryness, grittiness and lens awareness. Furthermore, the scales used (0–10, 0–100, 1–10, 1–100 *etc.*) have not been validated for contact lens discomfort and repeatability of the scales has also not been tested. [11]

Researchers have also applied specific questionnaires developed for use in dry eye disease to contact lens discomfort studies. The Ocular Surface Disease Index (OSDI) is a popular questionnaire used in these studies. [11] It comprises three areas: ocular symptoms, vision related functioning and environmental triggers. The final score categorizes the patients as having a normal ocular surface or having mild, moderate or severe ocular surface disease. [12] The OSDI has demonstrated internal consistency, reliability, validity and good sensitivity and specificity for differentiating between patients considered normal and those with dry eye disease. [13]

The McMonnies dry eye index is a questionnaire used as a screening tool for dry eye based on risk factors for the disease. The final score gives a diagnosis of dry eye disease. [14,15] This questionnaire has been shown to have poor internal consistency with fair validity and accuracy but does not measure the severity of the disease. [15] It has been used in contact lens studies but not in recent years. [11] The Ocular Comfort Index (OCI) examines the frequency and intensity of ocular symptoms and has been shown to have acceptable repeatability and reliability and correlates with the OSDI. An advantage of the OCI is that the estimates are produced on a linear interval scale so that change over time or with treatment can be better quantified. [16] However, one study has shown that it did not perform as well as the McMonnies dry eye index, in predicting contact lens induced dry eye. [17]

The problem with using an instrument specific to dry eye disease, such as those mentioned above, is that contact lens discomfort often is seen to be a separate phenomenon with a different etiology to actual dry eye disease. [18] For example, the incidence of intense symptoms occurring later in the day is higher in contact lens wearers compared to non-contact lens wearers and contact lens related dryness is not correlated with gender. [19] Removal of the contact lens successfully relieves the problem but the solution for true dry eye disease is not that simple. [19] Hence, using an instrument designed for dry eye disease may not capture all the factors which may contribute to contact lens related discomfort.

Currently, the Contact Lens Dry Eye Questionnaire in its shortened version (CLDEQ-8) [20] is the only validated instrument for use in contact lens discomfort and dryness. It also satisfies the other COSMIN measurement properties of responsiveness and interpretability. [21] The frequency and intensity of selected symptoms most often experienced by contact lens wearers is examined in a quick to administer questionnaire and the score obtained can be used to identify contact lens wearers who are experiencing frequent or intense symptoms. The questionnaire can also be used to measure changes with treatment over time. The separation of the symptoms of discomfort and dryness in the CLDEQ-8 assumes that these two symptoms can be perceived independently. This may not be true however, as most patients associate contact lens discomfort and dryness together, [6,22,23] particularly at the end of the day. As yet, this questionnaire has not been used extensively in contact lens research [11].

The latest development in contact lens related questionnaires is the Contact Lens User Experience (CLUE) Scale. [24] The scale focuses more on the patient evaluation of contact lenses in the domains of comfort, vision, handling and packaging and claims reliability and validity in these domains. There are currently 377 items and therefore this scale might better be considered as a question bank within these four domains rather than a readily usable questionnaire which can be quickly administered.

With the above mentioned questionnaires, only the CLUE scale utilised interviews and focus groups to assist in the initial development of their scale. The other questionnaires were developed relying on the expertise and experience of the developer in the area of dry eye and contact lens related discomfort and the knowledge of typical signs and symptoms of the problem before being tested out on a group of participants. The advantages of using qualitative interviewing to help in questionnaire development is that it allows the interviewee's perspective and own interpretation of meanings to be explored without input from the researcher's own opinions and assumptions. [25,26] This is important in contact lens related discomfort as the cause is often elusive and understanding the sensation from lens wearers may aid in understanding the problem further.

From a research perspective, there is a need for an assessment tool that encapsulates the general subjective response to contact lens wear and yet has the ability to be specific with respect to the component parts of the sensations experienced. Learnings from previous research have prompted the trialling of a new paradigm in assessing satisfaction with contact lens wear, where patient discomfort and dissatisfaction are not considered symptoms but rather the integration of multiple underlying symptoms. Moreover, the relevance, rather than the frequency and severity, of these symptoms to the overall dissatisfaction, is assumed to be patient specific. Therefore, the purpose of this work is to describe an instrument that was developed to discriminate subjective responses to contact lens wear in various situations while also offering additional information on the contact lens wear experience. Its use is demonstrated by administering the new instrument along with a traditional rating scale in comparing subjective responses to two contact lens types at different time points.

2. Materials and methods

This investigation received ethics approval through a local Human Research Ethics Committee and was conducted in accordance with the principles of the Declaration of Helsinki. Written consent was obtained from each participant prior to commencing any trial procedures. The investigation was conducted in two parts.

2.1. Part I: focus interviews

Forty experienced trial participants who had previously completed at least two contact lens related clinical trials at the Brien Holden Vision Institute took part in focus interviews to investigate their perceptions and opinions of 9 instruments (questionnaires and subjective scales) used at various times to assess ocular subjective responses during contact lens clinical trials.

The instruments assessed comprised four NRS variants [1–10 in 1-point steps, 1–10 in 0.5-point steps, 1–100 in 1-point steps, 1–200 in 1-point steps], one 5-point symptoms grading scale, one 5-point Likert scale, two VAS and one forced choice dichotomous questionnaire (Yes/No response). Participants expressed their impressions about each instrument and how it could be improved, as a means of gathering appropriate information relative to their contact lens wearing experience. Participants were also asked to describe various symptoms experienced during contact lens wear in their own words.