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Comparison of Two Questionnaires for Dry Eye Symptom Assessment: The Ocular Surface Disease Index and the Symptom Assessment iN Dry Eye

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Abstract

Purpose—The aim of this study was to compare patient reported symptoms of dry eye disease (DED) as assessed by the Ocular Surface Disease Index (OSDI©), a 12-item symptom frequency-based questionnaire, and the Symptom Assessment iN Dry Eye (SANDE), a 2-item frequency- and severity-based visual analog scale.

Design—Clinic-based evaluation of diagnostic test.

Participants—One hundred fourteen patients with dry eye disease.

Methods—Patients were administered the OSDI and SANDE questionnaires at baseline and follow-up visits to evaluate dry eye disease-related symptoms. The correlations between both questionnaires' scores were evaluated using the Spearman coefficient and their clinical differences were assessed using the Bland-Altman analysis.

Main Outcome Measures—Baseline and follow-up visit OSDI and SANDE dry eye symptom scores.

Results—At the baseline visit, the OSDI and SANDE questionnaire scores significantly correlated (R = 0.64; P <0.001). Moreover, a significant correlation was found between changes in the OSDI and SANDE scores from baseline to follow-up visits (R = 0.47; P <0.001). A Bland-Altman analysis, after score normalization, revealed a difference (bias) of less than two centesimal units between the scores of the two questionnaires.

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Conclusions—Data collected from the SANDE questionnaire showed a significant correlation and negligible score differences with those from the OSDI, suggesting that the SANDE visual analog scale-based questionnaire has the potential to provide clinicians with a short, quick and reliable measure for DED symptoms.

Introduction

Dry eye disease (DED) is a multifactorial disorder of the ocular surface that affects millions of people in the United States alone.[1–3] It represents one of the most frequent reasons for ophthalmic consultations, with 5% to 30% of the general population affected depending on the diagnostic criteria used.[3,4] DED symptoms severely affect patients' activity of daily living either continuously or triggered by specific tasks (e.g. driving or computer monitor use).[5] These symptoms include discomfort, blurred vision, burning sensation, irritation, photophobia, and contact lens intolerance.[6] The measurement of patient's signs and symptoms, and their impact on patients' quality of life are critical aspects in DED evaluation. Since there is no "gold standard" diagnostic test for DED, a combination of signs and symptoms are commonly used as diagnostic criteria.[7–9]

Because of the variability of dry eye symptoms and the limitations of the available clinical tests, questionnaires that record patients' symptoms are very useful tools for diagnosis and follow-up of dry eye disease.[6,7] The Ocular Surface Disease Index (OSDI; Allergan Inc., Irvine, CA),[10] is one of the most frequently used instruments to assess DED. This questionnaire is comprised of 12 questions and evaluates the frequency of symptoms over the preceding week. The questionnaire requires approximately 5 minutes for the patient to complete, and the scores range from 0 to 100. Based on the score, the patients' symptoms can be categorized as normal (0–12), mild dry eye (13–22), moderate dry eye (23–32), or severe dry eye (33–100).[9–12] The OSDI is copyrighted by Allergan, Inc.

The Symptom Assessment Questionnaire iN Dry Eye (SANDE) is a short and intuitive questionnaire based on a visual analog scale that quantifies both severity and frequency of dry eye symptoms. The SANDE is comprised of two questions, and each question employs a 100 mm horizontal linear visual analog scale. The measurement of symptom frequency ranges from "rarely" to "all of the time," and the symptom severity from "very mild" to "very severe."[13,14] Previously, it has been shown that both tests are reliable and valid measures of dry eye symptoms. [11,13] The main objective of this study was to compare the SANDE and OSDI questionnaires in a clinic-based cohort of patients with dry eye disease. Additionally, we sought to expand on evidence in support of the use of the SANDE questionnaire for DED diagnosis and follow-up.

Methods

This study was conducted in compliance with the Institutional Review Board (IRB) at the Massachusetts Eye and Ear Infirmary (MEEI), Boston, MA, in accordance with the tenets of the Declaration of Helsinki and informed consent was obtained from all participants. Data were collected at the Cornea Service, MEEI, from patients who had a previous diagnosis of

dry eye disease and were representative of the subset of DED seen in our clinic, a specialized ocular surface unit.

The OSDI and SANDE scores from baseline and follow-up visits of a total of 114 patients were analyzed. Patients were selected based on the following criteria at the initial visit: punctate epithelial keratopathy (CFS) ≥ 0.5, symptoms of dry eye (e.g., burning, irritation, grittiness, foreign body sensation, or fluctuating vision), and OSDI ≥ 13.[12] Patients who had signs of epitheliopathy (corneal staining) with minimal or no symptoms were not included; similarly, those with symptoms of ocular irritation but without signs of epitheliopathy were not included. Patients with active infection, history of allergy, refractive surgery, penetrating keratoplasty and herpetic eye disease, as well as contact lens wearers, were excluded. Corneal fluorescein staining evaluation was performed using commercially available fluorescein sodium strips, followed by slit-lamp examination with cobalt-blue light. Three minutes after application of fluorescein, CFS was graded using the modified Oxford system (Grades 0–5). At both visits, patients were asked to complete the OSDI and SANDE questionnaires, and the results were used to evaluate their symptoms.

The 12-item OSDI questionnaire scores range from 0 to 100, it contains 3 ocular symptom questions, 6 vision-related function questions, and 3 environmental trigger questions. Each question score ranges from 0 (“none of the time”) to 4 (“all of the time”). The total score is calculated based on the following formula:
$$\mathrm{OSDI}=([\text{sum of scores for all questions answered}\times 100]/[\text{total number of questions answered}\times 4])$$
.[10,11]

The SANDE questionnaire is comprised of two questions: 1) How often do your eyes feel dry and/or irritated? And 2) How severe you feel your symptoms of dryness and/or irritation are? This questionnaire uses a 100 mm horizontal line for each question to assess ocular discomfort and/or dryness experienced by the patients. In the SANDE questionnaire, frequency of symptoms ranges from “rarely” to “all of the time” and the severity of symptoms ranges from “very mild” to “very severe” (Fig 1).[13,14] At each visit, patients were asked to place a mark on the two given lines based on the extent of their symptoms. The locations of the marks made by the patients on the 100 mm horizontal lines were measured in mm from left to right and recorded. Data collected from the SANDE questionnaire were calculated by multiplying the frequency score by the severity score and obtaining the square root.[13,14]

We then assessed the correlation between data obtained from the two questionnaires, including the change in symptoms between the two visits. Statistical analysis of the data and correlations between the questionnaires responses were assessed by the Spearman coefficient of correlation. A P value of less than 0.05 was considered statistically significant. Additionally, we evaluated the clinical differences between OSDI and SANDE using the Bland and Altman analysis.[15] First, we compared the original scores obtained from the 2 questionnaires. Since the two methods do not measure symptoms in the same way (although both utilize a centesimal scale) we normalized the scores by applying the algebraic method of the norm of a vector (normalization to a norm of one). Once the scores from both questionnaires were transformed to a normalized scale, we compared them using the Bland-

Altman analysis. Normalization was obtained by: 1) summing the squares of all the scores (y) obtained with each questionnaire (Σy^2), 2) obtaining the square root of this sum ($\sqrt{\Sigma y^2}$), 3) dividing each of the original scores by $\sqrt{\Sigma y^2}$ to obtain each of the final normalized individual scores (the square root of the sum of the squared normalized scores equals one for all the data sets transformed). Finally, we divided the one SANDE score that was equal to 100 by its normalized value (to obtain their ratio), and multiplied all the normalized scores by the same figure (ratio) to ultimately transform all the normalized scores back to a centesimal scale.

Results

We evaluated 114 patients (43 men; 71 women) at two different visits (baseline and follow-up). The average age of the subjects was 51.8 ± 15 years (Table 1). The mean time interval between the baseline and follow-up visits was 81 ± 43 days (median 71; range 20–283).

At the baseline visit, symptom-severity data collected by the SANDE questionnaire ranged between 4 and 100, and the symptom frequency ranged between 7 and 100. The mean SANDE score was 63.48 ± 23.49. The OSDI ranged between 13 and 100 with a mean score of 48.9 ± 22.42. Based on scores generated by the OSDI questionnaire, of the 114 subjects evaluated, 84 patients (73.7%) reported severe ocular surface symptoms (33–100), while 30 patients (26.3%) reported mild to moderate (13–33) symptoms.[12] At the baseline visit, CFS scores ranged between 0.5 and 5, with mean score of 2 (± 1.6) (Table 1).

At the follow-up visit, symptom frequency, as measured by SANDE, ranged from 1 to 100, and symptom severity ranged between 0 and 100. The mean SANDE score was 52.1 ± 24. Symptom frequency, as measured by OSDI, ranged from 0 to 100, with a mean score of 43.25 ± 22.9.

Spearman correlation coefficient results revealed a significant correlation between the OSDI and SANDE scores at the baseline visit (R = 0.64; $P < 0.0001$) (Fig 2A). Based on the data generated by the OSDI questionnaire, patients were categorized with severe (OSDI ≥ 33; n = 84) or mild to moderate (OSDI 13–33; n = 30) DED.[12] At the baseline visit, there was a significant correlation between OSDI and SANDE scores in patients with severe DED (R = 0.39; $P < 0.0001$) (Fig 2B). In patients with mild to moderate DED a significant correlation between OSDI and SANDE scores was also noted (R = 0.37; $P = 0.045$) (Fig 2C).

Changes in patients' dry eye symptoms from baseline to follow-up visits, as scored by OSDI and SANDE, were evaluated, revealing a significant correlation (R = 0.47; $P < 0.0001$) (Fig 3A). The correlation coefficient between symptom changes in patients with severe DED, as scored by OSDI and SANDE, was also significant (R= 0.46; $P < 0.0001$) (Fig 3B). Likewise, there was a significant correlation between the changes scored by OSDI and SANDE in patients with mild to moderate DED symptoms (R = 0.42; $P = 0.02$) (Fig 3C). Overall, the OSDI significantly correlated with the SANDE severity (R = 0.62; $P = 0.0001$) and frequency (R = 0.60; $P = 0.0001$) scores.

To determine the utility of measuring both frequency and severity with the SANDE questionnaire, we evaluated the correlation between the SANDE severity and frequency

changes from baseline to follow-up visit (R = 0.57; $P < 0.0001$). In some patients the frequency of symptoms decreased while there was no change in severity, or vice versa. If the regression were linear, it would be unnecessary to measure both frequency and severity and measuring one would be enough, but that was not the case (Fig. 4).

The Bland-Altman analysis for clinical agreement between the normalized OSDI and SANDE scores revealed a clinical difference (bias) of −1.5 units for the baseline visit and 1.8 units for the follow-up visit (Fig 5).

Discussion

Dry eye disease (DED), a common disorder of the ocular surface, is a multifactorial condition that can present with various symptoms complicating diagnosis and treatment.[1] Although a number of questionnaires are available to measure dry eye symptoms, a valid, short, and easily comprehensible questionnaire that allows for the monitoring of symptom frequency and severity over time is essential. The OSDI is a validated questionnaire that only measures the frequency of dry eye symptoms.[11] In contrast, the SANDE is an intuitive and quick questionnaire that measures both severity and frequency of DED symptoms. It has shown reproducibility, satisfactory validity, repeatability, as well as sensitivity and specificity in assessing patients with ocular surface disease.[13,14]

In this study we compared the short visual analog scale-based SANDE questionnaire with the longer OSDI questionnaire in evaluating and monitoring symptoms in a subset of patients with DED and concurrent signs and symptoms of the disease. The SANDE scores at the baseline visit were found to correlate well with those of the OSDI. Similarly, the correlation between changes in OSDI and SANDE scores, from baseline to follow-up visits, remained significant. Moreover, SANDE scores correlated well with those of OSDI when the questionnaire was administered to subgroups of patients with severe or mild to moderate DED (based on OSDI baseline scores).

While there was a statistically significant correlation between the two questionnaires, when clinical agreement was evaluated using the original scores from both questionnaires, the Bland-Altman analysis revealed that SANDE scored 14 units higher than OSDI. This is in agreement with the results reported by Chen et al., who found that SANDE consistently scored symptoms higher than OSDI in various groups of patients with DED.[17] A difference of 14 points would be, in fact, of clinical significance according to Miller et al.[12] However, when algebraic-vectorial normalization was applied to the scores obtained with both questionnaires, we found a difference of less than 2 units. While the magnitude of this difference remained constant in the two different measurements (baseline and follow-up) the signs alternated between both measurements, supporting the idea that the difference is negligible.

SANDE is a short, intuitive tool that consists of two simple questions. In contrast, OSDI requires the patient to read, understand, and answer 12 questions. While the OSDI questionnaire is an unequivocally established and well-recognized method for evaluating DED symptoms, it is not completely clear that it offers genuine advantages over the SANDE

questionnaire. Finally, the OSDI is copyrighted by Allergan Inc., potentially limiting its use by other industry concerns for pivotal clinical trial use for drug registration purposes.

The correlations shown herein between OSDI and SANDE scores, coupled with their clinically negligible differences obtained from the Bland-Altman analysis of the normalized data, suggest that the SANDE questionnaire scores are equivalent to those from OSDI. In this regard, the SANDE questionnaire appears to hold promise as a quick and valid method for evaluating the frequency and severity of symptoms of patients with dry eye disease.

Acknowledgments

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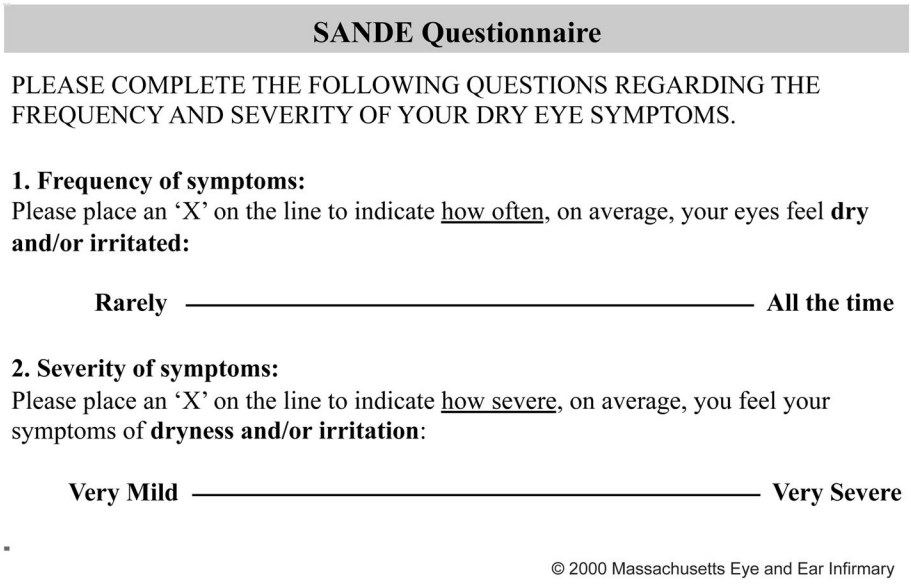

SANDE Questionnaire

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS.

1. Frequency of symptoms:
Please place an 'X' on the line to indicate how often, on average, your eyes feel **dry and/or irritated:**

Rarely ——— **All the time**

2. Severity of symptoms:
Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of **dryness and/or irritation**:

Very Mild ——— **Very Severe**

Figure 1.
Symptom Assessment iN Dry Eye questionnaire.

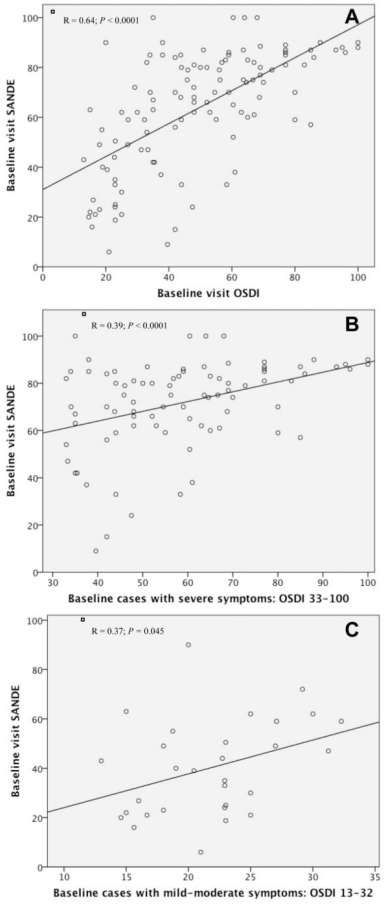

Figure 2.

Scatter plots showing the correlation between SANDE and OSDI scores from patients with dry eye disease at the baseline visit. **A**, Correlation between OSDI and SANDE scores (R = 0.64; $P < 0.0001$). **B**, Correlation between OSDI and SANDE scores in cases with severe symptoms (R = 0.39; $P < 0.0001$). **C**, Correlation between OSDI and SANDE scores in cases with mild to moderate symptoms (R = 0.37; $P = 0.045$).

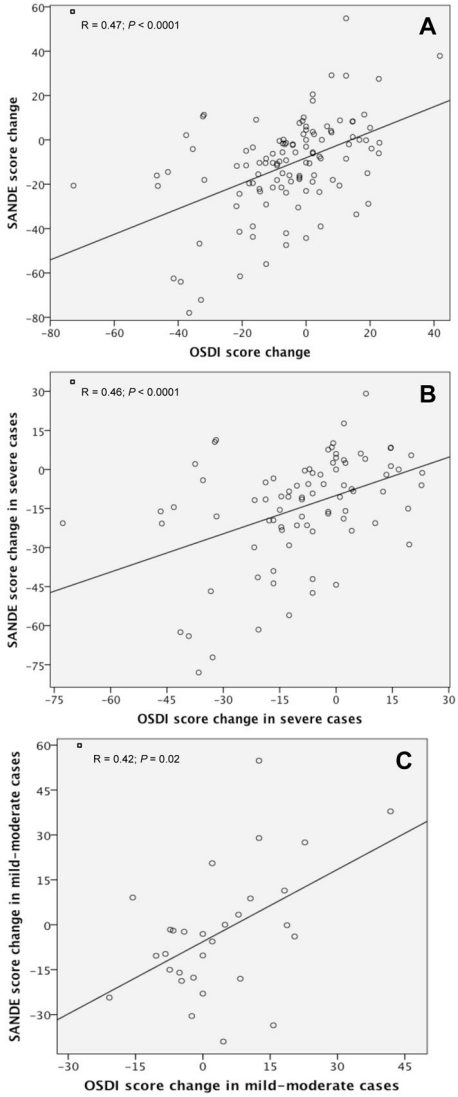

Figure 3.

Scatter plots showing the correlation between the SANDE and OSDI changes (from baseline to follow-up visit) in patients with dry eye disease. **A**, Correlation between changes in OSDI and SANDE scores (R = 0.47; $P < 0.0001$). **B**, Correlation between changes in OSDI and SANDE scores in cases with severe symptoms (R = 0.46; $P < 0.0001$). **C**, Correlation between changes in OSDI and SANDE scores in cases with mild to moderate symptoms (R = 0.42; $P = 0.02$).

Figure 4.
Representative plot showing SANDE frequency change and SANDE severity change in each patient.

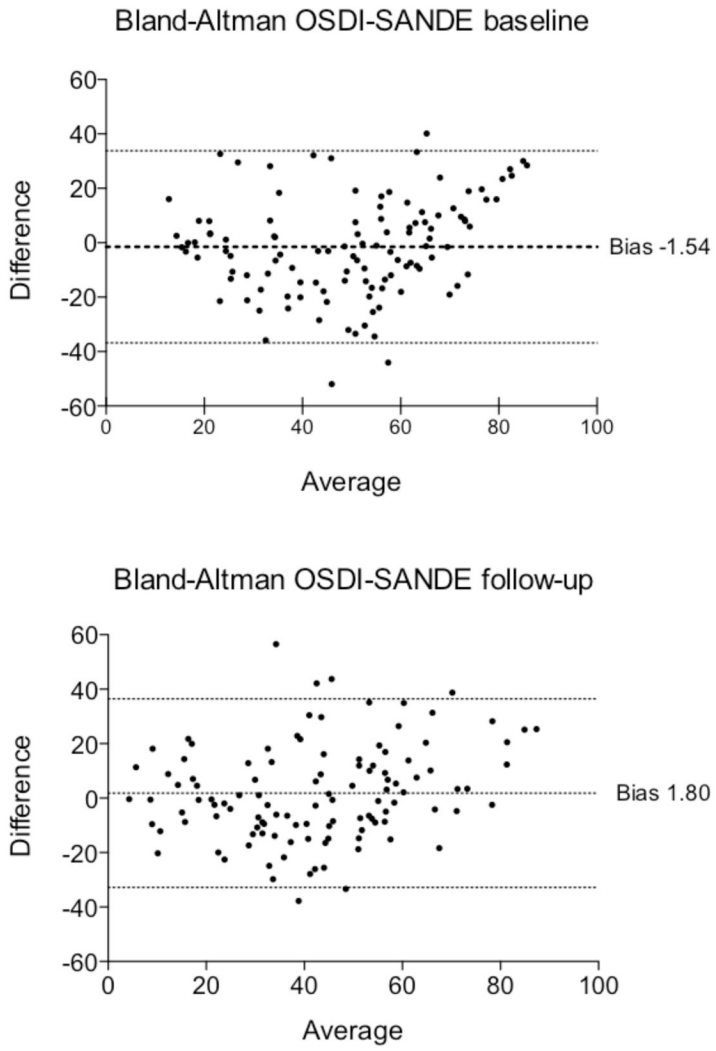

Figure 5.

Bland–Altman plot for the normalized SANDE and OSDI scores. The *x*-axis indicates the average of the two questionnaire scores, and the *y*-axis indicates the difference between the two questionnaires scores (OSDI-SANDE). The central line indicates the mean difference (bias) between the normalized scores from the two questionnaires, while the superior and inferior lines depict the intervals that include 95.6% of all the differences.

Table 1

Baseline Characteristics of the Study Population

Patient characteristics	
Age (mean, sd)	51.8 ±15
Sex	
Female	71 (62%)
Male	43 (38%)
Eye-specific characteristics	
Corneal fluorescein staining (mean, sd)	2 ± 1.6
Overall OSDI score (mean, sd)	48.9 ± 22.4
Overall SANDE score (mean, sd)	63.5 ± 23.5

OSDI: Ocular Surface Disease Index; SANDE: Symptom Assessment iN Dry Eye; sd: standard deviation