# Objective Signs *versus* Subjective Disease Index in Dry Eye Disease

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## ABSTRACT

**Objective:** To compare the ocular surface disease index (OSDI) questionnaire with objective tests in dry eye disease.

**Study Design:** A prospective observational study.

**Place and Duration of the Study:** Department of Ophthalmology, Nigde Omer Halisdemir University, Nigde, Turkiye, from 9th June to 31st December 2022.

**Methodology:** All clinically diagnosed 323 eyes of patients with dry eye disease (DED) were included. The subjects were evaluated by the Oxford classification of corneal and conjunctival fluorescein staining, Schirmer I test, and fluorescein tear breakup time (TBUT). Symptoms of the patients were interpreted with OSDI and correlations of symptoms and objective markers were analysed.

**Results:** There was no significant association between any objective signs (Schirmer I, TBUT, and Oxford), and OSDI ($p = 0.26$, 0.52, 0.18, and respectively). Schirmer I score showed a significant positive correlation with TBUT ($p < 0.001$, $r = 0.21$) and a significant negative correlation with Oxford scale ($p < 0.001$, $r = -0.19$). There was a statistically negative correlation between TBUT and Oxford scale ($p < 0.001$, $r = -0.37$).

**Conclusion:** Except for the Schirmer test, TBUT and Oxford scale are effective tools in the diagnosis of DED. Symptom markers, such as OSDI may have lower reliability in diagnosing DED and determining its severity. Diagnostic tests are important in the detection of asymptomatic or less severe dry eye disease that can be ignored.

**Key Words:** *Dry eye disease, Diagnosis, Ocular surface disease index (OSDI), Tear breakup time (TBUT), Oxford grading scale, Schirmer I test.*

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## INTRODUCTION

Dry eye disease (DED) is a multifactorial disease characterised by tear film instability. In addition, it is accompanied by ocular surface inflammation, disrupted homeostasis of the tear film, hyperosmolarity, neurosensory abnormalities, and aetiological factors.[1,2] Dry eye is associated with age, femininity, systemic disease, and environmental factors.[3] Its prevalence around the world is between 5% and 34% and the prevalence rises with age.[2,4] The most common ocular symptoms in dry eye patients are foreign body sensation, fluctuating vision acuity, ocular discomfort, feelings of dryness, redness, and photophobia.[1,4,5]

The diagnostic examinations of DED involve the Schirmer I test, tear film breakup time (TBUT), upper and lower tear meniscus height, cornea and conjunctival staining score, construction, and function of the meibomian gland. However, in several previous studies on the association between symptoms and dry eye clinical tests, rare correlations have been found.[6,7]

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In order to analyse the correlation between the ocular surface disease index (OSDI) and the parameters, three ocular surface parameters (TBUT, Schirmer I test, cornea and conjunctival staining score) were examined. Therefore, the main objective of the study was to compare the OSDI questionnaire with objective tests (TBUT, Schirmer I test, and Oxford grading scale).

## METHODOLOGY

It was a prospective observational study conducted on patients who visited Nigde Omer Halisdemir University Hospital with the complaint of dry eye, and were diagnosed with DED between June and December in 2022. Only the eyes of the participants diagnosed with DED were included in the study. According to the Tear Film and Ocular Surface Society Dry Eye Workshop (TFOS DEWS II) definition and classification report 2017, whenever just a single eye satisfies the diagnosis standards, it will be chosen.[1] The reason why only one eye was included was that it would protect the heterogeneity of the patients. On the other hand, whenever both eyes meet diagnosis standards, the right eye will always be chosen. Approval from the Institutional Review Board at the University was obtained (N-2022/62) and informed consent was taken from all of the participants before the commencement of the study.

Inclusion criteria for the study were the participants having experienced dry eye symptoms (at least one item foreign body

sensation, fluctuating vision acuity, ocular discomfort, feelings of dryness, redness, or photophobia); a rapid tear breakup time <10 seconds; Schirmer I test ≤10 mm/5min; ocular surface lesions (punctate staining with fluorescein dyes – evaluation of Oxford Scale).[1-4] If the first two sets of symptom score is ≤5 s or ≤10 s, the diagnosis of DED might be considered; the next two criteria increase the reliability in the presence of the third criteria of such diagnosis. Exclusion criteria for the study were: Being under 18 years of age, having any ocular disease other than DED, undergoing ocular surgery, and having any systemic disease.

The symptoms of DED were appraised (OSDI - Allergan, Irvine, CA, USA) that comprised of 12 questions associated with symptoms. The scores representing symptoms were 0: none of the time; 1: some of the time; 2: half of the time; 3: Most of the time; 4: All of the time. OSDI score was calculated as the [sum of scores for all questions answered × 100] / [total number of questions answered × 4].

The ocular surface was dyed with fluorescein and then examined through slit lamp. TBUT was used to evaluate the stability of the tear film. Corneal staining was graded by means of the Modified Oxford Grading Scales (0 absent i.e., no staining; 1 minimal i.e., dot count of upto 10 per sector of upto 10; 2 mild i.e., dot count of 32 per sector; 3 moderate i.e., dot count of 100 per sector; 4 marked i.e., dot count of 316 per sector; 5 severe i.e., count per sector greater than 316 under cobalt blue filter). In the Schirmer I test without anaesthesia, the test strips (35×5 mm) were placed in the conjunctival sac of the temporal third of the lower eyelid and the strip was measured after five minutes (Schirmer I test ≤10 mm / 5 min).

Statistical analysis was performed through SPSS I3.0 (SPSS, Inc., Chicago, IL, USA). The $p < 0.05$ value was considered statistically significant in the study. Mean ± standard deviation and percentage values were used in the complementary statistics of the data. After normal Shapiro-Wilk's test, Pearson correlation analysis was used for normally dispensed data and Spearman correlation analysis was adopted for the abnormally dispensed data. Correlation analysis was performed between OSDI score and the three ocular surface signs of patients.

## RESULTS

There were 323 patients with the disease (323 eyes), including 231 females (231 eyes, 72.51%) and 92 males (92 eyes, 28, 48%) in this study. The mean age of the patients was 53.34 ± 14.95 years (ranging from 21 to 82 years); 231 of 323 patients were females (72.51%). The mean TBUT was 4.11 ± 2.51 seconds, the mean Schirmer I score was 11.61 ± 7.91 mm, the mean Oxford scale was 1.91 ± 1.30, and the mean OSDI was 49.41 ± 20.73.

A statistically significant difference was found between female and male TBUT, which showed less values in females ($p < 0.001$, $r = 0.19$). A statistically significant difference was found between female and male Oxford grading scale ($p = 0.001$, $r = -0.18$). A statistically significant difference was found between female and male OSDI questionnaires which was in fewer females ($p < 0.001$, $r = -0.29$). It was also found that there were no differences between female and male Schirmer I test results ($p = 0.1$). The differences between different variables regarding gender and TBUT, Oxford grading scale, Schirmer I, and OSDI are given in Table I.

Among the four variables recorded, Schirmer I score showed significant positive correlation with TBUT ($p < 0.001$, $r = 0.21$) and significant negative correlations with Oxford scale ($p < 0.001$, $r = -0.19$). There was also a negative correlation between TBUT and Oxford scale ($p < 0.001$, $r = -0.37$). Three dry eye parameters (Schirmer I, TBUT, and Oxford scale) did not reveal any statistically significant correlations with OSDI ($p = 0.26, 0.52, 0$, and 18, respectively).

When examining the correlation analysis according to age, it was found that there was a statistically significant positive correlation between TBUT and age, and a statistically significant negative correlation with the Oxford scale ($p = 0.02$, $r = 0.12$; $p = 0.001$, and $r = -0.17$, respectively). There was no significant difference between age and Schirmer I test and OSDI ($p = 0.67$, $r = -0.24$; $p = 0.14$, $r = -0.82$).

**Table I: The differences between different variables regarding gender and TBUT, Oxford Grading Scale, Schirmer I, and OSDI.**

| | Male | Female | p-value | r-value |
|---|---|---|---|---|
| TBUT | 4.90 ± 3.11 | 3.80 ± 2.16 | <0.001 | 0.19 |
| Oxford Grading Scale | 1.53 ± 0.81 | 2.06 ± 1.42 | 0.001 | -0.18 |
| Schirmer I | 12.76 ± 7.30 | 11.16 ± 8.11 | 0.1 | 0.9 |
| OSDI | 39.93 ± 21.24 | 53.22 ± 19.29 | <0.001 | -0.29 |

*TBUT: Time breakup time, OSDI: Ocular surface disease index. Values are presented as numbers or mean ± standard deviation.*

## DISCUSSION

In the present study, symptom analysis using OSDI scoring was combined with objective testing and no consistent relationship was found between any of the common signs and symptoms of DED ($p > 0.05$). On the contrary, statistically significant correlations between objective tests were noted ($p < 0.05$). Despite the widespread prevalence of dry eye symptoms, objective clinical data often contradicted patient symptoms.[8,9] In the TFOS DEWS II diagnostic and methodology report, attention was drawn towards the limited use of severity tables due to the lack of a strong correlation between the characteristics of dry eye.[1]

Contrary to these findings, Lin *et al.* concluded that the Schirmer I test result was significantly associated with dry eye symptoms.[10] The result of the Schirmer test has been shown to be higher in patients with ocular irritation due to meibomian gland disease than in those due to aqueous tear deficiency.[11]

Consistent with this study, Lee *et al.* also found no statistically significant difference between OSDI and TBUT, and Schirmer I tests.[12] In addition, the correlation coefficients between OSDI and TBUT, Schirmer I, and fluorescent staining were very low in the study of Schiffman *et al*.[13] On the other hand, according to the study conducted by Bartlett *et al.,* there was a significant difference between common symptoms and low Schirmer I scores, low TBUT scores, and high fluorescein staining in the

Chinese population. However, it was found that there was no statistically significant difference in its population in Taiwan.[14]

The OSDI score and the Oxford scale were found to be statistically significantly higher in the female gender, while Shirmer I and TBUT were statistically significantly lower in the female gender. Another important assumption made was that there was a positive correlation between age and TBUT, and a statistically significant negative correlation with the Oxford scale. According to these data, it can be stated that dry eye symptoms are more common in the female gender and dry eye severity is more common based on objective tests. The importance of objective markers in the early detection of DED in asymptomatic or less symptomatic individuals was emphasised in the current study. In addition, the reliability of the highly reproducible objective markers (TBUT, Schirmer I, corneal, and conjunctival staining) with each other was emphasised. Since only subjects with dry eye symptoms were evaluated in the study, it can be stated that the lack of a control group was a limitation of the current study. All subjects in the study reported few or severe symptoms and were diagnosed with DED based on objective examinations. Moreover, it was considered that the large number of subjects could increase the reliability of the statistical data.

## CONCLUSION

As a result, it was seen that there was not enough consensus regarding the symptom analysis and objective tests, the current study findings are the first in the diagnosis of dry eye. According to gender, both symptoms and objective dry eye tests are more severe in females; however, there were no statistically significant correlations found between OSDI and diagnostic tests.

### ETHICAL APPROVAL:

An approval was obtained from the Clinical Research Ethical Committee of Nigde Omer Halisdemir, Nigde, Turkiye, on 9th June 2022 with registration number N-2022/62.

### PATIENTS' CONSENT:

Informed consent was taken from all the patients.

### COMPETING INTEREST:

The author declared no conflict of interest.

### AUTHOR'S CONTRIBUTION:

CT: Study design, material and data collection or processing, literature review, manuscript preparation, study conception, critical review, supervision, statistical analysis, and data interpretation.

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