

# Correlation between ocular-surface disease index questionnaire, tear film break-up time and schirmer tests for evaluation of the tear film in patients of dry eye syndrome

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## Abstract

**Background:** The purpose of this study is examining the correlation between clinical tests in patients of dry eye. **Methods:** Medical records of all cases of clinically diagnosed dry eye syndrome [DES] attending the corneal clinic of department of Ophthalmology, L.N. medical college Bhopal, India from September 2015 to December 2015 were retrospectively analyzed. Parameters such as OSDI (Ocular surface disease index), TBUT (Tear film breakup time), ST (Schirmer's test), age, sex were evaluated. **Result:** One hundred and two patients were included in the study. Patients were predominantly males (51.92%) in group 1 and females (52 %) in group 2. Average female: male ratio was 0.92:1 in group 1 and 1.08: 1 in group 2. Mean age in group 1 was 41.1 years, in group 2 was 44.54years. The OSDI was not correlated with TBUT and ST in group 1 and in group 2. The TBUT and ST test was not correlated in group 1 and group 2 ( $p > 0.05\%$ ). **Conclusion:** At present there is no diagnostic test available that can be considered as a gold standard test for DES. Which represents further studies may be necessary to increase our understanding and diagnosis.

**Key words:** Ocular-surface disease, schirmer tests, dry eye syndrome.

## Introduction

In 2007, the International Dry Eye Work Shop's (DEWS) subcommittee for Definition and Classification presented a revised definition of dry eye, which emphasized Dry eye is multifactorial diseases of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface [1]. It is classified into aqueous tear deficient dry eye and evaporative dry eye. Due to the large variety of clinical expressions it is very important to have a correct diagnosis to be aware of the severity of the condition. For many years, the dry eye syndrome (DES) diagnosis has been exclusively clinical, with a number of objective and subjective measures aimed at confirming the diagnosis. It can affect any race, is more common in

women, especially those aged > 40 years old and is one of the most frequent reasons for seeking eye care [2, 3]. Studies based on the tests of tear function, including ST, TBUT, corneal and conjunctival staining have generally found lower prevalence rates than questionnaire-based studies [4,5]. The Ocular Surface Disease Index (OSDI) is the best validated questionnaire [6] The objective of our study is to determine the degree of correlation between the various diagnostic tests including ST, TBUT and OSDI which is generally applied for studying DES.

## Material and Method

Medical records of all cases of clinically diagnosed dry eye attending the corneal clinic of department of Ophthalmology, L.N. Medical College Bhopal, India from September 2015 to December 2015 were retrospectively analyzed. The protocol for this study

was approved by local Institutional review board/Ethical Committee. We excluded cases where dry eye was secondary to some ocular or systemic disease, and patients with any concurrent disease or condition that could have complicated or interfered with the administration or evaluation of the test. The Ocular Surface Disease Index (OSDI) is a validated questionnaire based scoring system for diagnosis of dry eye [6, 7, 8]. It consists of twelve questions that provide a rapid assessment of the symptoms of ocular irritation and their impact on vision-related functioning. The response to each item was scored from 0 (none of the time) to 4 (all of the time); an average score was generated and transformed into a scale of 0–100, with higher scores representing greater disability. TBUT is defined as the interval between the last complete eyelid closure and the first disruption in the lachrymal film. It provides a measurement of tear stability and it has a sensitivity of 83% and a precision of 85% [9, 10]. It is measured in seconds (s) and values of <10 are regarded as abnormal. Three consecutive measurements were taken of each eye, taking the mean value of all three. The Schirmer test gives an estimate of the lachrymal film aqueous layer amount. The current trend is to locate the reference line at 5mm [9, 10]

The diagnosis of DES was made in the case that any of the following three conditions were present: (i) Schirmer I test (ST) value of <5 mm/5 min, (ii) tear film breakup time (TBUT) of <10 seconds and (iii) OSDI >12. The cases were assigned into two groups; group 1 included cases of DES without treatment and group 2 included the cases of DES who were on treatment for dry eye. Parameters such as OSDI, TBUT, ST, age, sex were evaluated. Analysis of correlation was done to determine the degree of correlation between the various diagnostic tests including ST, TBUT and OSDI.

**Statistical Methods:** Data were entered in MS Excel and analyzed using Stata 11.0. Correlation analysis (Correlation coefficients) was performed between the OSDI, TBUT and Schirmer's test scores using Pearson's correlation coefficient (r). A P value of < 0.05 was considered significant. Descriptive statistics such as frequencies (percentage) and mean scores (SD) for continuous variables were reported. Two sample t tests were used to find out the difference between two means of the diagnostic test scores. 95% Confidence Intervals (CI) were also reported. Chi-square test was used to compare treatment group differences in demographic characteristics.

## Result

One hundred and two patients were included in the study. Group 1, Group 2 included 52 and 50 number of cases respectively.

**Demographic and baseline characteristics-** Patients were predominantly males (51.92%) in group 1 and females (52 %) in group 2. Average female: male ratio was 0.92:1 in group 1 and 1.08: 1 in group 2. Mean age in group 1 was 41.1 years (SD: 12.72 years, range: 19-77), in group was 44.54years (SD: 14.66, range: 20-70). Mean OSDI in group 1 was 26.92 ( SD : 15.15, range :0-70 ) and in group 2 was 23.7 (SD : 12.81 , range : 0-55.5) .

**Table 1: Summary of Patients baseline characteristics in group 1 and 2**

Mean	Group 1 (n=52)	Group 2 (n=50)	P value
Mean ( SD) (range)			
Age	41.1years (12.72) ( 19-77)	44.54 (14.6) ( 20-70)	0.162
OSDI	26.92 (15.15) (0-70)	23.7 (12.81) (0-55.5)	0.2650
TBUT	7.08 (4.07) (1-20)	8.48 (2.94) (4-15)	0.0494
ST	18.56 (11.13) (0-30)	26.94 (7.47) (5-30)	0.000
*Sex ratio F:M	0.92:1	1.08:1	0.446

Mean TBUT in group 1 was 7.08 ( SD : 4.07 , range : 1-20) and in group 2 was 8.48 ( SD: 2.94 ,range : 9-14). Mean ST in group 1 was 18.56 ( SD : 11.13 , range : 0-30) and in group 2 was 29.94 ( SD: 7.47 ,range : 5-30). (Table-1).

F- Female, M- male, OSDI-ocular protection disease index,

TBUT- Tear film breakup time, ST- Schiormers test.

Two sample T test applied for group 1 and group 2 and Difference between two means of OSDI was not found to be statistically significant (p=0.2650), the difference between two means of Schirmer’s test (p=0.000) and TBUT test was found to be statistically significant (p=0.0494) (table1).

**Correlation-** The analysis of the correlations between the different clinical ocular surface parameters, the following associations were found:

The results obtained after the application of diagnostic tests are shown in tables 2 and 3. The OSDI was not correlated with TBUT in group 1 (r-0.1162, p=0.4120) and in group 2(r-0.0856, p=0.5543). In the assessment of ST results no correlation were observed with OSDI in group 1 (r-0.1112, p=0.4325) and in group 2 (r-0.0047, p=0.9740). The TBUT and ST test was not correlated in group 1 (r-0.1983, p=0.1588) and group 2 (r-0.2549, p=0.0740).

**Table 2: Correlation between different clinical tests, expressed by means of the Pearson’s correlation coefficient (r) based on the group 1 (n= 52)**

	OSDI	ST
TBUT -Correlation coefficient	0.1162	0.1983
-p value	0.4120	0.1588
ST -Correlation coefficient	0.1112	
-p value	0.4325	

**Table 3: Correlation between different clinical tests, expressed by means of the Pearson’s correlation coefficient (r) based on the group 2 (n= 52).**

	OSDI	ST
TBUT -Correlation coefficient	0.0856	0.2549
-p value	0.5543	0.0740
ST -Correlation Coefficient	0.0047	
-p value	0.9740	

**Discussion**

DES is a very common public health problem encountered by ophthalmologists; however, diagnosis is not straightforward and the symptoms and signs do not correlate well. The usefulness of the diagnostic tests which is most frequently utilized in DES has been questioned in multiple literatures [11]. Many authors

studied the reproducibility [12] and the correlation between them and many ophthalmologists will not be surprised by the contradicting and mismatched results reported by many of them. The diminished tear production can be evidenced through ST. A patient may have no symptoms besides eye tiredness even though

the result of a Schirmer's test is below 5 mm or even zero on the other hand reflex epiphora might result in the misdiagnosis of dry-eye patients as being normal. Singh Bhinder and Singh Bhinder reported that test results of ST changed according to reflex epiphora, therefore, there was no correlation with symptoms in DES [13]. This test alone does not seem to be a good test for diagnosis of DES by the high variability of its results and its low reproducibility [12] as obtaining normal values does not exclude the DES, it simply indicates a higher production of tears, and it would be appropriate to use a different test. This was proved by Nichols [11] who found values <5mm only in 21% of his group of cases, similar to our study with 11.76%. The TBUT test has been considered by many authors as the main diagnostic test, with high reproducibility and low variability virtually in all the dry eye types [9]. But TBUT test has limitations like the instillation of large volumes of fluorescein, which could produce false higher values. To resolve this problem, some authors propose to reduce the set point. Seventy two % percent of our cases exhibited values <10s similar to Vitale [14] who established a set point of <5s, and reported 87% of cases (severe cases). The OSDI quality of life test is considered to have excellent validity and reliability. In our study, the OSDI score was significantly higher in group 1 than in group 2, with a mean score of group 1 was 26.92 similar to Vitale reported a value of 30 (severe cases) [14]. The lack of association between symptoms and signs in this study are due to the virtually nil correlation between OSDI and the majority of tests [11].

## Conclusion

In conclusion, despite all the efforts applied in this regard, at present there is no diagnostic test that can be considered gold. Which represents further studies may be necessary to increase our understanding and diagnosis in DES.

**Funding:** Nil,

**Conflict of interest:** None.

**Permission of IRB:** Yes

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**How to cite this article?**

Raghuwanshi S, Agarwal R, Raghuwansh SK, Shidhaye PR Correlation between ocular-surface disease index questionnaire, tear film break-up time and schirmer tests for evaluation of the tear film in patients of dry eye syndrome . *Int J Med Res Rev* 2016;4(3):309-313. doi: 10.17511/ijmrr.2016.i03.04.  
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