

Original Research Article

Correlation between OSDI Score, Tear Break-Up Time and Schirmer Test in Patients with Dry Eye Disease: A Cross-Sectional Observational Study

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ABSTRACT

Background: Dry eye disease is clinically heterogeneous, and symptom burden does not always parallel individual ocular surface signs. The Ocular Surface Disease Index (OSDI), tear break-up time (TBUT) and Schirmer I test assess complementary dimensions of dry eye, making their relationship relevant to routine evaluation.

Objective: To determine the correlation of OSDI score with TBUT and Schirmer I test values in patients with dry eye disease.

Methods: This cross-sectional observational study enrolled 50 consecutive patients with symptomatic dry eye disease. Dry eye was operationally defined by an OSDI score ≥ 13 together with either fluorescein TBUT < 10 seconds or Schirmer I test < 10 mm/5 min without anaesthesia. Final eligibility validation identified one enrolled participant who did not meet the objective-test criterion; 49 eligible participants were therefore included in the analysis. Spearman rank correlation was used to examine relationships among OSDI, TBUT and Schirmer I values.

Results: Among 49 eligible participants, mean age was 56.24 ± 11.27 years and 28 (57.1%) were female. Mean OSDI score was 43.22 ± 11.47 , mean TBUT was 5.46 ± 2.36 seconds and mean Schirmer I value was 6.74 ± 2.96 mm/5 min. Eleven (22.4%) participants had moderate and 38 (77.6%) had severe disease by OSDI classification. OSDI showed very strong inverse correlations with TBUT (Spearman $\rho = -0.986$, $p < 0.001$) and Schirmer I ($\rho = -0.988$, $p < 0.001$), while TBUT and Schirmer I were very strongly positively correlated ($\rho = 0.993$, $p < 0.001$).

Conclusion: In this moderate-to-severe dry eye cohort, greater symptom burden was accompanied by shorter tear-film break-up time and lower Schirmer I values. The exceptionally strong correlations should be interpreted within the restricted clinical spectrum and the limitations of a single-centre cross-sectional study. Combined symptom and objective tear-film assessment remains clinically appropriate.

Keywords: Dry Eye Disease; Ocular Surface Disease Index; OSDI; Tear Break-Up Time; TBUT; Schirmer I Test; Correlation

INTRODUCTION

Dry eye disease (DED) is a multifactorial disorder characterised by disruption of tear-film and ocular-surface homeostasis, with tear-film instability, inflammation, ocular surface damage and neurosensory abnormalities contributing to the clinical phenotype.^[1,2] Its burden extends beyond ocular discomfort. Fluctuating vision, reading difficulty and reduced tolerance to visual tasks can interfere with daily function, while the underlying

mechanisms vary substantially between patients.^[3]

Patient-reported symptoms and objective signs therefore provide different, but complementary, clinical information. The Ocular Surface Disease Index (OSDI) is a validated 12-item questionnaire that quantifies ocular discomfort, vision-related functional limitation and environmental triggers on a 0-100 scale.^[4] Scores of 0-12 are commonly interpreted as normal, 13-22 as mild, 23-32 as

moderate and 33-100 as severe.^[5] OSDI is useful for documenting symptom burden, although it does not directly measure tear-film stability or aqueous tear output.

TBUT is widely used as a practical indicator of tear-film stability, while the Schirmer test assesses tear secretion under specified conditions. Contemporary diagnostic frameworks emphasise that DED should not be reduced to a single measurement because symptoms and individual signs may diverge.^[6] This discordance is clinically relevant: a patient can report substantial discomfort despite limited objective abnormalities, whereas another may show marked tear-film dysfunction with comparatively modest symptoms.

Previous studies have reported inconsistent symptom-sign relationships. Begley et al. observed that these relationships varied with disease severity,^[7] while Nichols et al. found little association between symptoms and commonly used clinical signs.^[8] A systematic review similarly showed that most reported correlation coefficients between dry-eye symptoms and signs were low to moderate, with considerable heterogeneity across tests and populations.^[9]

Indian clinical studies have also demonstrated substantial variability in DED presentation and severity.^[10-12] Because OSDI, TBUT and Schirmer testing are inexpensive and widely available in routine ophthalmology practice, clarifying how these measures relate within a symptomatic cohort has practical value, particularly in settings where advanced tear-film diagnostics may not be routinely accessible.

The present study was undertaken to evaluate the correlation between OSDI score, fluorescein TBUT and Schirmer I test values in patients with dry eye disease. The primary objective was to determine whether increasing symptom burden was associated with measurable deterioration in tear-film stability and tear production.

MATERIALS AND METHODS

Study Design and Setting

This cross-sectional observational study was conducted in the Department of Ophthalmology at KVG Medical College Sullia, Dakshina Kannada for a period of 8 months. Fifty consecutive patients with dry eye disease were enrolled, with the final analysis restricted

to participants who fulfilled the prespecified diagnostic criteria.

Study Population and Diagnostic Criteria

Eligible patients presenting to the dry eye clinic were enrolled consecutively until the target enrolment was achieved. Dry eye disease was operationally defined by the presence of ocular symptoms corresponding to an OSDI score ≥ 13 together with at least one abnormal objective test: fluorescein TBUT < 10 seconds or Schirmer I test < 10 mm/5 min without topical anaesthesia.

Sample Size and Sampling Method

Consecutive sampling was used. A pilot assessment of 10 patients suggested a Spearman correlation of approximately 0.50 between OSDI and TBUT. Using a two-sided significance level of 0.05 and 80% power, the minimum required sample size was 29. The target enrolment was increased to 50 to allow for incomplete observations and protocol deviations.

OSDI Assessment

OSDI was scored on its conventional 0-100 scale. For descriptive severity classification, scores were categorised as normal (0-12), mild (13-22), moderate (23-32) and severe (33-100).

Tear Break-Up Time Measurement

For fluorescein TBUT, 2 μ L of 2% sodium fluorescein solution was instilled into the inferior conjunctival fornix. The participant was asked to blink naturally three times and then refrain from blinking. Using the cobalt-blue filter of a slit-lamp biomicroscope, the interval between the last complete blink and the first visible dry spot or discontinuity in the tear film was recorded in seconds. Three consecutive measurements were obtained, and their arithmetic mean was used as the final TBUT value.

Schirmer I Test

Schirmer I testing was performed without topical anaesthesia. A standard sterile Schirmer strip measuring 5 $\times$ 35 mm was folded at the notch and placed at the junction of the middle and lateral one-third of the lower eyelid margin. Participants were instructed to close their eyes gently for 5 minutes. The length of strip wetting from the fold was then measured in millimetres. Bright light or irritating drops were avoided before testing to minimise reflex-inducing stimuli.

Data Quality and Statistical Analysis

Participant identifiers were checked for duplication and all variables were screened for completeness, valid numeric ranges, severity-label consistency and concordance with the prespecified eligibility definition. All 50 enrolled records were complete. One participant had OSDI 25, TBUT 10.0 seconds and Schirmer I 13.0 mm/5 min. and therefore did not satisfy the requirement for at least one abnormal objective test; this record was excluded from analysis without altering any recorded measurement. The final analytic cohort comprised 49 participants. Continuous variables were summarised using mean $\pm$ standard deviation, median with interquartile range and range as appropriate. Categorical variables were expressed as frequency and percentage. Spearman rank correlation assessed the relationships between OSDI, TBUT and Schirmer I values. Objective test values were compared between moderate and severe OSDI groups using the Mann-Whitney U test. All tests were two-sided, and $p < 0.05$ was considered statistically significant.

Ethical Considerations

The study was conducted after obtaining institutional ethical clearance and in accordance with accepted ethical principles for research involving human participants. Participation was voluntary, informed consent was obtained before enrolment, and confidentiality of participant information was maintained throughout the study. No experimental therapeutic intervention was administered as part of the study.

RESULTS

Fifty patients were enrolled. Final eligibility verification excluded one participant who did not meet the prespecified objective-test criterion, leaving 49 participants for analysis. Mean age was 56.24 ± 11.27 years (range 37-75 years), with a median of 56.0 years (IQR 47.0-66.0). Females constituted 28 (57.1%) and males 21 (42.9%). Mean OSDI score was 43.22 ± 11.47 , mean TBUT was 5.46 ± 2.36 seconds and mean Schirmer I value was 6.74 ± 2.96 mm/5 min (Table 1).

Characteristic	Value	Distribution
Age (years)	56.24 ± 11.27	Median 56.0 (IQR 47.0-66.0); range 37-75
Female	28 (57.1%)	
Male	21 (42.9%)	
OSDI score	43.22 ± 11.47	Median 42.0 (IQR 33.0-53.0); range 26-64
TBUT (seconds)	5.46 ± 2.36	Median 5.5 (IQR 3.5-7.0); range 1.5-9.5
Schirmer I (mm/5 min)	6.74 ± 2.96	Median 6.5 (IQR 4.0-9.0); range 2.0-12.5
Table 1. Demographic and clinical characteristics of the analysed study population (N=49)		
Values are mean $\pm$ SD or n (%), unless otherwise stated. IQR: interquartile range; OSDI: Ocular Surface Disease Index; TBUT: tear break-up time		

OSDI severity classification identified 11 (22.4%) participants with moderate and 38 (77.6%) with severe disease; no participant fell within the normal or mild categories (Figure 1). Mean TBUT was 8.64 ± 0.64

seconds in moderate DED and 4.54 ± 1.79 seconds in severe DED. Corresponding mean Schirmer I values were 10.77 ± 1.01 and 5.58 ± 2.20 mm/5 min, respectively (Table 2).

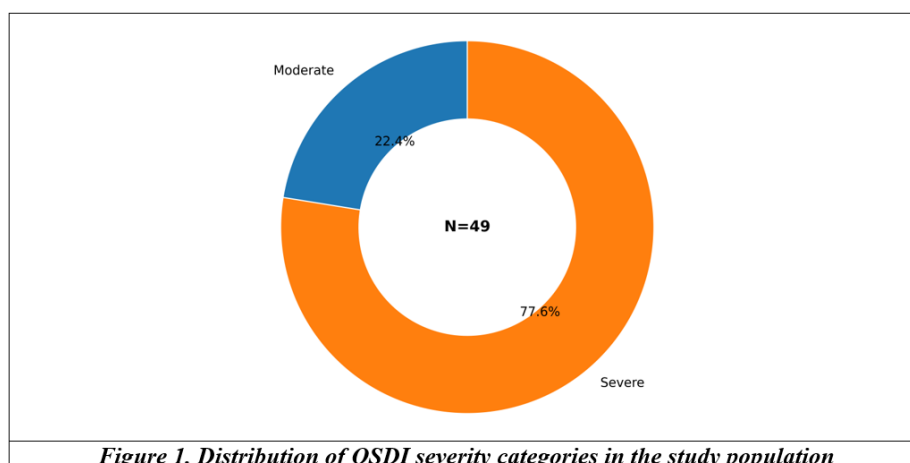


Figure 1. Distribution of OSDI severity categories in the study population

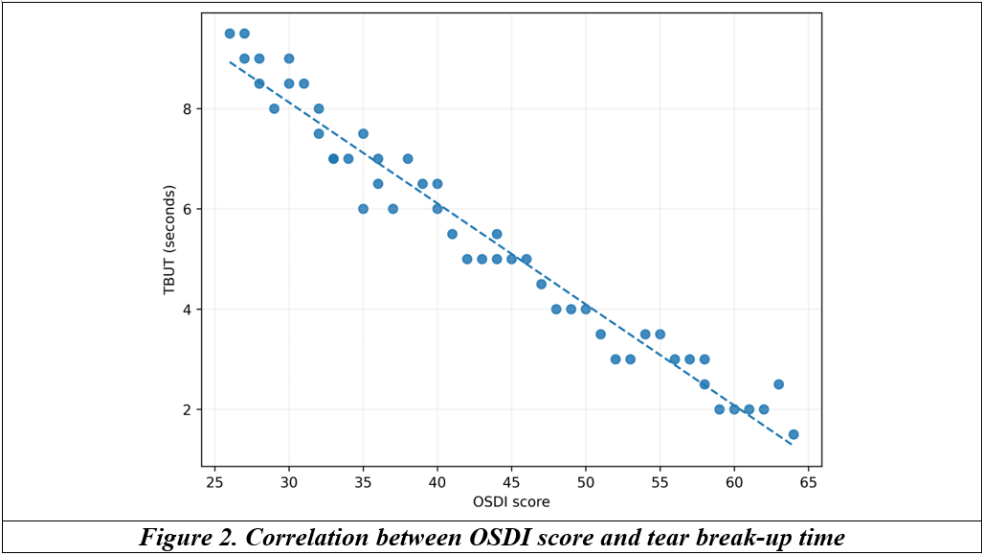
Donut segments show the distribution of the 49 eligible participants by OSDI severity. No normal or mild OSDI categories were represented.

OSDI severity	n (%)	Mean OSDI ± SD	TBUT, mean ± SD (s)	Schirmer I, mean ± SD (mm/5 min)
Moderate	11 (22.4%)	29.09 ± 2.07	8.64 ± 0.64	10.77 ± 1.01
Severe	38 (77.6%)	47.32 ± 9.64	4.54 ± 1.79	5.58 ± 2.20

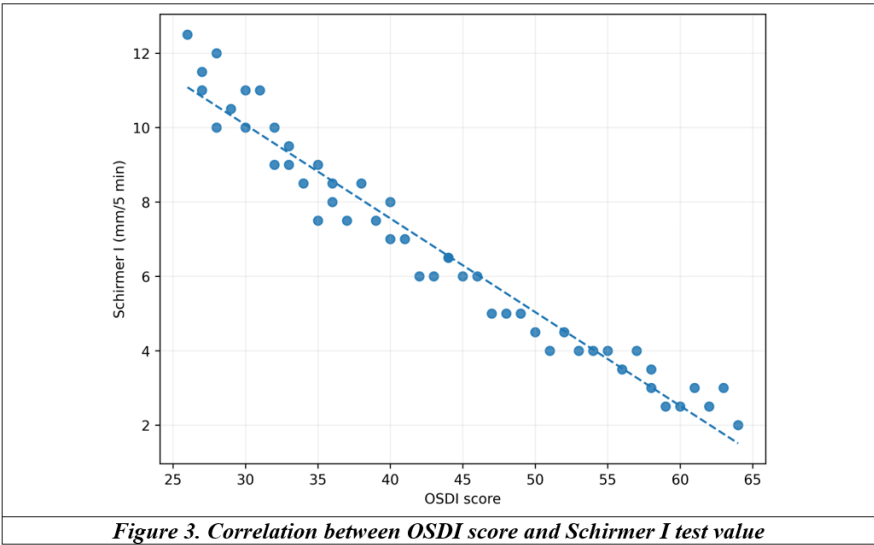
Table 2. OSDI severity distribution and objective tear-film measurements

OSDI severity thresholds: moderate 23-32 and severe 33-100

The primary analysis showed a very strong inverse correlation between OSDI score and TBUT (Spearman rho=-0.986, p<0.001). Higher symptom scores were associated with progressively shorter tear-film break-up times (Figure 2).



Each point represents one participant. The dashed line is a fitted linear trend for visual reference; inference used Spearman rank correlation. OSDI score also showed a very strong inverse correlation with Schirmer I values (rho=-0.988, p<0.001) (Figure 3). TBUT and Schirmer I values were very strongly positively correlated (rho=0.993, p<0.001). The three pairwise associations are summarised in Table 3.

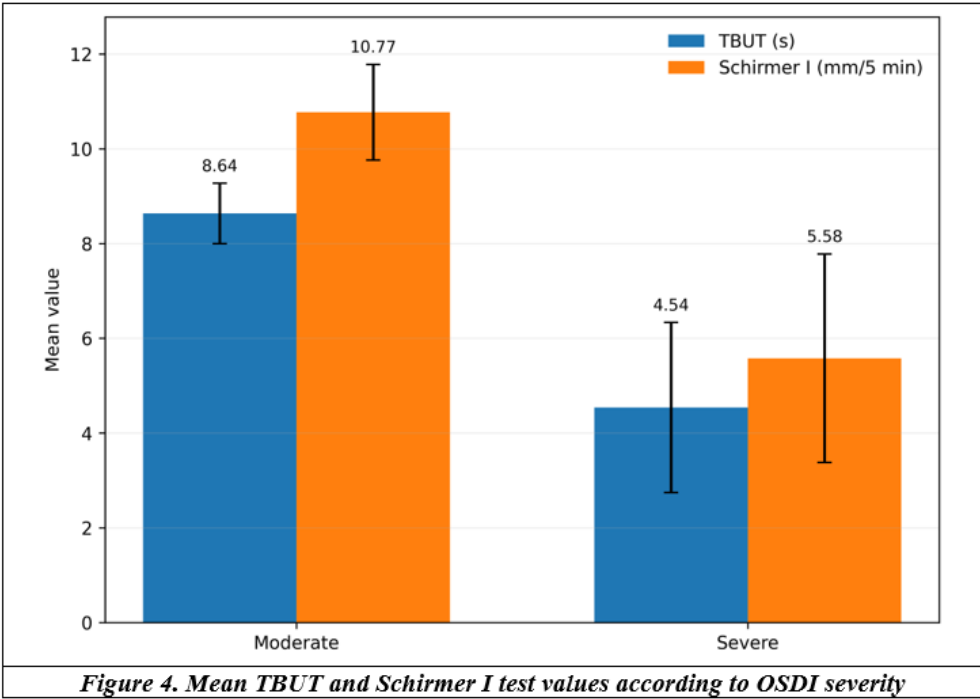


Each point represents one participant. The dashed line is a fitted linear trend for visual reference; inference used Spearman rank correlation.

Variable pair	Spearman rho	p-value	Interpretation
OSDI vs TBUT	-0.986	<0.001	Very strong inverse
OSDI vs Schirmer I	-0.988	<0.001	Very strong inverse
TBUT vs Schirmer I	0.993	<0.001	Very strong positive

Table 3. Spearman correlation among OSDI, TBUT and Schirmer I measurements

Objective test values were significantly lower in the severe OSDI group than in the moderate group. For TBUT, the Mann-Whitney U statistic was 0.5 ($p<0.001$); for Schirmer I, U was 2.0 ($p<0.001$). The group differences are illustrated in Figure 4.



Bars show mean values and error bars show standard deviation. TBUT is expressed in seconds and Schirmer I in mm/5 min.

DISCUSSION

The study demonstrated a consistent directional relationship between patient-reported symptom burden and two routinely used tear-film tests. Higher OSDI scores were associated with shorter fluorescein TBUT and lower Schirmer I values, while TBUT and Schirmer I moved in the same direction. Participants classified as severe by OSDI also had substantially lower mean objective test values than those in the moderate group.

The magnitude of the observed associations was exceptionally high: Spearman rho was -0.986 for OSDI versus TBUT, -0.988 for OSDI versus Schirmer I, and 0.993 for TBUT versus Schirmer I. Earlier literature has often reported weaker and more

heterogeneous symptom-sign relationships in dry eye disease.^[7-9] Accordingly, the present coefficients should not be interpreted as evidence that symptoms and signs are interchangeable. They describe this specific cohort, which contained only moderate and severe OSDI categories and showed a highly ordered pattern across the three measurements. Replication in a broader clinical spectrum would be necessary before assuming similar effect sizes in routine populations.

The methodological detail improves reproducibility. TBUT was measured after a defined fluorescein instillation protocol, three readings were averaged, and Schirmer I testing was performed without topical anaesthesia using a standard five-minute procedure. The operational diagnostic rule required symptoms together with at least one abnormal objective test, thereby avoiding

classification on questionnaire score alone. Consecutive enrolment also reduced discretionary selection compared with convenience sampling.

The clinical spectrum of the cohort remained narrow. After final eligibility validation, all 49 analysed participants had OSDI scores in the moderate or severe range, with no normal or mild comparator group. This limits generalisability and prevents assessment of whether the same relationships persist across the full continuum of ocular surface disease. The single-centre, cross-sectional design further precludes temporal or causal inference.

The findings are nevertheless directionally compatible with Indian hospital-based observations. Gupta et al. reported clinically meaningful relationships between questionnaire-based symptom assessment and ocular tests among adults attending a tertiary ophthalmology clinic in New Delhi.^[11] Titiyal et al. documented progressively lower TBUT and Schirmer values with increasing OSDI severity in a large North Indian cohort.^[12] In the present study, mean TBUT in severe DED was approximately 4.59 seconds, broadly similar to the low tear-film stability reported in severe disease in that study, although differences in case mix and testing procedures limit direct numerical comparison.

From a clinical perspective, the findings reinforce the value of multimodal assessment. OSDI quantifies the patient experience, TBUT reflects tear-film stability and Schirmer I provides information on tear secretion. The diagnostic utility of OSDI has been demonstrated in dry-eye populations,^[13] while the recognised repeatability limitations of individual clinical measurements^[14] and multidimensional approaches to objective disease severity^[15] further support integrated interpretation. Even when these measures correlate closely in a particular cohort, they assess different domains of disease and should be interpreted together rather than used as substitutes for one another.

Strengths and Limitations

Important strengths include a clearly stated operational diagnostic definition, consecutive enrolment, explicit fluorescein TBUT methodology with averaging of three readings, standardised Schirmer I testing without anaesthesia, and use of non-parametric correlation analysis. A further strength was prespecified eligibility validation before final

analysis; one enrolled participant who did not satisfy the objective-test criterion was excluded without alteration of the recorded measurements.

Limitations include the modest final analytic sample of 49 participants, single-centre setting, absence of normal or mild OSDI categories, and the cross-sectional design, which precludes temporal or causal inference. The exceptionally strong correlations also warrant cautious interpretation because they may reflect the restricted clinical spectrum and the highly ordered measurements in this cohort. The study did not include detailed dry-eye phenotyping, ocular surface staining, tear osmolarity, meibomian gland assessment or longitudinal follow-up. Larger multicentre studies including milder disease and asymptomatic comparators would provide a more robust estimate of symptom-sign concordance.

CONCLUSION

Among 49 eligible patients with moderate-to-severe dry eye disease, higher OSDI scores were associated with shorter fluorescein tear break-up time and lower Schirmer I values, while TBUT and Schirmer I were strongly positively related. The findings support combined symptom and objective tear-film assessment in routine clinical evaluation, although the unusually strong correlations should be interpreted cautiously and confirmed in broader populations.

Source of Funding

Nil.

Conflict of Interest

None declared.

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