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Original Research Article

Ocular surface disease index (OSDI) vs standardized patient evaluation of eye dryness (SPEED) questionnaire for assessment of patient reported symptoms in dry eye disease

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Abstract

Background: Dry Eye Disease (DED) presents diagnostic challenges due to its multifactorial nature and variable symptoms. Patient-reported outcome (PRO) questionnaires like the Ocular Surface Disease Index (OSDI) and the Standardized Patient Evaluation of Eye Dryness (SPEED) aid in assessing DED symptoms. However, their correlation with clinical tests, particularly among young adults, is underexplored.

Methodology: This cross-sectional study was carried out among young adults aged 18-35 in a tertiary hospital setting. Participants underwent comprehensive eye examinations, administration of OSDI and SPEED questionnaires, and Objective clinical tests including Schirmer's test, Tear Film Breakup Time (TBUT), and Ocular Surface Staining. Data analysis included mean scores, correlation analyses, and receiver operating characteristic (ROC) curve analysis.

Results: Out of 248 participants, OSDI mean score was 12.56 ± 12.86, with 62.1% scoring 0-12. SPEED mean score was 4.06 ± 3.70, with 50.8% scoring 1-4. Correlations between OSDI/SPEED and clinical tests were moderate, showing associations with TBUT, Schirmer's test, and Ocular Surface Staining. OSDI and SPEED scores revealed a positive correlation in the study (R=0.35; P=0.0001), indicating their reliability in assessing DED severity. Higher questionnaire scores correlated with lower TBUT values and higher Oxford Scores, reflecting more severe symptoms and ocular surface damage.

Conclusion: The study underscores the utility of OSDI and SPEED questionnaires in evaluating DED severity, with both demonstrating reliability in clinical and research contexts. However, integrating subjective symptoms with clinical findings remains crucial**.**

Keywords: Dry eye disease, Patient-reported outcome questionnaires, Ocular surface disease index, Standardized patient evaluation of eye dryness.

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1. Introduction

The International Dry eye workshop (DEWS) II, 2017 of the Tear film and ocular surface society (TFOS), defines dry eye disease as, " a multifactorial disease of ocular surface characterized by loss of homeostasis of tear film, accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles."[1]

Red-eye, burning sensation, and gritty feeling are the common indicators of dry eye disease (DED). Other symptoms include ocular irritation and discomfort, lacrimation, pain, blurring of vision, photophobia, eye fatigue associated with limitation in performing daily activities.[2,3]

In DED, there is often a discrepancy between patient reported symptoms and clinical ocular signs.[4] Poor repeatability of the clinical test is more worrying, because the same tests on the same individuals at different times are generally poorly correlated.[5] The most repeatable diagnostic test is the symptom questionnaire. Several symptom questionnaires are available for dry eye with various levels of validation; notable among them are Ocular Surface Disease Index (OSDI). The Standardized patient evaluation of eye dryness (SPEED) questionnaire was also validated using OSDI; both target the frequency of dry eye symptoms, whereas SPEED targets severity of symptoms.[6]

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OSDI questionnaire was introduced by the outcomes research department at Allergan Inc., Irvine, California, and the questionnaire were evaluated for its reliability and validity. It consists of a 12-item questionnaire.[7,8] The SPEED questionnaire was introduced by Korb and Blackie. It is an 8-item questionnaire.[5,6] While both questionnaires target dry eye symptoms, they differ in their structure and focus.

The main objective of the study was to compare the two commonly utilized questionnaires, OSDI and SPEED, in assessing symptoms of Dry Eye Disease (DED) within a hospital-based cohort of dry eye patients. Additionally, the study explores the correlations between the subjective assessments provided by these questionnaires and objective clinical tests commonly used in dry eye assessment, namely the Schirmer's basic test, Tear Film Breakup Time (TBUT), and Ocular Surface Staining by Oxford score.

2. Materials and Methods

This cross-sectional study was conducted at a tertiary eye care institute in south India from January 2020 to Jan 2021. All consecutive patients aged 18-35 years who visited the ophthalmology department of S.V. Medical College, Tirupati, with symptoms related to dry eyes, including eye irritation leading to itching, grittiness, foreign body sensation, redness, excessive periodic tearing or reflex epiphora, and temporary visual blurring during the study period, were included in the study. Participants with any ocular infection or uveitis, eyelid or ocular surface anatomical abnormalities, and any history of previous ocular surgery were excluded. The study received approval from the Institutional Ethics Committee (IEC) of S.V. Medical College, Letter No. 121/2019, and adhered to the Declaration of Helsinki. Written informed consent was obtained from all participants before the examination. A total of 248 subjects were enrolled in the study.

All the participants had a thorough eye examination that included symptom history, slit-lamp examination, applanation tonometry, fundus evaluation, and dry eye evaluation tests. The dry eye evaluation was done on the same day, include the administration of the questionnaires (OSDI and SPEED), Shirmer's test I, TBUT, Ocular surface staining and Oxford staining score.

Both OSDI and SPEED II questionnaires were distributed to the study participants for completion. For illiterate patients the questions were clarified in an understandable language. The questionnaire was presented in the local language (Telugu) for participants who did not comprehend English. Total scores were obtained from each questionnaire, and severity of the dry eye was assessed based on the distinct scoring systems of each questionnaires.

The OSDI questionnaire consists of 12 questions aimed at evaluating symptoms that patients have experienced through the last week. The questionnaire is organized into three sections: assessing the frequency of symptoms, their impact on vision-related quality of life, and the identification of environmental triggers. Participants are required to choose from five possibilities for each question, that are rated on a scale of 0 to 4: Never (0), occasionally (1), some time (2), often (3), and always (4). The OSDI score is calculated by summing the scores for each question, multiplying by 100, and dividing by the total number of answered questions multiplied by 4. The final OSDI score lies in the ranges of 0 to 100, with higher scores corresponds to a greater disability. Normal scores fall between 0 and 12, mild disease between 13 and 22, moderate dry eye disease (DED) between 23 and 32, and severe DED between 33 and 100.

The SPEED questionnaire comprises four sections. The first three sections assess the presence, frequency, and severity of symptoms such as dryness, grittiness or scratchiness, soreness or irritation, burning or watering, and eye fatigue. The fourth section records the use of eye drops for lubrication. Additionally, the questionnaire captures changes in symptoms at the current visit, within the past 72 hours, and within the past 3 months. Symptom frequency is assessed using a 4-point scale: Never (0), Occasionally (1), Frequently (2), or Constantly (3). The severity of symptoms is assessed on a 5-point scale: No problems (0), Tolerable (1), Uncomfortable (2), Bothersome (3), or Intolerable (4). Cumulative SPEED scores are obtained by adding responses to the eight questions, resulting in a final SPEED score ranges from 0 to 28. The scores are graded as follows: 0 – normal, 1 to 4 – mild, 5 to 9 – moderate, and ≥ 10 – severe.

Schirmer's Basic test (tear quantity): Test was performed by using sterile Whatman Filter paper no: 41, 5x35mm2. The value of >10mm is taken as no dry eye, <5mm as severe dry eye, and 5 - 10mm is taken as mild to moderate disease.

TBUT test (TBUT for quality of tear film): It was recorded after fluorescein staining. If the average TBUT was less than 10, the test was determined to be positive.

Ocular surface evaluation included the use of diagnostic dyes: fluorescein staining at 1mg/ml, Lissamine green at 1.5 mg/mL, and Rose Bengal at 1%. Sterile fluorescein strips, Lissamine green paper strips, and Rose Bengal paper strips were applied for 2 minutes in the lower outer conjunctival cul-de-sac. These dyes highlighted areas of the epithelial surface that lacked mucin protein protection, exposing epithelial cell membranes.

The stain is seen in all three regions of an interpalpebral ocular surface, at the triangular wedge of nasal interpalpebral conjunctiva, corneal surface, the wedge of temporal conjunctiva and graded according to modified oxford staining scores (grade 0 to 5). Drawings were used to depict the increasing density of dots with each grade, demonstrating that the increased number of stained dots distributed unevenly within each zone. The modified Oxford grading scale ranged as follows.[8]

1. Grade 0: Absent staining, indicating no staining observed.
2. Grade 1: Minimal staining, with up to 10 dots per sector.
3. Grade 2: Mild staining, with up to 32 dots per sector.
4. Grade 3: Moderate staining, with up to 100 dots per sector.
5. Grade 4: Marked staining, with up to 316 dots per sector.
6. Grade 5: Severe staining, with more than 316 dots per sector.

Data from all participants was recorded in a standardized form. The *statistical analysis* was done using version 20 of the Statistical Package for the Social Sciences (SPSS). The eye with signs of more severe Dry Eye Disease (DED) was chosen for analysis. Mean and standard deviation (SD) were calculated for each parameter. Kendall's correlation was used to determine the strength of association between quantitative variables, whereas chi square test was used to know the degree of association of categorical variables. Statistical tests were performed with a significance threshold of $p < 0.05$.

3. Results

Out of 248 patients enrolled in our study, 98 (39.5%) were male, and 150 (60.5%) were female with a mean age of the patients was 22.44 ± 3.49 (18-35) yrs.

3.1. Results of DED tests

The OSDI mean score was 12.56 ± 12.86, with 62.1% scoring between 0-12 and 37.9% scoring ≥13. SPEED mean score was 4.06 ± 3.70, with 50.8% scoring 1-4 and 26.6% scoring 5-9. Schirmer's test mean was 20.71 ± 8.57, and TBUT mean was 14.60 ± 5.75. Majority of them had grade 0 in oxford score, i.e., 59.3%, followed by grade 1, 23%.

The relation between the OSDI and SPEED questionnaires and the variables, such as age, gender, and various clinical tests, was analysed (**Table 1**). For age, there was a negligible correlation with both OSDI ($r = -0.017$, $p = 0.796$) and SPEED ($r = 0.052$, $p = 0.40$). Gender also showed minimal correlation with OSDI ($R = -0.074$, $P = 0.244$) and SPEED ($R = 0.012$, $P = 0.80$). However, correlations between OSDI/SPEED questionnaires and clinical tests showed moderate associations. Tear Breakup Time (TBUT) exhibited a moderate negative correlation with OSDI ($R = -0.283$, $P < 0.0001$) and SPEED ($R = -0.320$, $P < 0.0001$). Similarly, Schirmer's test showed a moderate negative correlation with OSDI ($R = -0.225$, $P < 0.0001$) and SPEED ($R = -0.233$, $P < 0.0001$). Moreover, the Oxford score demonstrated a moderate positive correlation with OSDI ($R = 0.286$, $P< 0.0001$) and SPEED ($R = 0.359$, $P < 0.0001$).

The association between OSDI grading and dry eye tests in assessing dry eye severity was examined (**Table 2**). For Schirmer's Basic test results, there was a substantial correlation between tear production and OSDI scores. Higher OSDI scores were more prevalent in individuals with lower Schirmer's scores ($P< 0.001$), indicating a statistical correlation between reduced tear production and subjective symptoms of dry eye. Similarly, a substantial correlation ($P < 0.0001$) was seen between OSDI scores and Tear Breakup Time 4 (TBUT) values. Higher OSDI scores were typically seen in those with lower TBUT values, which could be a sign of rapid tear film break down and possibly more severe dry eye symptoms.

The Oxford Score, which measures ocular surface staining, reveals a significant correlation between subjective dry eye symptoms measured by OSDI scores and greater ocular surface damage ($P < 0.0001$), indicating a higher prevalence of OSDI in individuals with higher Oxford scores.

The correlation between OSDI scores and SPEED scores was determined (**Table 3**). Higher SPEED scores were corresponded with higher OSDI scores. A statistically significant positive correlation (R=0.35; $P < 0.0001$) was seen between OSDI and SPEED scores in measuring the subjective dry eye symptoms.

This suggests that individuals reporting more severe symptoms on the OSDI questionnaire also tended to report higher severity on the SPEED questionnaire, further supporting the reliability and validity of both measures in assessing dry eye symptoms. Participants were categorized based on OSDI questionnaire scores into four groups, and mean SPEED scores were measured for each group. The study explored the correlation between the severity of dry eye, as assessed by OSDI scores, and the corresponding SPEED scores (**Table 4**). An analysis of these scores revealed a significant difference in SPEED scores across the various OSDI severity categories ($p < 0.0001$), as determined by one-way ANOVA. These findings indicate a positive association between OSDI scores representing greater dry eye severity and higher SPEED scores, reflecting more severe symptoms reported by participants. The association between SPEED scores and objective tests in assessing dry eye severity was investigated (**Table 5**). Individuals with higher SPEED scores, indicative of intensified dry eye symptoms, tended to have lower Schirmer scores, suggesting reduced tear production. Lower TBUT values, indicating faster tear film breakup, and higher Oxford Scores, indicating severe ocular surface damage and staining. These observations imply that increased SPEED scores, reflective of more pronounced dry eye symptoms, align with outcomes from commonly employed objective tests in dry eye evaluation. The receiver operating characteristic (ROC) curve for the SPEED questionnaire was generated using diagnostic sensitivity and specificity measures of true positive results with analyzed pathology and true negative results in normal subjects without any pathology. In this study, the clinical significance of a test was assessed through its AUC value. The obtained AUC of 0.75 indicated significant diagnostic value (P=0.001). (**Figure 1**)

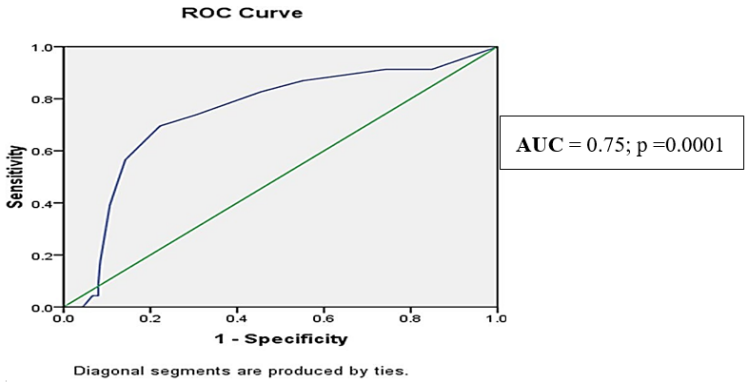

Figure 1: Receiver operating characteristics (roc) curve analysis of speed

Table 1: Correlation between the OSDI, SPEED questionnaire, and age, gender and various clinical tests

Variables	OSDI		SPEED	
	Correlation	P-value	Correlation	p-value
Age	-0.017	0.796	0.052	0.40
Gender	-0.074	0.244	0.012	0.80
TBUT	-0.283	0.0001	-0.320	0.0001
Schirmer	-0.225	0.0001	-0.233	0.0001
Oxford score	0.286	0.0001	0.359	0.0001

Table 2: Association of OSDI grading and dry eye tests in dry eye severity

Schirmer's Basic	OSDI Score				Total	Chi sq	Correlation	p-value
	0-12	13-22	23-32	>=33				
>10	140	43	14	13	210	42	0.15	0.001
5 to 10	12	5	5	9	31			
<5	2	1	4	0	7			
Total	154	49	23	22	248			
TBUT								
≥10	134	39	11	10	194	33.39	0.27	0.0001
<10	20	10	12	12	54			
Total	154	49	23	22	248			
OXFORD Score								
Grade 0	106	24	9	8	147			
Grade 1	34	15	7	1	57			
Grade 2	5	6	5	7	23			
Grade 3	7	2	2	1	12	60.36	0.21	0.0001
Grade 4	2	2	0	5	9			
Total	154	49	23	22	248			

Table 3: Correlation of OSDI score with SPEED score

SPEED Scores	OSDI Scores					Chi sq	Correlation*	p value
	0-12	13-22	23-32	>=33	Total			
0	28	5	2	1	36	104.5	0.35	0.0001
1 to 4	99	22	4	1	126			
5 to 9	26	16	15	9	66			
>=10	1	6	2	11	20			
Total	154	49	23	22	248			

***** Kendal's correlation

Table 4: OSDI descriptive statistics of SPEED scores

	No of subjects	SPEED score (Mean ± SD)	One way ANOVA	p value
No dry eye (0-12)	154	2.64 ± 2.15	**48.58**	**0.0001**
Mild dry eye (13-22)	49	4.82 ± 3.62		
Moderate dry eye (23-32)	23	6.26 ± 3		
Severe dry eye (33 – 100)	22	10.14 ± 5.26		
Total	248			

Table 5: Association of SPEED score and objective tests in dry eye severity

Schirmer basic test	SPEED score				Total	Chi sq	Correlation	p- value
	0	1 to 4	5 to 9	>=10				
>10	34	115	50	11	210	26.32	0.16	0.0001
5 to 10	2	9	12	8	31			
<5	0	2	4	1	7			
Total	36	126	66	20	248			
TBUT								
≥10	33	111	42	8	194	36.43	0.31	0.0001
<10	3	15	24	12	54			
Total	36	126	66	20	248			
OXFORD SCORE								
Grade 0	28	83	32	4	147			
Grade 1	8	29	19	1	57	64.21	0.25	0.0001 (SS)
Grade 2	0	6	9	8	23			
Grade 3	0	5	4	3	12			
Grade 4	0	3	2	4	9			
Total	36	126	66	20	248			

4. Discussion

The diagnosis and classification of dry eye disease (DED) present significant challenges due to its multifactorial nature and the variability of symptoms, signs, and clinical test results. Various studies have attempted to correlate patient-reported questionnaires with objective clinical tests to better understand and evaluate DED. Bartlett et al. found a low to moderate correlation between symptoms and signs, indicating potential implications for DED management.[4]

Patient-reported outcome (PRO) questionnaires play a crucial role in diagnosing and grading DED symptoms. The Ocular surface disease index (OSDI) and the Standard patient evaluation of eye dryness (SPEED) questionnaire are two widely used tools, each with its advantages. OSDI is a clinically validated and widely used PRO with many advantages.[9] SPEED questionnaire is a short and valid questionnaire that inquiries about the most common dry eye symptoms such as burning, dryness and tearing.[10] However, limited research exists on their association with clinical tests, particularly among young adults.

This cross-sectional study aimed to compare the SPEED and OSDI questionnaires in assessing DED symptoms and to correlate questionnaire scores with objective clinical test results, including Schirmer's test, Tear film Break-up Time (TBUT), and Ocular Surface Staining. Conducted among a large sample of young adults aged 35 or below, the study revealed a weak correlation between symptoms and clinical test results for DED.

Interestingly, there was no noticeable correlation between questionnaire scores and age or gender. However, significant associations were noted with objective clinical tests; positive correlation with ocular surface staining, and a negative correlation with Schirmer’s test and TBUT values.

The mean SPEED scores were calculated according to OSDI categorization, and the reliability of OSDI and SPEED questionnaires were measured. A moderate correlation was observed between the total scores of both questionnaires for DED diagnosis. This study was comparable and showed consistent results with several studies.[5,9,11-13]

In our study, the mean SPEED score was 4.06 ± 3.70, comparable to findings from Kofi Asiedu et al. Despite

differences in sample size, the similarity in mean SPEED scores between our study and previous research indicates a consistent distribution of DED severity across different populations. Notably, a significant proportion of participants exhibited mild forms of DED based on SPEED scores ranging from 1 to 4.[5]

Furthermore, we found that the mean SPEED score increased with the severity of DED as per OSDI categorization. This relatively positive correlation between the total scores of both questionnaires suggests that the SPEED questionnaire can effectively measure disease severity, similar to the OSDI. These findings are in line with previous studies by Kofi Asiedu et al. and Nauman Hashmani et al., supporting the concurrent reliability of the SPEED questionnaire for assessing DED severity.[5,9]

The Schirmer basic test, a parameter of aqueous tear deficiency is the most commonly used test to evaluate dry eye in clinical practice.[14] The results obtained in the present study revealed a weak negative association between Schirmer test results and the OSDI and SPEED scores. The test results, suggests that as OSDI/SPEED scores improve, Schirmer test results tend to increase, aligning with previous research.[13] In assessing the dry eye severity grading, OSDI grading shows a significant positive association with Schirmer test value in both no dry eye and symptomatic dry eye. However, the SPEED score of more than 1 to 4 shows a Schirmer basic test of >10mm, emphasizing the need for further investigation into SPEED's cutoff score. In their respective studies, Nauman Hashmani et al.[9] and Kofi et al.[5] noted that the optimal cut-off score for the SPEED questionnaire, determined by maximizing sensitivity and specificity, was 4. This determination was made using Cohen's kappa coefficient and demonstrated a higher agreement percentage with the Ocular Surface Disease Index (OSDI) for diagnosing dry eye.

Tear film instability, characterized by tear film break-up, is assessed using tear film break-up time.[15] In the present study, TBUT values exhibited a significant negative correlation with OSDI and SPEED scores, indicating that lower TBUT values were associated with more severe DED symptoms. TBUT value was associated with OSDI and SPEED score with significant correlation in assessing the dry eye severity. No dry group as per OSDI grading had TBUT ≥10. However, most of the symptomatic patients with the mild score in SPEED questionnaires found TBUT value ≥10. Short TBUT values were associated with severe dry eye symptoms with a significant moderate correlation with SPEED score rather than with OSDI.

Ocular surface staining by Oxford grading is appropriate for dry eye severity.[16] In the present study, there was a significant positive correlation between Oxford grading and questionnaire scores of both OSDI and SPEED and in assessing the dry eye severity. No dry group as per OSDI grading had a grade 0 Oxford score. However, most symptomatic individuals with a mild score in SPEED questionnaires were found to have Oxford score of grade of 0. Higher grade values were associated with severe dry eye symptoms with a significant moderate correlation with SPEED score rather than with OSDI.

The SPEED questionnaire demonstrates a strong correlation with parameters indicative of evaporative dry eye. Conversely, the Ocular Surface Disease Index (OSDI) correlates with parameters associated with aqueous tear deficiency in dry eye. However, it's important to note that distinguishing between evaporative and aqueous tear deficient dry eye solely based on questionnaire results is not feasible. The area under the curve (AUC) of 0.75 for ROC analysis of SPEED scores indicates its effectiveness in distinguishing between symptomatic and asymptomatic participants.

The study identified an inconsistent relationship between the symptoms and objective tests for dry eye within the younger population. This discrepancy can be attributed to natural variations in disease processes, the subjective nature of symptoms, and differences in pain thresholds and cognitive responses to questions concerning ocular sensations.

The study's *limitations* include the lack of valuation of the internal consistency of individual questions and the absence of evaluation of the psychometric properties and vision-related quality of daily living as patient-reported outcome measures.

5. Conclusion

Our study highlights the effectiveness of OSDI and SPEED questionnaires in evaluating dry eye disease severity, supporting their reliability in clinical and research settings. However, integrating subjective symptoms with clinical findings is crucial for comprehensive assessment. Understanding questionnaire differences is important for selecting the optimal tool for evaluation of DED. Further research needs to take into consideration towards additional factors influencing DED severity and validate questionnaire utility across diverse populations. The future of dry eye treatment lies in personalized medicine, tailoring approaches to individual symptoms. Despite questionnaire limitations in determining patient-reported outcomes, their careful assessment is essential for effective incorporation. Ultimately, precise subjective symptom evaluation will increasingly shape medical care.

6. Source of Funding

None.

7. Conflict of Interest

None.

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