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Ocular Surface Profile of Post-Menopausal Females: A Cross-Sectional Study in A Tertiary Care Centre

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ABSTRACT

Purpose: This study aimed to evaluate the ocular surface profile and prevalence of Dry Eye Disease (DED) in post-menopausal women and to establish correlations between disease severity, duration of menopause, and systemic co-morbidities.

Methods: A cross-sectional study of 228 post-menopausal females was conducted at tertiary care hospital in North India over 18 months. Diagnostic evaluations included the Ocular Surface Disease Index (OSDI), Schirmer's Test 1, Tear Film Break-Up Time (TBUT), and Conjunctival Impression Cytology (CIC).

Results: DED prevalence was high, with 57.89% of subjects testing positive on two objective tests. A very strong positive correlation was found between years since menopause and symptom severity (OSDI: $\rho = 0.827$, $p < 0.001$). Systemic co-morbidities such as Diabetes Mellitus (DM) and Hypertension (HTN) were significantly associated with poorer ocular surface metrics ($p < 0.05$).

Conclusion: Post-menopausal women suffer a high burden of DED that worsens progressively with the duration of menopause, requiring a multimodal diagnostic approach.

KEYWORDS: Post-menopausal women; Dry Eye Disease (DED); Ocular Surface Profile; Ocular Surface Disease Index (OSDI); Schirmer's Test; Tear Film Break-Up Time (TBUT); Conjunctival Impression Cytology (CIC); Duration of Menopause; Diabetes Mellitus; Hypertension; Ocular Surface Disorders; Cross-Sectional Study.

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INTRODUCTION

The ocular surface is a vital functional unit comprising the cornea, conjunctiva, eyelids, and lacrimal glands.[1,2] The tear film, a dynamic lipid-aqueous-mucin structure, provides a smooth refractive surface, maintains epithelial health, and acts as the first line of defense against infection.[1,3,4] DED is a multifactorial disorder characterized by a loss of tear film homeostasis, often leading to visual disturbance and ocular discomfort.[1,5]

The conceptualization of DED has shifted from Wolff's mid-20th-century trilaminar model to the 2017 TFOS DEWS II definition, which emphasizes hyperosmolarity, inflammation, and neurosensory abnormalities.[1,5] Recent research has highlighted Meibomian Gland Dysfunction (MGD) as the leading cause of evaporative DED, while emerging concepts like neurosensory adaptation explain why some patients remain asymptomatic despite objective ocular surface damage.[6,7]

The ocular surface tissues contain receptors for androgens, estrogens, and progesterone. Androgens are particularly crucial as they stimulate lipid synthesis and exert anti-inflammatory effects. Menopause marks a permanent drop in estrogen and a gradual decline in androgens, leading to:

- Lacrimal Gland Dysfunction: Reduced aqueous production and increased proinflammatory cytokines.
- MGD: Impaired lipid secretion leading to increased evaporation.
- Mucin Deficiency: Altered goblet cell function affecting tear film stability.

Post-menopausal women are disproportionately affected due to androgen deficiency, as androgens regulate the morphology and secretory functions of the lacrimal and meibomian glands.[8,9] This population often experiences the "iceberg phenomenon," where non-specific symptoms like grittiness and burning lead to a large percentage of undiagnosed cases.

This study aimed to quantifydisease burden and identify the best screening tools for Dry Eye Disease.

MATERIALS AND METHODS

• Cross-sectional studyconducted from April 2024 to March 2025 at Integral Hospital and IIMSR, Lucknow.
• Sample Size:228 subjects, calculated using a 32% predicted prevalence and 95% confidence level.
• Duration: 18 months, with data collection spanning April 2024 to March 2025.

2.1 Inclusion and Exclusion Criteria

Inclusion was limited to post-menopausal females (no menses for ≥12 months) who provided consent. Exclusion criteria included active ocular infections, history of trauma, use of medications containing benzalkonium chloride, or prior surgeries that altered the ocular surface profile.

2.2 Methodology

Detailed history including Ocular symptoms, Topical ocular medication history, Menopausal history (age of onset, duration), Systemic history (co-morbidities – Diabetes Mellitus, Hypertension)

Ophthalmological Evaluation including -
A) Visual Acuity on Snellen's Chart
B) Slit Lamp Examination -
Ocular and Peri-Ocular structures including
- Lids
- Conjunctiva
- Cornea
- Anterior Chamber
C) Tests for dry eye
Objective Tests
- Schimer's Test 1
- Tear Film Break Up Time
- Conjunctival Impression Cytology
Subjective Test
- Ocular Surface Disease Index

2.3 Diagnostic Protocols

1**. OSDI:** A questionnaire containing 12 questions which assess symptoms and functional impact
Interpretation:
0–12 - Normal
13-22 - Mild dry eye
23-32 - Moderate dry eye
>32 - Severe dry eye

2. Schirmer's Test 1: Aqueous production measured with Whatman-41 filter paper for 5 minutes
Interpretation:
>15mm – Normal
10-15 mm - Mild dry eye
5-10 mm - Moderate dry eye
<5mm – Severe dry eye

3. TBUT: Tear stability measured using fluorescein dye and cobalt blue light
Interpretation:
15–35s – Normal
10-15 sec - Mild dry eye
<10 seconds – Moderate - Severe dry eye).

4. CIC: Assessment of goblet cell density and squamous metaplasia using Millipore filter paper and Nelson's classification for squamous metaplasia.

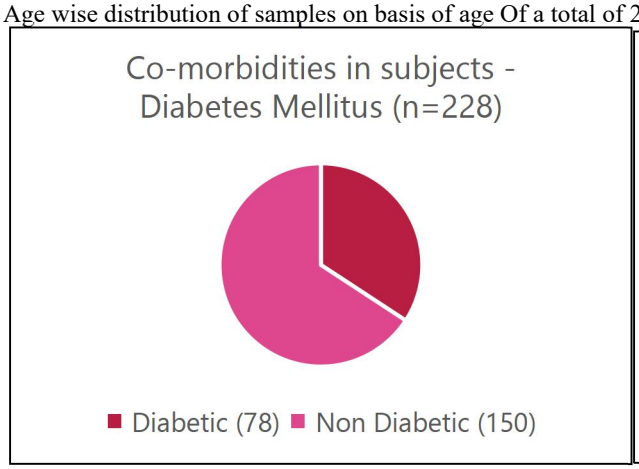
RESULTS

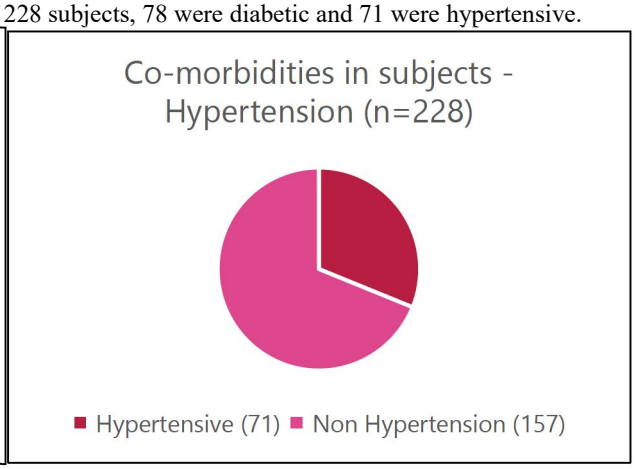
3.1 Demographic Data

In the total subject population of 228,68.45 yearswas the mean age of the subjects, and mean age of menopause onset was48.91 years. The distribution was equitable across age brackets, with the largest representation in the 70–79 (25.44%) and 80–89 (22.81%) year groups.

Age Group	No. of subjects (n=228)	Percentage
40-49 years	18	7.89
50-59 years	51	22.37
60-69 years	46	20.18
70-79 years	58	25.44
80-89 years	52	22.81
90+ years	3	1.32

Age wise distribution of samples on basis of age Of a total of 228 subjects, 78 were diabetic and 71 were hypertensive.





3.2 Prevalence of Dry Eye

• Subjective - OSDI:73.7% symptomatic (31.6% mild, 24.1% moderate, 18.0% severe).

OSDI	Frequency (n=228)	Percentage
Normal	60	26.3
Mild	72	31.6
Moderate	55	24.1
Severe	41	18.0
Total	228	100.0

• Objective - Schirmer's:72.4% abnormal (19.7% severe).

Schirmer's Test 1	Frequency (n=228)	Percentage
Normal	63	27.6
Subnormal	58	25.4
Moderate	62	27.2
Severe	45	19.7
Total	228	100.0

• Objective – TBUT:65.8% abnormal (33.3% moderate-severe).

TBUT	Frequency (n=228)	Percentage
Normal	78	34.2
Mild	74	32.5
Moderate - Severe	76	33.3
Total	228	100.0

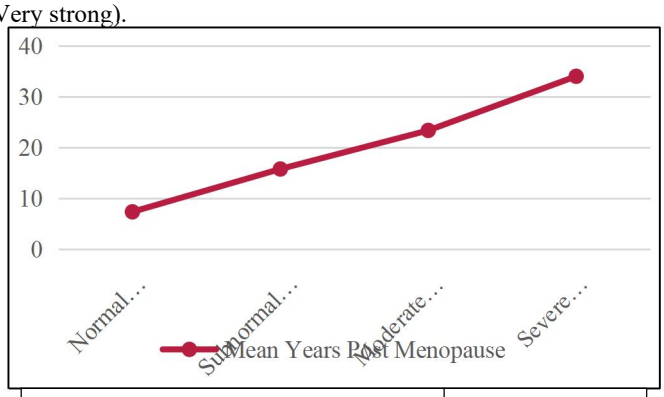
• Combined Prevalence:57.89% of subjects were positive for DED based on two abnormal objective tests.

	Frequency (n=228)	Percentage
Normal Levels	96	42.11
Sub-normal Levels	132	57.89
Total	228	100.0

3.3 Correlation with Menopausal Duration

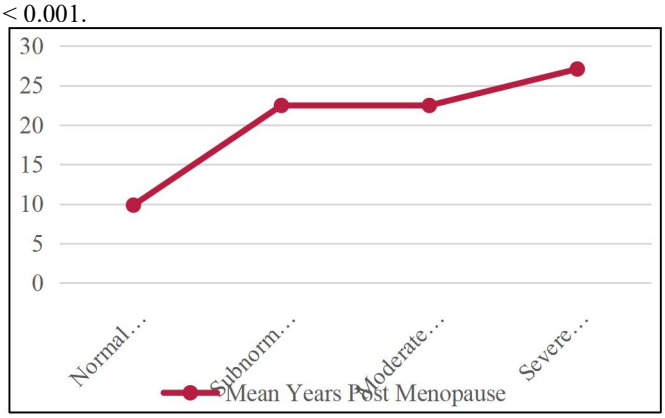
The Years post Menopause and disease severity correlated positively (statistically significant) across all metrics:

• OSDI: ρ = 0.827, p < 0.001 (Very strong).



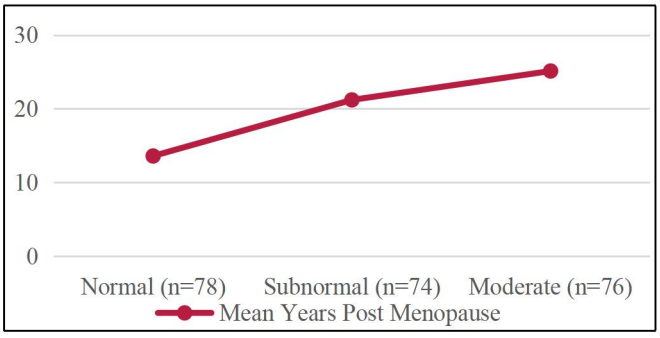
Spearman's rho		Years since menopause
OSDI	rrelation Coefficient	.827
	Sig. (2-tailed)	<0.001
	N	228

• Schirmer's Test: ρ = 0.490, p < 0.001.



Spearman's rho		Years since menopause
Schirmer	rrelation Coefficient	.490
	Sig. (2-tailed)	<0.001
	N	228

• TBUT:Moderately strong positive correlation of ρ = 0.401 (p < 0.001). Age groups of 70-79 and 80-89 had the highest incidence of sub-normal results (31.32% in each decade).



Spearman's rho		Years since menopause
TBUT	Correlation Coefficient	.401
	Sig. (2-tailed)	<0.001
	N	228

3.4 Systemic Co-morbidities

• Diabetes (n=78): Correlated significantly with reduced tear production (Schirmer: ρ = 0.180, p = 0.006) and instability (TBUT: ρ = 0.131, p = 0.048).

• Hypertension (n=71): Significantly correlated with increased symptom burden (OSDI: ρ = 0.217, p = 0.001).

3.5 Correlation between tests

The results demonstrated a moderately positive (ρ = 0.496) correlationbetween OSDI and Schirmer's test values (p < 0.001) and a weak-to-moderately positive (ρ = 0.368) correlation between OSDI and TBUT (p < 0.001).

A strong positive correlation was also observed between Schirmer's test 1 results and results of TBUT(ρ = 0.653, p < 0.001), indicating that subjects with better tear production (higher Schirmer values) generally had more stable tear films (longer TBUT).

Spearman's rho		OSDI	Schirmer	TBUT
OSDI	Coefficient of Correlation		.496**	.368**
	Significance		<.001	<.001
	N		228	228
Schirmer	Coefficient of Correlation	.496**		.653**
	Significance	<.001		<.001
	N	228		228
TBUT	Coefficient of Correlation	.368**	.653**	
	Significance	<.001	<.001	
	N	228	228	
**. Significant Correlation at 0.01 level (Tests were 2-tailed)				

DISCUSSION

The tertiary care centre based study confirmed that DED is highly prevalent in post-menopausal women in North India. When defined using two abnormal objective tests (Schirmer's Test 1 and TBUT), 57.9% of women were diagnosed with dry eye disease.

These findings echo those of earlier studies that have reported increased prevalence of DED in this demographic. They underscore the substantial burden of ocular surface disease in post-menopausal females

Similar results showing high prevalence of dry eye disease have been found in multiple studies with prevalence in post-menopausal women varying from ~55.3% in rural areas of North India to 39.5% in metropolitan cities like Hyderabad, Telangana.[11,12,13] Large scale (~1947 subjects) international studies have found similarly high incidence of the disease (~66.8%).[11,14]

The strong correlation between menopause duration and symptoms indicates that chronic hormonal deprivation leads to cumulative damage, including lacrimal gland atrophy and neural sensitization.These findings are consistent with previous epidemiological studies that have reported an noticeable increase inthe prevalence of Dry Eye Disease, specifically in the post-menopausal age group, with studies reporting prevalence of the disease ranging from 40% to over 70%, depending on the study diagnostic criteria and population. Large population-based studies such as the Women's Health Study and the Beaver Dam Eye Study have demonstrated a higher prevalence of dry eye symptoms in older women, highlighting the role of hormonal influences in disease pathogenesis. [14,15]Indian hospital- and community-based studies have also reported a high prevalence of DED in post-menopausal women, supporting the relevance of the present findings in the local population.[11,12,13]

Hormonal deficiency following menopause, particularly reduced androgen levels, leads to lacrimal gland hyposecretion, meibomian gland dysfunction, increased tear evaporation, and ocular surface inflammation. [8,9]

The relationship between dry eye disease severity and most common co-morbidities (Diabetes and hypertension) was also studied.
Reduced tear secretion in diabetic subjects was indicated by a statistically significantpositive correlation of Schirmer's Test 1 with diabetes mellitus which was ($\rho = 0.180$, $p = 0.006$),. This may be attributed to autonomic neuropathy and microvascular changes affecting the lacrimal gland in diabetes.[16,17] TBUT results demonstrated a mildly positive but statistically significant correlation with diabetes mellitus ($\rho = 0.131$, $p = 0.048$), suggesting increased tear film instability in diabetic individuals. OSDI scores showed a mildly positive correlation with hypertension (statistically significant) ($\rho = 0.217$, $p = 0.001$), indicating higher symptom burden in hypertensive subjects. Chronic vascular changes, long-term medication use, and systemic inflammation associated with hypertension may contribute to ocular surface dysfunction.[18]

Overall, these findings suggest that systemic co-morbidities, particularly diabetes mellitus and hypertension, play a contributory role in the severity of dry eye disease in post-menopausal women and should be actively considered during clinical evaluation.
The variability in prevalence across different diagnostic tests observed in the present study further emphasizes the multifactorial nature of DED and supports recommendations for combining subjective and objective evaluation methods as well as evaluation of other associated risk factors.

The relationship between subjective symptoms of dry eye disease (DED), commonly assessed using the Ocular Surface Disease Index (OSDI), and objective clinical tests such as Schirmer's test and tear break-up time (TBUT) has been widely investigated, with studies reporting variable but generally weak to moderate correlations.[19,20] Several authors have observed that OSDI scores often do not correlate strongly with objective tear film parameters, highlighting the multifactorial nature of DED. In a landmark study, Nichols et al. reported poor correlation between subject-reported symptoms and clinical signs, including Schirmer's and TBUT values, emphasizing that symptoms and signs represent distinct dimensions of the disease.

Similar findings were documented by Sullivan et al., who demonstrated significant discordance between OSDI scores and objective tear function tests, particularly in mild to moderate DED. Indian studies have also echoed these observations; Gupta et al. observed that although higher OSDI scores were generally associated with lower Schirmer's and TBUT values, the correlation coefficients were modest, indicating that subjective symptom severity may not reliably predict objective tear film deficiency.

Conversely, some studies have reported a negative correlation between score of OSDI scores and grading of TBUT, suggesting that tear film instability may be more closely associated with symptom perception than aqueous tear deficiency alone. This discrepancy may be attributed to factors such as neurosensory dysfunction, psychological influences, environmental exposure, and adaptive behaviour, which can alter symptom perception independently of clinical signs.

This study included conjunctival impression cytology as one of the objective parameters for dry eye severity assessment and to monitor cellular level ocular surface changes. The results of the test were not conclusive. Collectively, existing evidence indicates that OSDI, Schirmer's test, and TBUT assess complementary but non-overlapping aspects of dry eye disease, underscoring the advantage of using a combined subjective and objective assessment approach for accurate diagnosis and severity grading in both clinical practice and research settings.

Conjunctival Impression Cytology (CIC) results were largely inconclusive; most positive cases revealed Grade 3 squamous metaplasia (goblet cells $<100/mm^2$), which did not always align with functional tests, suggesting that cellular changes might represent a different stage of disease.

CONCLUSION

DED in post-menopausal women is a progressive condition driven by androgen deficiency and exacerbated by aging, diabetes, and hypertension.[8,16,18]
Recommendations for Clinical Practice:
1. Multimodal Screening: Use OSDI, TBUT, and Schirmer together to enhance diagnostic accuracy.[15]
2. Individualized Management: Employ lipid-enhanced artificial tears, warm compresses for MGD, and anti-inflammatory therapies like cyclosporine.
3. Collaborative Care: Ophthalmologists should coordinate with menopause specialists to optimize systemic and ocular health.
4. Early Intervention: Routine checks are essential for post-menopausal women to prevent complications like corneal scarring or functional blindness.[15]

Future research should focus on:
- Standardized hormone profiling in DED cohorts,
- Mechanistic studies examining hormone-receptor signalling in ocular tissues,
- Longitudinal analyses of tear film changes through the menopausal transition,
- Controlled trials of hormone-modulating therapies targeted to ocular tissues.
- Large, longitudinal studies combining OSDI, tear film metrics, CIC, and possibly newer markers (e.g., tear osmolarity, inflammatory cytokines, meibomian gland assessment)
- Which metrics best predict symptom burden, progression, and response to therapy.

As the global population of postmenopausal women grows, optimizing care for menopause-associated DED is an increasingly important public health priority.Clinicians should maintain heightened awareness of commonly presenting symptoms of ocular surface disease in women of post-menopausal age group, even in the absence of traditional risk factors.

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