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Original Research Article

Incidence and Severity of Dry Eye Disease in Patients with Scleroderma: A Cross-Sectional Study

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Abstract: ***Background***: Systemic sclerosis is a chronic autoimmune connective tissue disorder characterized by fibrosis and microvascular dysfunction. However, existing literature data is scarce in Indian context. ***Aim***: The present study was aimed to evaluate the incidence and severity of Dry Eye Disease (DED) in scleroderma patients. ***Methods***: A prospective cross-sectional study including 60 scleroderma patients and 60 controls. OSDI scoring, TBUT, Schirmer's Test I, and fluorescein staining were performed. Statistical analysis used Student's t-test and Chi-square test. ***Results***: The study results showed that DED incidence was 68.3% in cases versus 18.3% in controls ($p<0.001$). TBUT and Schirmer's values were significantly reduced. Moderate-to-severe DED predominated. ***Conclusion***: The present study concludes that dry eye is highly prevalent and often moderate to severe in systemic sclerosis.

Keywords: Scleroderma, Systemic sclerosis, Dry eye disease, Schirmer's test, TBUT, Ocular surface.

INTRODUCTION

Systemic sclerosis (SSc), commonly known as scleroderma, is a rare, chronic autoimmune connective tissue disorder characterized by immune dysregulation, progressive fibrosis, and widespread microvascular dysfunction affecting the skin and multiple internal organs.[1,2] The global prevalence of systemic sclerosis varies between 50 and 300 cases per million, with a higher predominance in females and peak onset occurring between the third and fifth decades of life.[2] The hallmark pathological features include endothelial injury, excessive fibroblast activation, and abnormal deposition of extracellular matrix components, resulting in progressive tissue fibrosis and vascular compromise. These pathological processes contribute to multisystem involvement, affecting the skin, lungs, gastrointestinal tract, kidneys, heart, and exocrine glands, leading to significant morbidity and reduced quality of life.[3]

Systemic sclerosis is clinically classified into several subtypes based on the extent of skin involvement and systemic manifestations. The two major subsets include limited cutaneous systemic sclerosis (lcSSc), which primarily affects the distal extremities and face, and diffuse cutaneous systemic sclerosis (dcSSc), which involves widespread skin thickening and carries a higher risk of internal organ involvement.[4] In addition, less common forms include sine scleroderma, in which systemic manifestations occur

in the absence of overt skin changes, and overlap syndromes associated with other connective tissue diseases such as polymyositis or systemic lupus erythematosus.[4] More recently, the concept of "very early systemic sclerosis" has been introduced, characterized by Raynaud's phenomenon, disease-specific autoantibodies, puffy fingers, and characteristic microvascular abnormalities detected on nailfold capillaroscopy. This early stage often progresses to definite systemic sclerosis within a few years, highlighting the importance of early recognition and monitoring.[5]

Given that the eye contains abundant connective tissue, vascular structures, and secretory glands, it is particularly vulnerable to the pathological changes associated with systemic sclerosis. Ocular involvement in systemic sclerosis may affect various structures, including the eyelids, conjunctiva, cornea, lacrimal glands, and retina. Microvascular dysfunction, fibrosis, and immune-mediated inflammation contribute to structural and functional alterations of ocular tissues.[6] Among the various ophthalmic manifestations, dry eye disease (DED) is one of the most frequently reported and clinically significant complications.[7]

Dry eye disease is a multifactorial disorder characterized by tear film instability, increased tear osmolarity, ocular surface inflammation, and neurosensory abnormalities, resulting in symptoms such as irritation, burning, foreign body sensation, and visual disturbance. In systemic sclerosis, dry eye may develop due to both aqueous tear deficiency and evaporative mechanisms. Lacrimal gland fibrosis, lymphocytic infiltration, and microvascular damage impair tear production, while fibrosis of periocular tissues and meibomian gland dysfunction contribute to increased tear evaporation and tear film instability.[8] Additionally, eyelid skin tightening and reduced blink efficiency further exacerbate tear film abnormalities and ocular surface desiccation.[9]

Furthermore, the coexistence of secondary Sjögren's syndrome in systemic sclerosis patients may exacerbate lacrimal gland dysfunction and increase the severity of dry eye symptoms.[10] Histopathological studies have demonstrated conjunctival fibrosis, vascular abnormalities, and inflammatory cell infiltration in systemic sclerosis, supporting the role of immune-mediated and fibrotic mechanisms in ocular surface disease.[5] Meibomian gland abnormalities and eyelid structural changes have also been documented, contributing to evaporative dry eye and tear film instability.[11]

Despite the high prevalence of dry eye disease in systemic sclerosis, ocular manifestations are often underdiagnosed or overlooked, particularly in early disease stages. Chronic ocular surface inflammation and tear film instability may lead to complications such as corneal epithelial defects, ulceration, infection, and visual impairment if not identified and managed promptly. Moreover, ocular surface involvement may reflect systemic disease severity and progression, underscoring the importance of regular ophthalmic evaluation in these patients.[12]

There is limited data regarding the incidence and severity of dry eye disease in systemic sclerosis patients in the Indian population, particularly in rural and tertiary care settings. Regional variations in environmental factors, disease characteristics, and healthcare access may influence the prevalence and severity of ocular manifestations. Therefore, the present study was undertaken to evaluate the incidence and severity of dry eye disease in patients with systemic sclerosis using both subjective and objective ocular surface assessments. This study aims to provide region-specific clinical data, enhance understanding of ocular involvement in systemic sclerosis, and emphasize the importance of early detection and multidisciplinary management to improve patient outcomes and quality of life.[11]

This study aims to investigate the incidence and severity of dry eye in patients with systemic sclerosis, focusing on both subjective and objective ocular surface assessments. By evaluating these parameters in a rural tertiary care setting, this study also seeks to contribute region-specific data, which is currently limited in the Indian context. The findings are expected to enhance clinical awareness and potentially guide multidisciplinary care strategies for patients with systemic autoimmune diseases.[12]

The present study is among the first to provide specific data from a rural tertiary care center in central India, addressing a geographic gap in the literature on ocular manifestations of systemic sclerosis. By correlating dry eye severity with the duration or subtype of scleroderma, the study may identify predictive patterns or risk markers, which have not been well explored in the Indian population. The study was aimed to assess the incidence and severity of dry eye disease in patients with scleroderma.

MATERIALS AND METHODS

The present study was a hospital based observational cross-sectional study and was conducted at the Department of Ophthalmology, Acharya Vinobha Bhave Rural Hospital, Sawangi. The study was done for a duration of 6 months (February 2025 to July 2025) and assessed all the patients with coming to Ophthalmology OPD at AVBRH will be selected the for study after taking the inclusion and exclusion criteria into consideration.

The inclusion criteria for the study were patients diagnosed with scleroderma (systemic sclerosis) based on clinical and rheumatological evaluation, age >18 years, and willing to give informed consent. The exclusion criteria for the study were patients with other ocular surface diseases (e.g., Stevens-Johnson syndrome), history of ocular trauma or surgery in the past 6 months, history of allergic or infective ocular pathology, and use of contact lenses or topical eye medications affecting tear film. The study utilized simple random sampling technique.

For data collection, demographic and clinical profile was assessed including age, sex, duration of scleroderma, type of scleroderma (limited/diffuse), systemic comorbidities, and history of dry eye symptoms. For subjective assessment, Ocular surface disease index (OSDI) questionnaire was used which is a validated tool to evaluate the frequency and severity of dry eye symptoms and their effect on vision-related functioning. Objective clinical tests utilized Schirmer's test (without anesthesia): to assess aqueous tear production, Tear film break-up time (TBUT): to evaluate tear film stability, and Fluorescein staining: to assess corneal and conjunctival epithelial damage. Eye severity was graded as dry eye disease was classified and graded as per the dry eye workshop ii (dews ii) criteria.

For data recording and management, all findings were recorded in a pre-designed data collection form. Data were anonymized and stored securely; any abnormal or incidental findings was referred for further evaluation or treatment. Data gathered were analyzed using SPSS software. Mean, standard deviation, chi-square test, and correlation coefficients will be used where appropriate. A p-value <0.05 will be considered statistically significant.

RESULTS

- It was seen that the incidence of Dry Eye Disease was significantly higher in scleroderma patients (68.3%) compared to controls (18.3%) (p<0.001).
- It was seen that TBUT was significantly reduced in scleroderma patients compared to controls (p<0.001).
- The Schirmer I was significantly reduced in scleroderma patients compared to controls. (p<0.001).
- Using the student's t-test, a statistically significant difference was seen in mean OSDI scores in controls and cases of scleroderma with p<0.001.
- Also, Moderate-to-severe DED was significantly associated with disease duration >5 years (p=0.02).
- The incidence of Dry Eye Disease was significantly higher in scleroderma patients (68.3%) compared to controls (18.3%) (p<0.001) (Table 1-6).

S. No	Variable	Scleroderma (%)	Controls (%)	p-value
	DED incidence	68.3	18.3	<0.001

Table 1: Incidence of dry eye disease

S. No	Variable	Scleroderma (mean)	Controls (mean)	p-value
	Mean TBUT (sec)	6.8 ± 2.4	12.4 ± 2.1	<0.001

Table 2: Tear Film Parameters in two groups of study subjects

S. No	Variable	Scleroderma (mean)	Controls (mean)	p-value
	Schirmer's test	8.2 ± 3.6	16.5 ± 4.2	<0.001

Table 3: Schirmer's I (mm)in two groups of study subjects

S. No	Variable	Scleroderma (mean)	Controls (mean)	p-value
	OSDI scores	32.6 ± 11.4	14.8 ± 6.2	<0.001

Table 4: OSDI scores in two groups of study subjects

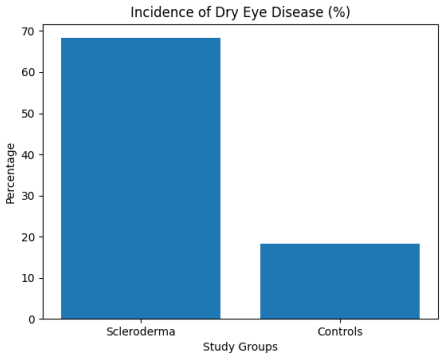
S. No	Variable	Mild	Moderate	Severe
	Severity Grading of DED (TFOS DEWS II) n	12	18	11
	Percentage (%)	29.3	43.9	26.8

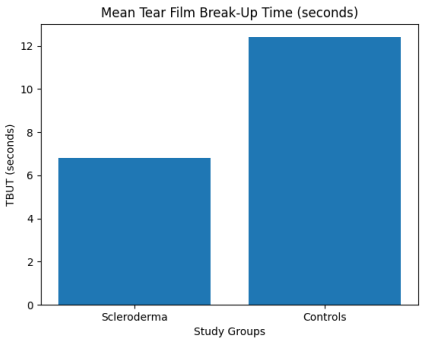
Table 5: Severity Grading of DED (TFOS DEWS II) in two groups of study subjects

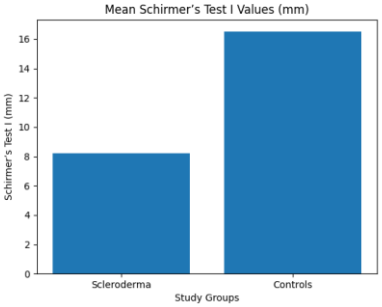
S. No	Variable	Scleroderma (mean)	Controls (mean)	p-value
	DED Incidence (%)	68.3%	18.3%	<0.001
	Mean TBUT (sec)	6.8 ± 2.4	12.4 ± 2.1	<0.001

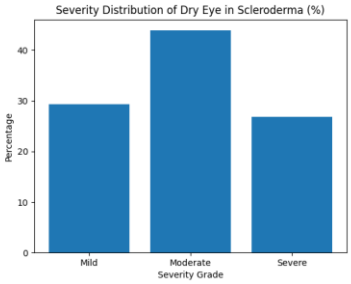
	Mean Schirmer's (mm)	8.2 ± 3.6	16.5 ± 4.2	<0.001

Table 6: DED incidence, mean TBUT, and mean Schirmer comparison in two groups of study subjects









DISCUSSION

The present study demonstrated a significantly higher incidence of dry eye disease (DED) in patients with systemic sclerosis (SSc) compared to healthy controls, with approximately two-thirds of patients affected. Tear film parameters, including Schirmer's test and tear film break-up time (TBUT), were significantly reduced, while Ocular Surface Disease Index (OSDI) scores were markedly elevated, indicating both objective and subjective impairment of the ocular surface. Furthermore, a substantial proportion of patients exhibited moderate-to-severe DED, and disease duration greater than five years was significantly associated with increased severity. These findings confirm that DED represents a common and clinically significant ocular manifestation of systemic sclerosis and may worsen with disease progression.

The prevalence of dry eye disease in systemic sclerosis patients has been reported to range from approximately 37% to 79%, reflecting variability in study populations, diagnostic criteria, and disease characteristics. Gomes et al. demonstrated significantly reduced tear production and increased ocular surface staining in systemic sclerosis patients compared to healthy controls, highlighting the impact of glandular fibrosis and inflammation on tear film function. Similarly, Rentka et al. reported significant correlations between objective tear film abnormalities and subjective symptoms, emphasizing the clinical burden of dry eye in this population. Microvascular damage, a central feature of systemic sclerosis, has also been implicated in ocular surface dysfunction by impairing perfusion of the lacrimal gland and conjunctival tissues, further contributing to tear film abnormalities.

Dry eye disease in systemic sclerosis is multifactorial, resulting from structural, vascular, and immunologic alterations affecting both aqueous and evaporative tear components.

Fibrosis is the hallmark pathological feature of systemic sclerosis and affects exocrine glands, including the lacrimal gland. Histopathological studies have demonstrated fibrotic replacement of lacrimal gland parenchyma, leading to reduced tear secretion and aqueous-deficient dry eye.[2] Chronic inflammation and fibroblast activation result in excessive extracellular matrix deposition, impairing glandular function and reducing basal and reflex tear production. Additionally, lymphocytic infiltration similar to that observed in Sjögren's syndrome has been reported, suggesting overlapping autoimmune mechanisms.[3]

Meibomian gland dysfunction (MGD) is another major contributor to DED in systemic sclerosis. Fibrosis of periocular tissues and eyelids can alter meibomian gland architecture, reduce lipid secretion, and destabilize the tear film lipid layer.[4] This results in increased tear evaporation and reduced TBUT, as observed in the present study. Eyelid skin thickening,

rigidity, and reduced blink efficiency further impair lipid distribution across the ocular surface, exacerbating tear film instability.

Microvascular dysfunction is a defining feature of systemic sclerosis and affects the ocular surface and adnexal structures. Endothelial injury, capillary dropout, and impaired perfusion lead to ischemia of the lacrimal and meibomian glands, contributing to glandular dysfunction [5]. These vascular abnormalities also impair corneal epithelial healing and maintenance, increasing susceptibility to ocular surface damage. Systemic sclerosis is characterized by immune dysregulation, including autoantibody production, cytokine release, and chronic inflammation. Elevated levels of pro-inflammatory mediators such as transforming growth factor-beta (TGF-β) promote fibrosis and tissue remodeling, further impairing tear production and ocular surface homeostasis [1]. In addition, secondary Sjögren's syndrome, reported in a subset of systemic sclerosis patients, can exacerbate lacrimal gland dysfunction and increase dry eye severity.[6]

The prevalence of DED observed in the present study (68.3%) is consistent with previously reported rates ranging from 37% to 79% in systemic sclerosis patients.[7] Gomes et al. reported dry eye prevalence of approximately 67% in systemic sclerosis, which closely aligns with the findings of the present study [2]. Similarly, Waszczykowska et al. reported ocular surface involvement in nearly 65% of systemic sclerosis patients, emphasizing the high burden of ocular morbidity in this population.

In terms of tear secretion, the reduced Schirmer's test values observed in this study are comparable to those reported by Rentka et al., who demonstrated significantly lower tear production in systemic sclerosis patients compared to controls.[8] Reduced Schirmer's values reflect lacrimal gland fibrosis and autoimmune-mediated glandular dysfunction. However, some studies have reported less pronounced reductions, which may reflect variations in disease duration, severity, and inclusion criteria.

Corneal staining and ocular surface damage have also been reported more frequently in systemic sclerosis patients, as described by Gomes et al. and Tailor et al.[2,8] These findings reflect chronic tear film instability and epithelial damage resulting from prolonged ocular surface desiccation.

Tear film instability, reflected by reduced TBUT in the present study, is consistent with findings reported by Sahin Atik et al., who demonstrated significantly decreased TBUT and increased meibomian gland abnormalities in systemic sclerosis patients. Similarly, Laovirojjanakul et al. identified tear film instability as a major predictor of dry eye severity in systemic sclerosis.[9-11]

Subjective symptom severity, as assessed by OSDI scores, was significantly higher in systemic sclerosis patients in the present study. Rentka et al. also reported significantly elevated symptom scores, highlighting the correlation between objective tear film abnormalities and patient-reported symptome. However, some studies have noted discrepancies between symptoms and clinical findings, possibly due to altered corneal sensitivity or neuropathic mechanisms.[13-15]

Variations in prevalence and severity across studies may be attributed to differences in sample size, ethnicity, disease duration, and methodology. Geographic and environmental factors, including climate and humidity, may also influence tear film stability. Furthermore, variations in diagnostic criteria and grading systems may contribute to discrepancies in reported prevalence rates.

CONCLUSION

The high prevalence and severity of dry eye disease observed in systemic sclerosis underscore the importance of routine ophthalmic evaluation in affected patients. Early detection and management are essential to prevent complications such as persistent epithelial defects, corneal ulceration, and secondary infections.

Dry eye disease significantly impacts visual function and quality of life. Symptoms such as irritation, blurred vision, and photophobia can impair daily activities, including reading and driving. Chronic ocular surface inflammation may also increase the risk of long-term ocular surface damage.

Given the progressive nature of systemic sclerosis, regular ophthalmic screening should be integrated into multidisciplinary care. Objective assessments such as Schirmer's test, TBUT, and ocular surface staining, combined with symptom evaluation using validated questionnaires, can facilitate early diagnosis and timely intervention.

REFERENCES

1. Glover, K.; Mishra, D.; Singh, T.R.R. Epidemiology of Ocular Manifestations in Autoimmune Disease. Front. Immunol. 2021, 12, 744396.
2. de AF Gomes, B.; Santhiago, M.R.; de Azevedo, M.N.; Moraes, H.V., Jr. Evaluation of dry eye signs and symptoms in patients with systemic sclerosis. Graefes Arch. Clin. Exp. Ophthalmol. 2012, 250, 1051–1056.
3. Denton, C.P.; Khanna, D. Systemic sclerosis. Lancet 2017, 390, 1685–1699.

4. Nikpour, M.; Stevens, W.M.; Herrick, A.L.; Proudman, S.M. Epidemiology of systemic sclerosis. Best Pract. Res. Clin. Rheumatol. 2010, 24, 857–869.
5. Sahin Atik, S.; Koc, F.; Akin Sari, S.; Sefi Yurdakul, N.; Ozmen, M.; Akar, S. Anterior segment parameters and eyelids in systemic sclerosis. Int. Ophthalmol. 2016, 36, 577–583.
6. Wollheim, F.A. Classification of systemic sclerosis. Visions and reality. Rheumatology 2005, 44, 1212–1216.
7. Gomes Bde, A.; Santhiago, M.R.; Magalha□es, P.; Kara-Junior, N.; Azevedo, M.N.; Moraes, H.V., Jr. Ocular findings in patients with systemic sclerosis. Clinics 2011, 66, 379–385.
8. Tailor, R.; Gupta, A.; Herrick, A.; Kwartz, J. Ocular manifestations of scleroderma. Surv. Ophthalmol. 2009, 54, 292–304.
9. Szucs, G.; Szekanecz, Z.; Aszalos, Z.; Gesztelyi, R.; Zsuga, J.; Szodoray, P.; Kemeny-Beke, A. A Wide Spectrum of Ocular Manifestations Signify Patients with Systemic Sclerosis. Ocul. Immunol. Inflamm. 2021, 29, 81–89.
10. Sheppard, J.; Shen Lee, B.; Periman, L.M. Dry eye disease: Identification and therapeutic strategies for primary care clinicians and clinical specialists. Ann. Med. 2023, 55, 241–252.
11. Hynnekleiv, L.; Magno, M.; Vernhardsdottir, R.R.; Moschowits, E.; Tønseth, K.A.; Dartt, D.A.; Vehof, J.; Utheim, T.P. Hyaluronic acid in the treatment of dry eye disease. Acta Ophthalmol. 2022, 100, 844–860.
12. Laovirojjanakul, W.; Yospaiboon, Y.; Anutarapongpan, O.; Mahakkanukrauh, A.; Suwannaroj, S.; Nanagara, R.; Foocharoen, C. Predictors for Dry Eye Diseases in Patients with Systemic Sclerosis. Clin. Ophthalmol. 2022, 16, 3447–3455.
13. Kudasiewicz-Kardaszewska, A.; Grant-Kels, J.M.; Grzybowski, A. Meibomian gland dysfunction and blepharitis: A common and still unsolved ophthalmic problem. Clin. Dermatol. 2023, 41, 491–502.
14. Wangkaew, S.; Kasitanon, N.; Sivasomboon, C.; Wichainun, R.; Sukitawut, W.; Louthrenoo, W. Sicca symptoms in Thai patients with rheumatoid arthritis, systemic lupus erythematosus and scleroderma: A comparison with age-matched controls and correlation with disease variables. Asian Pac. J. Allergy Immunol. 2006, 24, 213–221.
15. Rentka, A.; Nagy, A.; Harsfalvi, J.; Szucs, G.; Szekanecz, Z.; Gesztelyi, R.; Szodoray, P.; Kemeny-Beke, A. Association between objective signs and subjective symptoms of dry eye disease in patients with systemic sclerosis. Rheumatol. Int. 2017, 37, 1835–1845.

