Research Article

Effect of Oral Lactoferrin on Ocular Health Among Dry Eye Disease Patients: A Retrospective Analysis

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Background: Dry eye disease (DED) is a complex condition marked by tear film instability, inflammation of the ocular surface, and symptoms of ocular discomfort. Lactoferrin, an iron-binding glycoprotein secreted by the lacrimal gland, possesses antimicrobial and anti-inflammatory properties that help to maintain ocular surface homeostasis.

Aim: To assess the effect of oral lactoferrin supplement on ocular health among dry eye disease patients from a tertiary health care hospital in Central India.

Methods: This observational study was conducted using medical records from the Ophthalmology Department at a tertiary-care hospital in the Ujjain district. Records of 20 patients diagnosed with DED and treated with oral lactoferrin were reviewed retrospectively over 5 months, from October 2024 to February 2025. Clinical parameters, including schirmer test, tear film break-up time (TBUT), fluorescein staining, corneal sensation, and ocular surface disease index (OSDI) scores, were assessed at baseline and at follow-up visits after 15 and 30 days.

Results: The findings demonstrated improvements in tear secretion and tear film stability, along with a reduction in subjective symptoms after lactoferrin supplementation. A marked improvement was also observed in OSDI scores, reflecting enhanced ocular comfort and improved quality of life for patients.

Conclusion: Oral lactoferrin supplementation may serve as a beneficial adjunct in the management of DED. However, long-term studies with longer follow-up are needed to confirm its therapeutic efficacy.

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Keywords: Dry eye disease, Lactoferrin, Tear film break-up time, Schirmer test, Ocular surface disease index, Ocular surface, Follow-up.

Introduction

The ocular surface is the external and most essential component of vision. The ocular surface, which serves as the direct interface between the eye and the external environment, is constantly exposed to potentially harmful agents, including microbes and toxic substances. This exposes the eyes to potentially damaging immune-mediated reactions, which may compromise the structural integrity of the ocular surface and result in varying degrees of visual impairment. Dry eye disease (DED) is a multifactorial ocular surface disease characterized by impaired tear production and ocular discomfort resulting from tear film homeostasis disruption, tear hyperosmolarity, ocular surface inflammation, and neurosensory abnormalities.[1-3] The pathogenesis of the disease is associated with age-related changes and chronic inflammation of the lacrimal gland, resulting in dysfunction and loss of secretory acini cells.[1] According to the Tear Film and Ocular Surface Society DEWS II report[1], DED results in symptoms such as a burning sensation, foreign body sensation, itching, watering, and visual disturbances that markedly affect patients' quality of life.

Traditionally, dry eye disease has been considered more prevalent in the elderly; however, recent studies have reported increasing prevalence among younger individuals as well. This shift in age group may result from lifestyle-related factors, which include prolonged exposure to digital screens, environmental pollution, and increased visual demands.[4] Similar findings have been reported in studies evaluating the prevalence of dry eye among working-age populations.[5] Conventionally, the

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management of dry eye disease has primarily focused on symptomatic relief with ocular lubricants and topical anti-inflammatory drugs. However, recent advances in understanding the multifactorial pathophysiology of dry eye disease have led to the development of novel therapeutic approaches. Among these, agents such as lactoferrin gained attention because of their anti-inflammatory, immunomodulatory, and antioxidant properties, targeting the underlying disease mechanisms rather than merely alleviating symptoms.[6]

Lactoferrin is a major tear protein and an 80-kDa iron-binding glycoprotein present abundantly in various exocrine secretions, mainly in colostrum and tear fluid. Lactoferrin accounts for about 25% of the proteins in tear fluid. Lactoferrin is primarily secreted by the lacrimal gland and also produced by epithelial cells and meibomian acini, contributing to its final concentration of approximately 1.42 mg/mL in tears.[7] Lactoferrin's antimicrobial, anti-inflammatory, and antioxidant effects are essential for maintaining ocular surface homeostasis. Its antimicrobial action is mediated through iron sequestration, which limits microbial growth, while its anti-inflammatory properties help suppress pro-inflammatory cytokines on the ocular surface. In addition, its antioxidant activity protects epithelial cells from oxidative stress–induced damage. Through these combined actions, lactoferrin contributes to the stabilization of the tear film and protection of the ocular surface.[8]

Studies have shown that both forms of lactoferrin (i.e., oral and topical) help in improving tear stability, enhancing tear production, and reducing corneal inflammation, thus providing symptomatic relief, particularly in patients with Sjögren's syndrome, a chronic, systemic autoimmune disease where moisture-producing glands are attacked, causing severe dry eyes and dry mouth, and those following cataract surgery.[9] However, studies on the use of loctoferrin for DED are scarce in Indian settings, where the environment is dry, hot, and rough.

Aim

To evaluate the effect of oral lactoferrin supplementation on ocular health in patients with dry eye disease in a hospital in Central India.

Materials and Methods

Study Design

This was a retrospective, observational study.

Study Setting

The study was conducted among outpatients in the Ophthalmology Department of R. D. Gardi Medical College in the Ujjain district of Central India.

Study Population

All patients diagnosed with DED who received a 100 mg oral lactoferrin supplement twice daily for one month, from October 2024 to February 2025, were enrolled in the study.

Inclusion Criteria

- DED patients who are aged 18 years or older
- Patients who received oral lactoferrin therapy for DED
- Patients having complete clinical and follow-up records

Exclusion Criteria

- Patients who underwent ocular surgery within the past six months
- Patients having systemic diseases significantly affecting tear production
- Patients who did not give consent

Clinical Evaluation

A comprehensive ophthalmic examination was performed for all patients at baseline and during follow-up visits. The assessment included best corrected visual acuity (BCVA) measurement and a detailed slit lamp examination to evaluate the anterior segment and ocular surface. Tear production was assessed using the Schirmer test, while tear film stability was evaluated using tear film break-up time (TBUT).[10] Fluorescein staining of the ocular surface was performed to detect corneal epithelial defects and assess the severity of ocular surface damage. Corneal sensation was also evaluated to identify any neurosensory abnormalities associated with DED. In addition, the symptom severity and its impact on day-to-day activities were studied using the ocular surface disease index (OSDI) questionnaire.[11]

Treatment follow-up

Patients' follow-up records were also assessed to evaluate the therapeutic response. Follow-up assessments were conducted at 15 days and 1 month after initiation of the therapy. During follow-up, the clinical parameters and symptom scores were re-evaluated and compared with baseline findings.

Data Collection and Analysis

Clinical data, including demographic information, baseline ocular findings, and follow-up parameters,

Table 1: Demographic characteristics of study participants

Variable	*Category*	*Number of patients N=20*	Percentage (%)
Age (years)	21–30	6	30
	31–40	4	20
	41–50	8	40
	>51	2	10
Gender	Male	8	40
	Female	12	60
Literacy status	Illiterate	2	10
	Literate	18	90

were extracted by trained research assistants from patient records using a proforma. The extracted data was anonymised and randomly numbered. SPSS software was used for statistical analysis. Baseline and post-treatment values were compared using a paired student's t-test. A *p-value*< 0.05 was considered statistically significant.

Results

A total of 20 DED patients were treated with lactoferrin 100 mg supplementation and included in the analysis. All patients received oral lactoferrin (brand name Actoferrin; Bennet Pharmaceuticals Ltd.) at a dose of 100 mg twice daily for one month as part of their treatment regimen. Most patients were younger and middle-aged, with the highest proportion in patients aged 41 to 50 years (40%), followed by 21 to 30 years (30%). Females constituted 60% of the study population (Table 1). The majority of participants were literate (90%).

Burning sensation was the most common symptom (100%), followed by foreign body sensation (90%). After one month of oral lactoferrin therapy, symptoms showed a marked reduction, with burning decreasing from 20 to 10 patients, foreign body sensation from 18 to 6, itching from 13 to 8, and watering from 12 to 9 (Table 2). Diminution of vision (3 patients) persisted due to refractive error, while headache resolved completely within 15 days. Overall, the improvement was statistically significant ($p < 0.05$), indicating symptomatic benefit with lactoferrin supplementation.

The changes in the objective dry eye parameters, including Schirmer Test I, TBUT, and OSDI scores, before and after treatment (Table 3). In the Schirmer test, which measures tear secretion, most patients initially demonstrated moderate-to-severe dry eye. Before treatment, only a small number of patients had normal tear production (>10 mm). After a month of oral lactoferrin therapy, a significant number of patients shifted to the normal category, indicating improvement in lacrimal gland function and tear production.

Similarly, TBUT values showed improvement following treatment. Before medication, only a limited number of patients had TBUT values greater than 10 seconds, indicating stable tear film. After one month of therapy, most patients demonstrated TBUT values greater than 10 seconds in at least one eye, indicating improved tear film stability (Table 3). The OSDI scores also showed a marked shift from severe and moderate categories toward mild or normal categories following treatment. Overall, the improvements observed in Schirmer test values, TBUT measurements, and OSDI scores were statistically significant (p <0.01), suggesting that oral lactoferrin supplementation may have a beneficial effect on both objective and subjective parameters of DED.

Discussion

DED is a common multifactorial disorder of the ocular surface that results from a vicious cycle involving tear film instability and ocular surface inflammation. In the present study, the patient population showed a predominance of females, a younger age group (under 50 years), and a high literacy rate, suggesting more issues among females and better healthcare awareness and access among educated individuals. This study

Table 2: Change in presenting symptoms before and after treatment

Symptom	*Pre-treatment (n)*	*After 15 days (n)*	*After 1 month (n)*	*p-value**
Diminution of vision	3	3	3	NS
Itching	13	10	8	<0.05
Burning sensation	20	17	10	<0.01
Foreign body sensation	18	10	6	<0.01
Watering	12	10	9	<0.05
Headache	3	0	0	<0.05

*Chi-square test comparing the pre-treatment *vs* one-month values.

Table 3: Changes in objective dry eye parameters after lactoferrin therapy

Parameter	*Category*	*Pre-treatment*	*15 days*	*1 month*	*p-value**
Schirmer Test I (mm)	>10	RE 4 / LE 6	RE 8 /LE 10	RE 12/ LE 13	<0.01
	5–10	RE 11 / LE 10	RE 9 / LE 6	RE 7 / LE 5	
	<5	RE 5 / LE 5	RE 3 / LE 4	RE 1 / LE 2	
TBUT (sec)	>10	RE 6 / LE 7	RE 10 / LE 9	RE 13/ LE 10	<0.01
	5–10	RE 1 / LE 8	RE 7 / LE 8	RE 6 / LE 7	
	<5	RE 4 / LE 5	RE 3 / LE 3	RE 1 / LE 3	
OSDI score	0–12 (Normal)	RE 0 / LE 0	RE 0 / LE 0	RE 1 / LE 0	<0.01
	13–22 (Mild)	RE 2 / LE 3	RE 5 /LE 5	RE 8 / LE 9	
	23–32 (Moderate)	RE 7 / LE 8	RE 8 /LE 9	RE 6 / LE 7	
	33–100 (Severe)	RE 11/ LE9	RE 7 / LE 6	RE 5 / LE 4	

*Chi-square test comparing the pre-treatment *vs* one-month values.
Abbreviations RE: Right Eye; LE: Left Eye; TBUT: Tear Film Break-Up Time; OSDI: Ocular Surface Disease Index.

also indicates a shift in DED in the younger population. The burning and foreign-body sensations decreased significantly after one month of therapy. These results indicate the effectiveness of lactoferrin in alleviating ocular surface inflammation and thus boosting tear film stability. Additionally, objective diagnostic tests demonstrated promising results for treating DED with lactoferrin.

DED was previously considered to be more prevalent in the elderly; however, recent studies report an increasing prevalence among younger individuals[4], as supported by our results, with 90% of participants aged below 50 years. This shift may be linked to global lifestyle changes, such as prolonged exposure to digital screens, environmental pollution, and increased visual demands, particularly among working-age populations.

A female predominance (60%) was observed in the present study. Several epidemiological studies have demonstrated a higher DED prevalence among women as compared to men. Hormonal influences, particularly imbalances in oestrogen and androgen levels, are believed to contribute to lacrimal gland dysfunction and tear film instability in females. Studies by Matossian C and colleagues have highlighted hormonal factors as important contributors to ocular surface dysfunction and dry eye symptoms in women.[12]

Regarding literacy status, the majority of patients in this study were literate. This may reflect better awareness of ocular health and increased likelihood of seeking medical consultation among educated individuals. Access to healthcare facilities and awareness of ocular discomfort may influence early diagnosis and treatment of DED. The most common presenting symptom observed in this study was a burning sensation, followed by foreign body sensation, itching, and watering. These findings are consistent with previous reports indicating that burning and foreign body sensation are among the most frequently reported symptoms in patients with dry eye.[1]

Following oral lactoferrin supplementation, a noticeable reduction in these symptoms was observed during the follow-up period. After one month of therapy, the number of patients experiencing a burning sensation decreased from 20 to 10, and the number experiencing a foreign body sensation decreased from 18 to 6. Such improvement suggests a beneficial effect of lactoferrin on ocular surface inflammation and tear film stability. Objective diagnostic tests also demonstrated encouraging results. The Schirmer test I, which measures tear secretion, showed improvement following treatment. Initially, a large proportion of patients had moderate-to-severe dry eye, with Schirmer values less than 10 mm. After one month of therapy, most patients demonstrated improved tear secretion with values shifting toward the normal category. These findings clearly suggest that lactoferrin supplementation improved lacrimal gland function or enhanced tear production.

The TBUT values were also improved during follow-up. Before treatment, only a small proportion of patients had TBUT values greater than 10 seconds, indicating stable tear film. Following treatment, a considerable number of patients demonstrated TBUT values more than 10 seconds in at least one eye. An improvement in TBUT indicates better tear film stability and reduced evaporation, both of which are important

factors in the management of dry eye disease. The OSDI scores also showed a significant improvement after therapy. Before treatment, most patients had moderate-to-severe OSDI scores. After one month of treatment, many patients shifted toward mild or normal categories. Improvement in OSDI scores reflects reduced symptom severity and improved vision-related quality of life. The biological properties of lactoferrin may explain the beneficial effects observed in the present study.

Studies from high-income countries have demonstrated the association between decreased tear lactoferrin levels and dry eye disease. Davide Rusciano *et al*.[8] observed that age-related reduction in tear lactoferrin levels contributes to the pathogenesis of DED. The authors suggested that supplementation with lactoferrin may help restore tear film composition and has a protective phenomenon for the ocular surface towards oxidative stress and inflammatory damage. Similarly, C. J. McCollum *et al*. investigated tear lactoferrin levels in patients with keratoconjunctivitis sicca and found significantly reduced concentrations than in healthy individuals.[13] Their study highlighted the potential diagnostic and therapeutic role of lactoferrin in ocular surface disorders. Age-related changes in tear protein composition were also described by J. I. McGill *et al*., who demonstrated that tear lactoferrin levels decline with advancing age.[14] The antimicrobial, antioxidant, and anti-inflammatory effects of lactoferrin help stabilizing the tear film, thus in turn protecting the ocular surface. It may also preserve lacrimal gland function by reducing inflammation and oxidative stress, thereby enhancing tear production.

Strengths and Limitations

Some of the major limitations of the study are a small sample size, the absence of a control group, and a short follow-up period. All of these restrict the generalizability and causal inference of the results. However, being first of its kind, the findings provide important, preliminary, clinically relevant, evidence-based insights supporting oral lactoferrin as a potential adjunct in DED. It also highlights the need for future studies with a larger patient population. Larger, prospective randomized controlled trials are needed to strengthen the results obtained, which will thus help in establishing the standardized protocols.

Conclusion

Oral lactoferrin supplementation improved both subjective symptoms and objective parameters in DED. Symptoms such as burning, foreign body sensation, itching, and watering decreased, while Schirmer Test I, TBUT, and OSDI scores indicated better tear secretion, tear film stability, and ocular comfort. These findings suggest that lactoferrin may be a useful adjunct in DED management. However, larger, long-term controlled studies are needed to confirm its efficacy.

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Conflict of Interest

The authors declare no financial or commercial interest in the brand used, and the choice of formulation was solely based on availability at the time of the study.

Ethics Approval

Ethical approval was obtained for this study from the Institutional Ethics Committee (IEC Ref. No. 06/2026) of R.D. Gardi Medical College, Ujjain, M.P., India.

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