




Reconsidering the Role of Age in Tear Film Instability: Real-World Evidence From a Specialized Dry Eye Clinic

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Purpose: To examine the association between age and fluorescein tear film break-up time (FBUT) in a large cohort of patients presenting to a specialized dry eye clinic.

Methods: This is a retrospective observational analysis of prospectively collected data on 1044 patients referred to or self-presenting at a tertiary/specialized dry eye clinic in Norway. All participants underwent standardized ocular surface examination at initial presentation, including FBUT measurement. Associations between age and FBUT were assessed using Spearman correlation and linear and non-linear regression models, with analyses performed for each eye and stratified by sex.

Results: Age was significantly but weakly correlated with FBUT in both eyes (Spearman's r -0.16 to -0.27, $p < 0.001$). Age explained less than 4% of the variance in FBUT, and neither linear nor non-linear models identified a strong age-dependent decline in tear film stability.

Conclusion: In this symptomatic clinical population, age was only weakly associated with FBUT, indicating that tear film instability at presentation likely reflects disease-related and contextual factors rather than chronological aging alone. Importantly, the findings presented herein apply to a symptomatic clinical population.

Keywords: dry eye disease, DED, tear film break-up time, FBUT, aging, tear film stability, ocular surface

Introduction

Dry eye disease (DED) affects millions of individuals worldwide and is a major cause of ocular discomfort, visual disturbance, and reduced quality of life.¹ Patients with DED commonly report symptoms such as burning, stinging, tearing, photophobia, foreign body sensation, ocular pain, and fluctuating or blurred vision.² Clinically, DED is characterized by disruption of tear film and ocular surface homeostasis, which may manifest as tear film instability, hyperosmolarity, ocular surface staining, reduced tear volume, and eyelid or meibomian gland abnormalities.² A well-recognized feature of DED is the poor correlation between symptoms and clinical signs, reflecting the heterogeneous and complex nature of the disease.² Importantly, tear film stability is influenced by a wide range of factors beyond chronological age, including meibomian gland dysfunction, environmental exposures (eg, humidity, airflow, and digital device use), systemic diseases, medication use, and individual behavioral patterns. These interacting factors contribute to the multifactorial nature of DED and may confound the relationship between age and tear film parameters.

Among the clinical tests used to assess tear film stability, fluorescein tear film break-up time (FBUT) remains one of the most widely applied measures in both research and routine clinical practice.² The Tear Film & Ocular Surface Society (TFOS) Dry Eye Workshop (DEWS) III report recommends non-invasive tear film break-up time (NIBUT) as the preferred method for assessing tear film stability, as it avoids disruption of the tear film and may provide more physiologically representative measurements.² However, fluorescein-based FBUT remains an integral part of the TFOS DEWS III diagnostic framework and is widely used in clinical settings where non-invasive instrumentation is not available. A FBUT value of <5 seconds is considered indicative of tear film instability. In the present study, FBUT was used as the outcome measure as it reflects routine clinical practice in a tertiary dry eye setting and enables evaluation of tear film stability in a real-world patient population.

Historically, advancing age has been regarded as an important risk factor for DED and has often been assumed to be associated with a progressive decline in tear film stability.³ This is based on documented age-related changes in lacrimal gland function, meibomian gland morphology, eyelid anatomy, and ocular surface integrity, all of which may plausibly influence tear film dynamics.³ Despite the widespread clinical belief that tear film stability deteriorates uniformly with aging, the relationship between chronological age and FBUT remains uncertain.⁴⁻⁷ Prior studies have reported inconsistent findings, ranging from negative correlations to weak, absent, or context-dependent associations, depending on population characteristics, study design, and analytical approach.^{3,5,7,8} Consequently, reliance on chronological age alone as an indicator of tear film instability may be clinically misleading and overlook important underlying disease mechanisms.

In this context, an important knowledge gap remains regarding the extent to which chronological age influences tear film stability in symptomatic populations. Previous studies have reported inconsistent findings, likely reflecting differences in sample size, population characteristics (eg, healthy versus symptomatic individuals), and analytical approaches. Many investigations have been conducted in relatively small or selected cohorts, potentially limiting generalizability. The present study addresses these limitations by examining the association between age and FBUT in a large, real-world cohort of patients referred to, or self-presenting at, a specialized dry eye clinic in Norway. Specifically, we aimed to test the hypothesis that advancing age is associated with reduced tear film stability, as reflected by shorter FBUT values. By analyzing both linear and non-linear relationships across a broad age range, this study seeks to determine whether age represents a clinically meaningful contributor to tear film instability in a symptomatic population.

Methods

Patients

The present analysis is based on clinical data from the Norwegian Dry Eye Cohort 2023 (NDEC2023). NDEC2023 is a specialized, prospective observational cohort established at the Norwegian Dry Eye Clinic to investigate the pathophysiology of DED through biochemical analyses of Schirmer strips, clinical features, and treatment responses in patients diagnosed with various subtypes of DED. The cohort comprises 1044 patients referred to or presenting to the clinic due to dry eye related symptoms. The cohort enrolled patients between 2021 and 2023, with plans for long-term follow-up to enable the study of disease progression and therapeutic outcomes. It is predominantly composed of individuals of Northern European ancestry and is representative of patients receiving tertiary care for dry eye in a Scandinavian setting. While data from NDEC2023 may be used in future or parallel studies addressing different research questions, the present analysis constitutes a distinct and original evaluation of the association between age and fluorescein tear film break-up time (FBUT) at initial presentation.

Procedure

All clinical examinations were performed according to a predefined testing sequence and as part of routine clinical care using a standardized diagnostic protocol. The data presented herein is from the initial visit to the clinic. The Schirmer test without topical anesthesia was performed first, as tear fluid collected during this step was also used for biochemical analyses. Subsequently, FBUT was assessed using slit-lamp biomicroscopy with yellow filter and blue light, following instillation of one drop of fluorescein sodium 2% solution into the inferior conjunctival fornix. FBUT

was defined as the interval between a complete blink and the appearance of the first dry area in the precorneal tear film. FBUT was measured three times in each eye, and the mean of the three measurements was used for statistical analyses. All examinations were conducted between 8 AM and 8 PM and were performed by the same two experienced dry eye specialists. Although environmental factors such as humidity and temperature were not formally controlled, the standardized clinical workflow and consistent examination setting were maintained throughout the study period.

Ethics

The study was approved by the Regional Ethics Committee of South-East Norway (reference ID 6892) and adhered to the principles of the Declaration of Helsinki. All patients provided informed consent prior to inclusion. The study received no external funding, and no commercial sponsors were involved in the design of the study, data analysis, interpretation of the results, or preparation of the manuscript.

Statistical Analyses

Data extraction and analysis for the present study were conducted independently by the authors. Associations between age and FBUT were initially assessed using Spearman's rank correlation coefficient, which was chosen due to the non-normal distribution of FBUT values and the potential for non-linear relationships between age and tear film instability. To further explore the nature of the relationship between age and FBUT, both linear and non-linear regression models were applied. Linear regression was used to assess a potential monotonic association, while polynomial (non-linear) regression models were employed to detect more complex age-related patterns that may not be adequately captured by linear analyses alone. Specifically, second- and third-degree polynomial models were explored to assess potential curvilinear relationships between age and FBUT. The coefficient of determination (R^2) was used to quantify the proportion of variance in FBUT explained by age in the regression models. Model selection was based on visual inspection of fitted curves and comparison of goodness-of-fit using R^2 values. In addition, age-cohort-based analyses were performed to evaluate differences in FBUT distributions across predefined age groups. Because FBUT values were non-normally distributed, the Kruskal–Wallis test was used to assess overall differences between age cohorts. When the Kruskal–Wallis test indicated a statistically significant difference, post-hoc pairwise comparisons were conducted using Dunn's test with Bonferroni correction to account for multiple testing. All statistical analyses were performed using SPSS Statistics Version 22.0 (IBM Corp., Armonk, NY, USA). A two-sided p-value of <0.05 was considered statistically significant, except for post-hoc analyses where Bonferroni-adjusted significance thresholds were applied. As this study represents a retrospective analysis of an existing clinical cohort, no formal a priori power calculation was performed.

Results

Demographics

1044 DED patients with a mean age of 53 years, range 16–91 years, were evaluated. 741 (71%) were females, and the remaining 303 (29%) were males (Figure 1).

Age Cohort Difference

Mean FBUT values for the right eye (Oculus Dexter; OD) and left eye (Oculus Sinister; OS), stratified by sex and four age cohorts (16–29, 30–44, 45–64, and ≥ 65 years) were calculated (Table 1). For each age cohort, FBUT is reported as mean \pm standard deviation (SD) for pooled participants, as well as separately for males and females. Kruskal–Wallis testing revealed significant differences in pooled FBUT distributions across age cohorts for both the right eye ($\chi^2(3) = 35.82$, $p < 0.001$) and the left eye ($\chi^2(3) = 49.61$, $p < 0.001$). Post-hoc Dunn's tests with Bonferroni correction demonstrated that the two younger age cohorts differed significantly from the two older cohorts, whereas no significant differences were observed within the younger or within the older age groups for either eye.

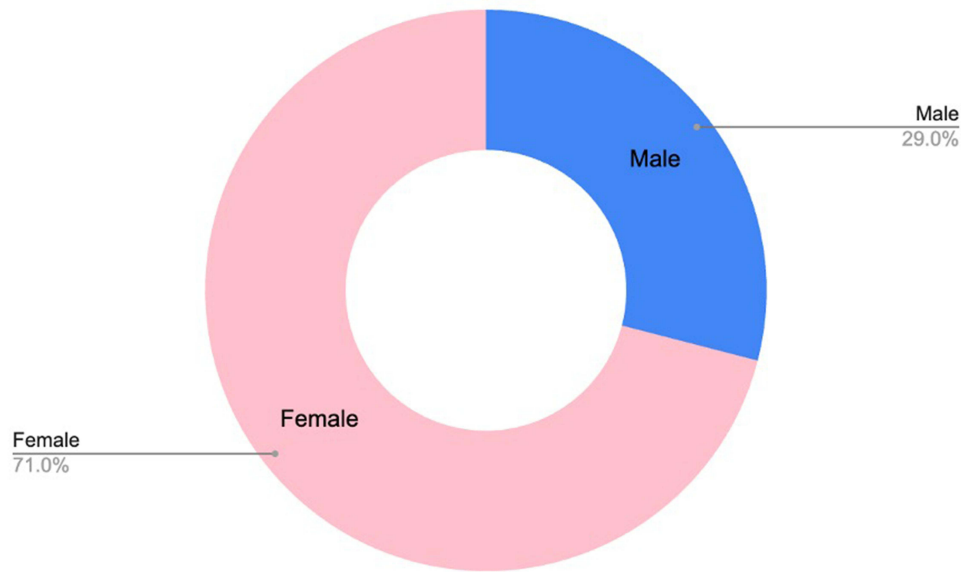


Figure 1 Sex distribution of the included patients.

Linear Correlation Analyses

Across the full cohort of dry eye patients, age demonstrated only a weak negative correlation with FBUT in both eyes. This pattern was consistent whether male and female patients were analyzed together or pooled together (Table 2).

Table 1 Mean Fluorescein Tear Film Break-Up Time Stratified by Age Cohort and Sex

Age Cohort (Years)	Number of Participants	Mean FBUT OD (± SD) (Seconds)			Mean FBUT OS (± SD) (Seconds)		
		Pooled	Males Only	Females Only	Pooled	Males Only	Females Only
16-29	110	5.3 ± 4 ^a	6.3 ± 5	4.8 ± 3	5.2 ± 3 ^a	5.5 ± 3	5.0 ± 3
30-44	222	5.2 ± 5 ^a	5.9 ± 4	4.8 ± 5	5.5 ± 5 ^a	6.1 ± 6	5.1 ± 5
45-64	425	4.0 ± 3 ^b	4.9 ± 4	3.8 ± 3	3.8 ± 3 ^b	4.3 ± 4	3.7 ± 4
≥65	287	3.7 ± 3 ^b	3.9 ± 3	3.6 ± 3	3.6 ± 3 ^b	3.7 ± 3	3.5 ± 3

Notes: Standard deviation of the mean (SD), right eye (Oculus Dexter; OD), left eye (Oculus Sinister; OS). Superscript letters (a, b) indicate results of pairwise comparisons between age cohorts using Dunn's post-hoc test with Bonferroni correction. Age groups sharing the same letter are not significantly different, whereas groups with different letters differ significantly at a Bonferroni-adjusted significance level of $p < 0.0083$.

Abbreviation: FBUT, Tear film break-up time.

Table 2 Correlation Between Age and Tear Film Break-Up Time (Spearman Correlation)

	r	p-value
Age vs. FBUT OD	-0.194	<0.001
Age vs. FBUT OS	-0.220	<0.001
Age vs. FBUT OD [males only]	-0.236	<0.001
Age vs. FBUT OS [males only]	-0.270	<0.001
Age vs. FBUT OD [females only]	-0.164	<0.001
Age vs. FBUT OS [females only]	-0.191	<0.001

Notes: Spearman correlation coefficient (r), right eye (OD), left eye (OS).

Abbreviation: FBUT, Tear film break-up time.

Although all correlations reached statistical significance, the magnitude of the correlation coefficients was small, indicating a limited association between advancing age and reduced tear film stability.

Non-Linear Correlation

To explore whether the relationship between age and FBUT followed a non-linear pattern, polynomial regression analyses were performed. These analyses similarly demonstrated no meaningful association between age and FBUT in either eye, irrespective of sex (Figure 2). The coefficients of determination (R^2) were consistently low across all models, with age explaining less than 4% of the variance in FBUT values across all regression models.

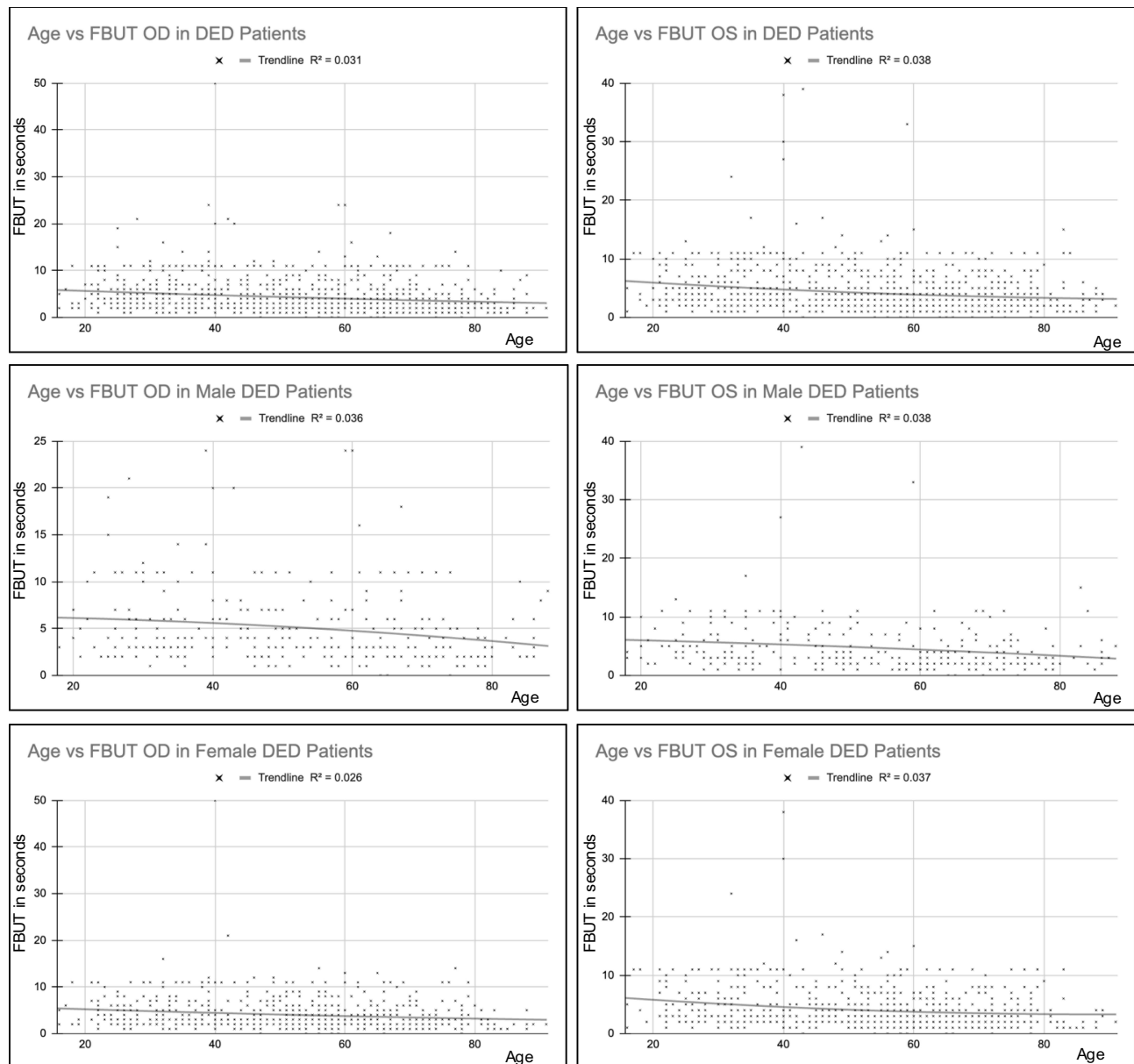


Figure 2 Polynomial regression analyses illustrating the relationship between age and fluorescein tear film break-up time (FBUT) in dry eye patients. R^2 values were consistently below 4% across all models, indicating that age explains only a small proportion of the variability in FBUT, regardless of sex or eye, coefficient of determination (R^2), right eye (Oculus Dexter; OD), left eye (Oculus Sinister; OS).
Abbreviations: DED, dry eye disease; FBUT, tear film break-up time.

Together, these findings indicate that, within this dry eye patient population, age accounts for only a minimal proportion of the variability in tear film break-up time, suggesting that factors other than chronological aging play a substantially greater role in determining tear film stability.

Discussion

In the present study, we observed a weak association between age and FBUT in a large sample of DED patients presenting to a specialized clinic in Norway. Although statistically significant, the strength of the correlation was low, indicating that age accounts for only a minor proportion of the variability in tear film stability among symptomatic patients.

The patients included in this analysis were either referred to, or self-referred to our specialized dry eye clinic and therefore do not represent a cross-sectional sample of the general population. Rather, they constitute a symptom-selected clinical cohort. In this context, individuals seek evaluation because they experience ocular discomfort, visual disturbance, or irritation, not because of their chronological age. Tear film instability sufficient to provoke symptoms can occur in both younger and older individuals, and patients across a wide age range may therefore present for care once tear film stability has deteriorated beyond a clinically relevant threshold.³ As a consequence, FBUT values at presentation, which is the parameter analyzed in the present study, may be relatively similar across different age groups, thereby attenuating any apparent association between FBUT and age. This introduces a degree of selection bias, as the cohort reflects individuals seeking care rather than a population-based sample, and this should be considered when interpreting the findings and their generalizability beyond similar symptomatic tertiary-care settings.

Based on well-documented age-related changes in the ocular surface and adnexa, including eyelid alterations,⁴ lid laxity,⁹ meibomian gland atrophy,^{4,10} and ductal orifice metaplasia,¹¹ we initially hypothesized that advancing age would be associated with progressively reduced tear film stability. This hypothesis reflects a common clinical assumption that cumulative structural and functional deterioration of the eyelids and meibomian glands leads to increased evaporative loss and, consequently, shorter FBUT. However, contrary to this simplified expectation, our findings demonstrated no strong linear or non-linear relationship between age and FBUT in either eye, irrespective of sex. While differing from common clinical assumptions, these findings align with several previous studies reporting lacking, weak and/or inconsistent associations between tear film parameters and age.^{3–5,7–9,12–15} For example, Hong et al measured non-invasive tear film break-up time (NIBUT) in 40 healthy individuals and found no significant correlation between NIBUT and age, suggesting that tear film dynamics do not necessarily decline in a uniform or linear manner with aging.⁵ Since the patient population from Hong et al was Chinese, the authors wondered whether tear physiology of the Chinese population may be different in comparison to other populations. But in a study conducted in India on 237 healthy individuals with the mean age of 40 years (range, 10–78 years), the authors reported similar findings of no association between age and NIBUT.⁷ In a study conducted on a U.S. population, Verticchio Vercellin et al also found a lack of association between age and lipid break-up time or inter-blink interval.¹⁴ Verticchio Vercellin et al did, however, find a statistically significant decrease in muco-aqueous layer thickness and a significant increase in lipid layer thickness with increasing age. Taken together, these observations suggest that the influence of aging on tear film dynamics is more complex and less deterministic than often presumed.

At the same time, other studies have reported age-related differences in FBUT when age is analyzed in discrete categories and assessed using group-based statistical approaches, highlighting how differences in analytical strategy, including the use of age as a categorical rather than continuous variable and the application of parametric regression models, may partly explain divergent findings across studies. For instance, in a 2024 cross-sectional study, Garcia-Queiruga et al investigated the influence of age and lifestyle factors on ocular surface parameters, including FBUT, in individuals with ocular discomfort.⁸ Participants were stratified into three age categories (<40, 40–60, and >60 years), and the authors reported statistically significant differences in FBUT between these age groups. In their multiple linear regression analysis, aging was identified as a primary factor associated with ocular surface homeostasis, with older age groups showing lower FBUT and maximum blink interval values and higher tear osmolarity, while prolonged video display terminal use was reported to further exacerbate these alterations. A notable methodological aspect of this analysis is that FBUT values, just as in the dataset presented herein, did not follow a normal distribution. To enable the use of

parametric statistical tests, the authors therefore applied a logarithmic transformation to the data prior to analysis. In practical terms, this means that the results emphasize relative differences between age groups rather than absolute differences in FBUT measured in seconds. Such transformations reduce the influence of extreme values and can improve the statistical behavior of the data, but they may also make relatively small proportional differences appear statistically significant, even when the actual clinical differences are modest.¹⁶ Additionally, age was treated as a categorical variable rather than a continuous measure, which can accentuate contrasts between predefined age groups while providing less information about gradual, year-by-year changes in tear film stability.

Taken together, findings from these studies conducted across different populations and using diverse analytical approaches suggest that the relationship between aging and tear film stability is context-dependent and non-deterministic, rather than reflecting a simple, universal process of progressive tear film destabilization with advancing age. Studies relying on continuous age analyses in healthy cohorts from Chinese,⁵ Indian,⁷ and U.S.¹⁴ populations report weak or absent associations between age and break-up time, whereas investigations that categorize age into discrete groups and apply parametric regression models, such as that by Garcia-Queiruga et al,¹⁷ identify statistically significant differences between broader age strata, similar to what we report herein. These discrepancies suggest that the influence of aging on tear film behavior is shaped not only by biological aging itself but also by study design, population characteristics, analytical strategy, and the specific tear film parameters assessed.

An additional consideration emerging from this context-dependent interpretation is that chronological age alone may not adequately capture lifetime exposure to environmental and lifestyle factors that influence tear film stability.¹⁸ Older and younger adults today have grown up under markedly different conditions. Individuals currently in their 50s or 60s experienced little exposure to prolonged screen use or sustained near work during early life, whereas younger generations have been exposed to digital devices from childhood. Prolonged screen use is associated with reduced blink rate, increased blink incompleteness, and greater evaporative stress on the tear film, all of which may adversely affect tear film stability over time.^{19–22} Beyond digital device use, broader lifestyle changes, including increased indoor work, altered sleep patterns, widespread use of air-conditioned environments, and evolving occupational demands, may differentially shape ocular surface health across generations. Consequently, individuals of the same chronological age but belonging to different birth cohorts may carry substantially different cumulative risks for tear film instability. From this perspective, the absence of a strong age-FBUT correlation may partly reflect cohort effects, whereby older patients evaluated today represent a population that was less exposed to modern ocular surface stressors earlier in life.

Several methodological considerations should be acknowledged. First, the analysis was primarily univariate and did not include adjustment for potential confounding variables such as DED subtype, disease severity, systemic comorbidities, medication use, or environmental exposures, as such data were not consistently available across the cohort. As a result, the independent effect of age on tear film stability cannot be fully isolated, and unmeasured confounding may have influenced the observed associations. Second, the study focused on a single clinical parameter, FBUT, which, while widely used, represents only one aspect of tear film dynamics and does not fully capture the complexity of dry eye disease. Complementary tear film and ocular surface parameters, such as tear osmolarity, ocular surface staining, meibomian gland assessments, or tear volume measures, were not incorporated into the analysis. Third, although the associations between age and FBUT were statistically significant, their magnitude was small, and the observed significance may partly reflect the large sample size rather than a clinically meaningful effect. Finally, although examinations were conducted within routine clinical hours, diurnal variation in tear film stability cannot be excluded and may have contributed to variability in FBUT measurements. These factors should be considered when interpreting the findings.

In summary, the present findings indicate that the association between age and tear film stability in DED is statistically significant but clinically weak within this symptomatic, clinic-based population, suggesting that age alone is a poor predictor of fluorescein tear film break-up time. These results should be interpreted within the context of a tertiary-care, symptom-driven cohort and not generalized to the broader population. While the findings suggest that tear film instability at presentation may be influenced by disease-related and contextual factors rather than chronological aging alone, it is important to note that these factors were not directly measured or controlled for in the present analysis. In this setting, FBUT appears to reflect tear film instability at the time of clinical presentation rather than gradual age-

related physiological change. Future studies incorporating multivariable analyses and including healthy control populations are needed to better isolate the independent contribution of age and to distinguish disease-related effects from normal aging processes. Such work may ultimately support more precise diagnostic thresholds and more individualized management strategies for patients with, or at risk of, DED.

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Disclosure

Tor Paaske Utheim has served on the global scientific advisory boards of Novartis and Alcon, as well as on the European advisory boards of Santen and Shire Pharmaceuticals. Utheim is the Norwegian Global Ambassador for the Tear Film and Ocular Surface Society, a board member of the International Ocular Surface Society, and an appointed consultant for the Norwegian Association for the Blind and Partially Sighted. Further, he is the Editor-in-Chief of *Ophthalmology*, an eye journal distributed to all eye doctors in the Nordic region since 1980. Utheim is co-founder and co-owner of The Norwegian Dry Eye Clinic and the Clinic of Eye Health, Oslo, Norway. Ayyad Zartasht Khan, Tore Steinkjer, and Fredrik Andreas Fineide also have ownership interests in these clinics. The clinics deliver talks for and/or receive financial support from ABIGO, Alcon, Allergan, AMWO, Bausch & Lomb, Bayer, the European School for Advanced Studies in Ophthalmology, InnZ Medical, Medilens Nordic, Medistim, Novartis, Santen, Specsavers, Shire Pharmaceuticals and Thea Laboratories. Ayyad Zartasht Khan, Tore Steinkjer and Fredrik Andreas Fineide have ownership interests in the Norwegian Dry Eye Clinic. The authors report no other conflicts of interest in this work.

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