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Original Article

Association of Dry Eye Severity with Headache of Unknown Etiology and Comparative Treatment Outcomes

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ABSTRACT

Background: Dry eye disease and headache disorders commonly coexist and may share trigeminal sensory pathways, but their clinical relationship and comparative response to ocular lubricants remain insufficiently characterized. Objective: To assess the association between dry-eye symptom severity and headache-related disability and compare four-week treatment outcomes between Systane Ultra and Vismed. Methods: This randomized comparative clinical trial included 104 adults aged 18–45 years with symptomatic dry eye disease and headache of initially undetermined etiology. Participants were allocated equally to Systane Ultra or preservative-free Vismed 0.18% sodium hyaluronate, administered four times daily for four weeks. Dry-eye assessment included OSDI, TBUT, and Schirmer's I test, while headache-related disability was assessed using HIT-6. Paired and independent-samples t-tests and Spearman correlation were applied. Results: The reported clinical symptom score decreased from 12.4 ± 2.1 to 7.2 ± 1.5 with Systane Ultra and from 12.1 ± 1.9 to 8.5 ± 1.8 with Vismed ($p < 0.001$ for both). Mean improvement was greater with Systane Ultra than with Vismed (5.2 ± 1.1 versus 3.6 ± 1.4; mean difference, 1.60; 95% CI, 1.11–2.09; $p < 0.001$; Cohen's $d = 1.27$). OSDI and HIT-6 scores were positively correlated ($r_s = 0.648$; $p = 0.001$). Conclusion: Greater dry-eye symptom severity was associated with greater headache-related disability, and both lubricants improved the reported symptom score, with greater improvement observed for Systane Ultra. Keywords: Dry eye disease; headache disorders; ocular surface disease; artificial tears; Ocular Surface Disease Index; Headache Impact Test-6.

INTRODUCTION

Dry eye disease is a multifactorial disorder of the ocular surface characterized by loss of tear-film homeostasis, tear-film instability, hyperosmolarity, inflammation, neurosensory abnormalities, and symptoms of ocular discomfort or visual disturbance. Although its prevalence increases with age, dry eye disease is also increasingly recognized among younger adults because of prolonged digital-device use, reduced blinking, environmental exposure, and other lifestyle-related factors. Common manifestations include burning, foreign-body sensation, fluctuating vision, ocular fatigue, photophobia, and reduced visual performance, all of which may adversely affect daily functioning and vision-related quality of life (1–3).

Headache disorders and dry eye disease frequently coexist. Epidemiological evidence indicates that patients with headache, particularly migraine, have a greater likelihood of experiencing dry-eye symptoms and objective tear-film abnormalities than individuals without headache (3,4). Conversely, patients with persistent ocular-surface discomfort may report frontal, periocular, temporal, or retro-orbital pain that is interpreted as headache. This clinical overlap can complicate diagnosis because ocular

discomfort, photophobia, visual fatigue, and craniofacial pain may occur in both dry eye disease and primary headache disorders (4,5).

The association between dry eye disease and headache may partly involve shared trigeminal sensory pathways. Tear-film instability, increased ocular-surface friction, hyperosmolarity, and inflammation can stimulate corneal and conjunctival nociceptors whose afferent signals are transmitted through the ophthalmic division of the trigeminal nerve. Persistent peripheral stimulation may contribute to sensitization of trigeminal pathways and amplification of ocular or craniofacial pain (5,9). However, the presence of dry-eye symptoms in a patient with headache does not establish that ocular-surface dysfunction is the sole cause of the headache. Migraine, tension-type headache, digital eye strain, uncorrected refractive error, sleep disturbance, musculoskeletal factors, systemic disease, and centrally mediated pain may coexist with or independently produce similar symptoms (10–15).

Artificial tears are commonly used as first-line treatment for dry eye disease because they supplement the tear film, reduce friction between the eyelid and ocular surface, dilute inflammatory mediators, and improve ocular comfort (6,9,16). Nevertheless, treatment response varies according to the underlying tear-film abnormality, formulation of the lubricant, severity of ocular-surface disease, adherence, and presence of concomitant pain mechanisms. Polyethylene glycol 400 and propylene glycol formulations containing hydroxypropyl guar are designed to form a protective matrix over the ocular surface, whereas sodium hyaluronate formulations provide viscoelastic lubrication, moisture retention, and support for epithelial surface recovery (17,20–23). Although both approaches are used clinically, comparative evidence regarding their effects among patients presenting with concurrent dry-eye symptoms and otherwise unexplained headache remains limited.

Clinical assessment of such patients should therefore distinguish an association between dry-eye severity and headache burden from a definitive causal attribution. Symptom-based instruments such as the Ocular Surface Disease Index can quantify the perceived effect of dry-eye symptoms, whereas tear-film break-up time and Schirmer's I testing provide complementary information regarding tear-film stability and aqueous tear production. Headache-related disability can be assessed separately using the Headache Impact Test-6. Evaluating these measures together may help determine whether greater ocular-surface disturbance is associated with greater headache-related impairment, without assuming that one condition necessarily causes the other.

The present study therefore aimed to assess the association between dry-eye severity and headache burden among adults presenting with dry eye disease and headache of initially undetermined etiology and to compare four-week changes in clinical symptoms between patients treated with Systane Ultra and those treated with Vismed 0.18% sodium hyaluronate. It was hypothesized that greater dry-eye severity would be associated with greater headache-related disability and that the magnitude of symptom improvement would differ between the two lubricant formulations.

MATERIALS AND METHODS

This randomized comparative clinical trial was conducted from February to May 2026 at Life Hospital, Bahria Town, and Sarwar Eye Centre, Raiwind Road, Lahore, Pakistan. The study evaluated the relationship between dry-eye severity and headache burden and compared the short-term clinical outcomes of two ocular-lubricant formulations among adults presenting with concurrent dry-eye symptoms and headache for which a definitive etiology had not initially been established.

A total of 104 participants, comprising 52 men and 52 women aged 18–45 years, were enrolled through non-probability consecutive sampling. Patients presenting at either study centre were assessed for eligibility and were recruited consecutively when they fulfilled the selection criteria. Eligible participants had symptomatic dry eye disease accompanied by recurrent headache symptoms. Patients were excluded if they had active ocular infection or allergic eye disease, ocular surgery during the

preceding six months, contact-lens use, concurrent ocular medication, or a known systemic inflammatory or neurological disorder that could independently account for the presenting symptoms. These criteria were applied to reduce the influence of identifiable ocular or neurological conditions on the assessment of dry-eye and headache measures.

The sample size was calculated using a single-population proportion formula with a 95% confidence level, an anticipated proportion of 50%, and an absolute precision of 9.6%, yielding a required sample of 104 participants. Although the calculation established the planned total enrolment, participants were subsequently assigned in a 1:1 ratio to the two treatment groups, with 52 participants allocated to each group.

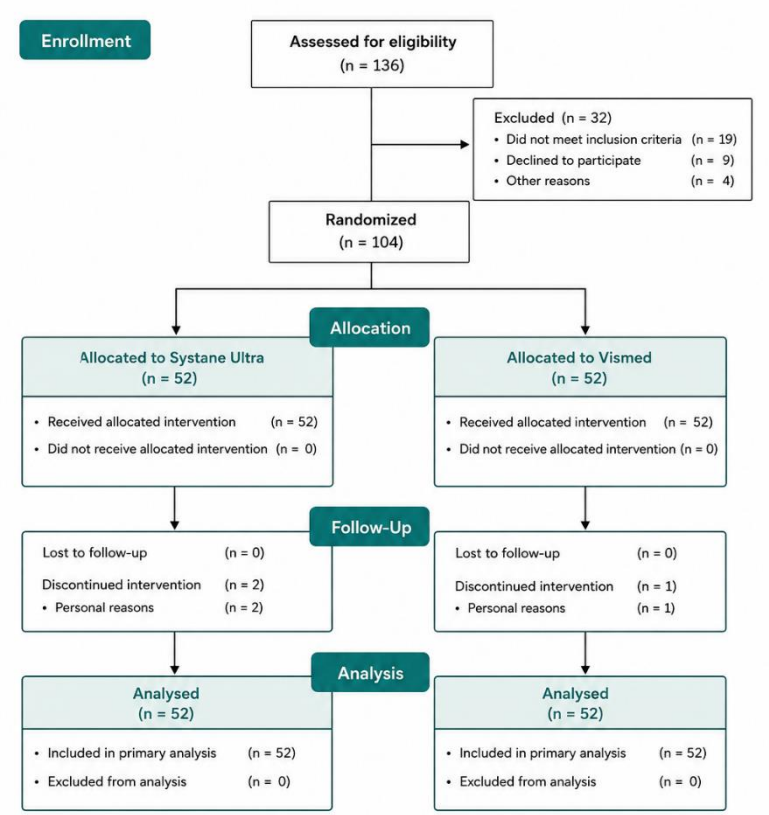

Figure 1 CONSORT Flowchart

Participants assigned to the first group received Systane Ultra, a lubricant formulation containing polyethylene glycol 400, propylene glycol, and hydroxypropyl guar. Participants assigned to the second group received Vismed, a preservative-free formulation containing 0.18% sodium hyaluronate. Both treatments were administered as ocular drops four times daily for four consecutive weeks. Participants were instructed to use only the allocated ocular lubricant during the intervention period and to follow the prescribed administration schedule.

Clinical assessments were performed at baseline and repeated after four weeks of treatment. Dry-eye symptoms were evaluated using the Ocular Surface Disease Index. Tear-film stability was assessed through tear-film break-up time using sodium fluorescein and slit-lamp biomicroscopy. Aqueous tear production was evaluated using Schirmer's I test. Because these measures represent different aspects of dry eye disease and have different scoring directions, they were considered as separate clinical variables rather than as an unvalidated combined dry-eye score.

Headache burden was assessed independently from the ocular-surface measures. Headache-related functional impairment was quantified using the Headache Impact Test-6, while the reported intensity of headache was recorded using the clinical headache-severity score employed during the baseline assessment. Ocular-surface symptom severity, objective tear-film findings, headache intensity, and

headache-related disability were therefore treated as distinct outcomes. The association analysis was intended to determine whether greater dry-eye symptom severity was accompanied by greater headache burden at the group level; it was not used as an individual diagnostic test for assigning the cause of headache.

Baseline information included age, sex, duration of symptoms, headache severity, systemic-illness status, hypertension, and diabetes. The same ocular-surface and headache measures were obtained at the four-week follow-up to assess changes after treatment. The principal comparative analysis examined the magnitude of symptom-score improvement in the Systane Ultra and Vismed groups. Secondary assessments included within-group changes and the association between dry-eye symptom severity and headache-related disability.

Data were analysed using IBM SPSS Statistics version 27.0. Continuous variables were summarized as mean and standard deviation, while categorical variables were summarized as frequencies and percentages. Within-group differences between baseline and four-week measurements were evaluated using paired-samples t-tests. Between-group differences in mean improvement were assessed using an independent-samples t-test. Spearman's rank correlation coefficient was used to evaluate the association between dry-eye symptom severity and headache-related disability because the analysis concerned the ranked relationship between two clinical severity measures. Statistical significance was set at a two-sided p-value of less than 0.05.

RESULTS

A total of 104 participants were included in the analysis, with 52 participants in the Systane Ultra group and 52 in the Vismed group. The study population comprised equal numbers of men and women. The mean age was 31.5 ± 8.1 years, the mean duration of symptoms was 2.5 ± 1.4 years, and the mean baseline headache-severity score was 5.5 ± 2.8. Systemic illness was reported in 17 participants, hypertension in 19, and diabetes mellitus in 14. The demographic and clinical characteristics of the study population are presented in Table 1.

Table 1. Demographic and Clinical Characteristics of the Study Population

Characteristic	n	%	Mean	SD
Age, years	—	—	31.5	8.1
Duration of symptoms, years	—	—	2.5	1.4
Baseline headache-severity score	—	—	5.5	2.8
Male sex	52	50.0	—	—
Female sex	52	50.0	—	—
Systemic illness	17	16.3	—	—
Hypertension	19	18.2	—	—
Diabetes mellitus	14	13.5	—	—
Systane Ultra group	52	50.0	—	—
Vismed group	52	50.0	—	—

SD: standard deviation. Systemic illness, hypertension, and diabetes mellitus were recorded as separate clinical variables.

Both treatment groups demonstrated reductions in the reported clinical symptom score after four weeks. In the Systane Ultra group, the mean score decreased from 12.4 ± 2.1 at baseline to 7.2 ± 1.5 at follow-up. The corresponding absolute reduction was 5.2 points, representing a relative reduction of 41.9% from baseline. In the Vismed group, the mean score decreased from 12.1 ± 1.9 to 8.5 ± 1.8, corresponding to an absolute reduction of 3.6 points and a relative reduction of 29.8%. The baseline mean score was 0.30 points higher in the Systane Ultra group than in the Vismed group. At four weeks, the mean score was 1.30 points lower in the Systane Ultra group. Paired-samples analyses demonstrated statistically significant within-group reductions in both groups, with $p < 0.001$ for each comparison. The descriptive treatment outcomes are presented in Table 2.

Table 2. Baseline, Follow-Up, and Change in Clinical Symptom Scores by Treatment Group

Outcome	Systane Ultra, n	Systane Ultra, mean	Systane Ultra, SD	Vismed, n	Vismed, mean	Vismed, SD	Between-group difference
Baseline score	52	12.4	2.1	52	12.1	1.9	0.30
Four-week score	52	7.2	1.5	52	8.5	1.8	−1.30
Absolute reduction	52	5.2	1.1	52	3.6	1.4	1.60
Relative reduction, %	52	41.9	—	52	29.8	—	12.1

Between-group differences were calculated as Systane Ultra minus Vismed. A negative value for the four-week score indicates a lower mean follow-up score in the Systane Ultra group. SD: standard deviation. The mean improvement was 1.60 points greater in the Systane Ultra group than in the Vismed group. Using the reported change-score means, standard deviations, and group sizes, the independent-samples t statistic was 6.48 with 102 degrees of freedom. The 95% confidence interval for the mean difference ranged from 1.11 to 2.09 points, and the difference was statistically significant at $p < 0.001$. The pooled standard deviation was approximately 1.26, yielding a Cohen's d of 1.27. Dry-eye symptom severity was positively associated with headache-related disability. The Spearman correlation between the Ocular Surface Disease Index and Headache Impact Test-6 scores was 0.648. The corresponding p-value was 0.001, and the Fisher z-derived 95% confidence interval ranged from 0.520 to 0.747. These inferential findings are summarized in Table 3.

Table 3. Inferential Analysis of Treatment Response and Dry Eye–Headache Association

Analysis	Estimate	Lower 95% CI	Upper 95% CI	Test statistic	df	p-value	Effect size
Between-group difference in mean improvement	1.60	1.11	2.09	6.48	102	<0.001	1.27
Difference in relative reduction, percentage points	12.1	—	—	—	—	—	—
OSDI–HIT-6 correlation	0.648	0.520	0.747	—	—	0.001	—

The test statistic for the between-group comparison is an independent-samples t value. The effect size is Cohen's d. The OSDI–HIT-6 estimate is Spearman's correlation coefficient. CI: confidence interval; df: degrees of freedom; HIT-6: Headache Impact Test-6; OSDI: Ocular Surface Disease Index.

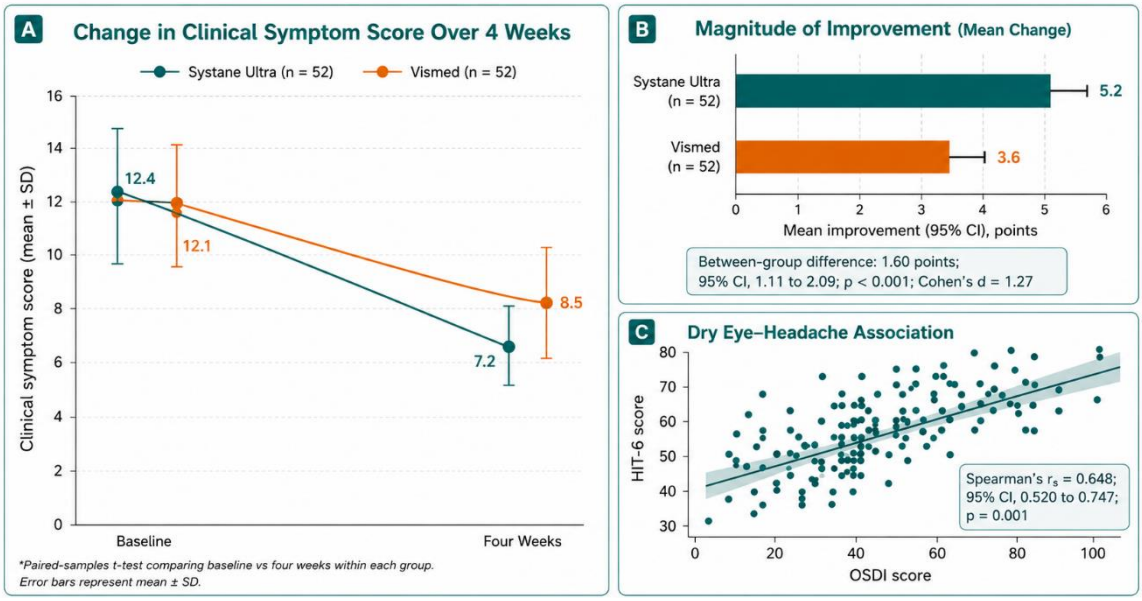

Figure 2. Comparative treatment response and association between dry-eye severity and headache burden. Panel A shows the change in mean clinical symptom score over four weeks in the Systane Ultra and Vismed groups. The score decreased from 12.4 ± 2.1 to 7.2 ± 1.5 in the Systane Ultra group and from 12.1 ± 1.9 to 8.5 ± 1.8 in the Vismed group, with significant within-group improvement in both groups ($p < 0.001$). Panel B presents the magnitude of mean improvement, which was greater with Systane Ultra than with Vismed (5.2 ± 1.1 versus 3.6 ± 1.4 points). The between-group difference was 1.60 points (95% CI, 1.11–2.09; $p < 0.001$; Cohen's $d = 1.27$). Panel C illustrates the positive association between OSDI and HIT-6 scores, indicating that greater dry-eye symptom severity was associated with greater headache-related disability (Spearman's $r_s = 0.648$; 95% CI, 0.520–0.747; $p = 0.001$). Error bars in Panel A represent standard deviations, whereas those in Panel B represent 95% confidence intervals.

Overall, both treatment groups demonstrated statistically significant four-week reductions in the reported clinical symptom score. The reduction was greater in the Systane Ultra group, which showed an absolute mean improvement of 5.2 points compared with 3.6 points in the Vismed group. The between-group difference of 1.60 points was statistically significant and corresponded to a large standardized effect. Dry-eye symptom severity was also moderately to strongly associated with headache-related disability. This association indicates that greater ocular-surface symptom burden accompanied greater headache-related functional impairment, but it does not independently establish that dry eye disease caused the reported headaches.

DISCUSSION

The present study identified a moderate-to-strong positive association between dry-eye symptom severity and headache-related disability among adults presenting with concurrent dry eye disease and headache of initially undetermined etiology. Both ocular-lubricant groups demonstrated significant reductions in the reported clinical symptom score after four weeks; however, the mean improvement was greater in the Systane Ultra group than in the Vismed group. These findings suggest that ocular-surface symptom burden and headache-related functional impairment frequently coexist and that improvement in ocular symptoms may vary according to the lubricant formulation used. Nevertheless, the observed association does not establish that dry eye disease was the primary cause of headache in individual participants.

The positive correlation between OSDI and HIT-6 scores was consistent with previous evidence indicating a substantial clinical overlap between dry eye disease and headache disorders. A systematic review and meta-analysis reported an increased risk of dry eye disease among patients with headache, while a large population-based study demonstrated a significant association between dry eye disease and migraine (3,4). Similar observations have been reported in clinical studies in which patients with migraine exhibited more prominent ocular-surface symptoms and tear-film abnormalities than individuals without migraine (8,9). The present correlation therefore supports the view that greater ocular discomfort may accompany greater headache-related disability, although the cross-sectional nature of the association prevents determination of temporal direction or causality.

Several biological mechanisms may explain the coexistence of dry-eye symptoms and headache burden. Tear-film instability, increased evaporation, hyperosmolarity, ocular-surface inflammation, and repetitive stimulation of corneal nociceptors can activate afferent fibres of the ophthalmic division of the trigeminal nerve (5,6). Persistent peripheral input may contribute to sensitization within trigeminal pathways, thereby increasing pain responsiveness and producing ocular, periocular, or craniofacial discomfort. Short tear-film break-up time may be particularly relevant because an unstable tear film increases ocular-surface exposure and sensory stimulation between blinks (5). However, these mechanisms were not directly measured in the present study, and the observed clinical association should therefore be considered compatible with, rather than confirmatory of, shared trigeminal or neurosensory mechanisms.

The relationship between dry eye disease and headache is also likely to be bidirectional and multifactorial. Primary headache disorders may increase photophobia, ocular discomfort, pain sensitivity, and symptom awareness, whereas dry-eye-related irritation may act as an aggravating factor in patients with an underlying headache disorder. Previous studies have shown that migraine patients may have a different dry-eye symptom profile from non-migraine populations and that ocular lubrication does not invariably produce meaningful improvement in migraine severity (7,21). Persistent headache after improvement in ocular-surface symptoms may therefore reflect migraine, tension-type headache, refractive strain, sleep disturbance, musculoskeletal factors, medication use, or central pain sensitization rather than failure of ocular lubrication alone. This complexity reinforces the need to evaluate dry-eye measures and headache characteristics separately rather than assuming that improvement in one necessarily confirms the cause of the other.

Both treatment groups showed significant four-week improvement, supporting the established symptomatic role of artificial tears in dry eye disease. Artificial tears can improve ocular comfort by supplementing the aqueous layer, reducing lid–surface friction, stabilizing the tear film, and diluting inflammatory mediators on the ocular surface (6,13,20). Previous clinical and systematic evidence has demonstrated that sodium hyaluronate can improve dry-eye symptoms and objective tear-film findings through its viscoelastic and water-retaining properties (14,16,18,19). The improvement observed in the Vismed group was therefore clinically plausible and consistent with the recognized role of 0.18% sodium hyaluronate in dry-eye management.

The greater mean improvement observed with Systane Ultra may be related to differences in formulation and ocular-surface retention. Its polyethylene glycol 400 and propylene glycol components provide lubrication, while hydroxypropyl guar forms a protective matrix that may prolong contact with the ocular surface and reduce friction. Previous comparative studies of lubricant formulations have shown that treatment response may differ according to tear-film characteristics, lipid-layer stability, preservative exposure, dosing frequency, and underlying dry-eye subtype (13,15). However, the present study did not measure tear-film retention, epithelial recovery, inflammatory biomarkers, or formulation-specific mechanisms. Consequently, the greater improvement associated with Systane Ultra should be interpreted as a comparative clinical finding rather than proof that hydroxypropyl guar was responsible for the difference.

The between-group difference in mean improvement was 1.60 points, with a 95% confidence interval of 1.11–2.09 and a large standardized effect size. Although this result suggested a substantial difference relative to the observed change-score variability, its clinical importance cannot be fully established because the manuscript did not clearly identify the scoring instrument represented by the reported baseline and follow-up values. Clinical interpretation requires the exact scale, scoring direction, range, validation status, and minimal clinically important difference. The finding should therefore be described as statistically robust within the reported dataset, while its patient-perceived importance remains uncertain until the outcome instrument is explicitly confirmed. The study had several strengths. It addressed a clinically relevant and underrecognized overlap between ocular-surface symptoms and headache-related impairment, used equal treatment-group sizes, included both subjective and objective dry-eye assessments in the study protocol, and incorporated a validated measure of headache-related disability. The use of separate treatment groups also permitted direct comparison of two commonly used lubricant formulations. In addition, recalculation of the between-group analysis from the reported change-score data provided confidence intervals and a standardized effect estimate that were absent from the original statistical presentation.

Several limitations should be considered. First, the four-week follow-up period was short and did not establish the durability of treatment response. Second, the diagnostic criteria for headache of unknown etiology were insufficiently detailed, and recognized primary or secondary headache disorders may have remained within the sample. Third, the random-sequence generation, allocation concealment, masking, adherence assessment, attrition, adverse events, and analysis population were not fully reported. Fourth, the sample-size calculation was based on a single-population proportion formula rather than the principal comparative outcome. Fifth, potentially important confounders—including digital-device exposure, refractive error, sleep, analgesic use, migraine history, environmental exposure, and systemic medication—were not incorporated into an adjusted analysis. Sixth, the principal symptom score presented in the Results was not explicitly identified, limiting clinical interpretation and comparison with previous studies. Finally, separate baseline and follow-up values for OSDI, HIT-6, TBUT, and Schirmer's I test were not available in the reported results, preventing a more complete evaluation of changes across subjective and objective outcomes.

The findings have practical implications for clinicians evaluating patients with concurrent ocular discomfort and recurrent headache. Ocular-surface assessment may identify a treatable contributor to

symptom burden, particularly when dryness, burning, visual fluctuation, or screen-related discomfort accompanies headache. Nevertheless, lubrication should not replace appropriate headache evaluation, especially when symptoms are persistent, progressive, atypical, or associated with neurological warning features. A coordinated approach involving ocular-surface examination, refractive assessment, headache characterization, and referral when indicated may reduce fragmented management and improve the precision of treatment decisions.

CONCLUSION

Dry-eye symptom severity was positively associated with headache-related disability among adults with concurrent dry eye disease and headache of initially undetermined etiology. Both Systane Ultra and Vismed were associated with significant four-week reductions in the reported clinical symptom score, while the improvement was greater in the Systane Ultra group. These findings support assessment and treatment of ocular-surface dysfunction in patients presenting with coexisting ocular discomfort and headache; however, the association does not establish dry eye disease as the sole cause of headache, and persistent symptoms require broader clinical evaluation.

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