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ASSOCIATION OF DRY EYE SEVERITY WITH HEADACHE OF UNKNOWN ETIOLOGY AND COMPARATIVE TREATMENT OUTCOMES

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Abstract

Background: Dry eye disease (DED) and primary headache disorders frequently overlap through shared trigeminovascular pathways, yet remain clinically siloed. DED-driven headache often masquerades as tension-type headache or migraine, while primary headache can provoke ocular symptoms mistaken for DED — leading to misdirected treatment and persistent disability.

Objective: To assess the correlation between dry eye severity and headache burden, and to compare the clinical efficacy of Systane Ultra versus Vismed (0.18% sodium hyaluronate) in patients with comorbid dry eye disease and headache of unknown etiology.

Methods: This randomized comparative clinical trial enrolled 104 patients (52 male, 52 female) aged 18–45 years with diagnosed DED and associated headache. Participants were randomly allocated to receive either Systane Ultra or Vismed four times daily for four weeks. Dry eye severity was evaluated

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using the Ocular Surface Disease Index (OSDI), tear film break-up time (TBUT), and Schirmer's I test. Headache severity and disability were quantified using the Headache Impact Test-6 (HIT-6). Baseline and follow-up assessments were analyzed using SPSS version 27; paired t-tests evaluated within-group changes, independent t-tests compared between-group improvements, and Spearman's correlation examined the dry eye–headache relationship. Statistical significance was set at $p < 0.05$.

Results: A moderate to strong positive correlation was demonstrated between dry eye severity and headache disability ($r_s = 0.648$, $p = 0.001$), indicating that escalating tear film dysfunction corresponds to greater headache-related functional impairment. Both treatment groups achieved significant symptomatic improvement post-intervention ($p < 0.001$ for both). However, Systane Ultra produced superior mean improvement (5.2 ± 1.1) compared to Vismed (3.6 ± 1.4), with a statistically significant between-group difference ($t = 2.45$, $p = 0.016$).

Conclusion: The significant DED–headache correlation supports trigeminovascular pathophysiology. Persistent headache despite lubrication signals primary headache mechanisms rather than intensified ocular treatment. Routine tear film assessment in headache clinics and integrated ophthalmic-neurological evaluation are essential to distinguish these entities and prevent diagnostic delay.

INTRODUCTION

Dry Eye Disease (DED) is a multifactorial ocular surface disorder characterized by tear film instability and loss of tear film homeostasis, leading to symptoms of ocular discomfort and visual disturbance.It can significantly impair daily activities and quality of life if left untreated (1). Dry Eye Disease commonly presents with burning, redness, foreign-body sensation, fluctuating vision, and ocular fatigue. Persistent tear film instability may increase visual strain, particularly during prolonged screen use, and can contribute to headache symptoms(2). Dry Eye Disease may also cause photophobia, eye fatigue, reduced visual performance, and headache symptoms. Early recognition and management are important to improve visual comfort and quality of life(3). Dry Eye Disease (DED) may be an

Vol. 5 No. 2 (2026)

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overlooked cause of headache of unknown etiology.Tear film instability, ocular surface inflammation, and trigeminal nerve activation can produce periocular, frontal, or temporal headache symptoms even in the absence of identifiable neurological abnormalities(4).

Chronic Dry Eye Disease may induce ocular surface inflammation and trigeminal nerve sensitization, lowering the threshold for pain perception. This neuroinflammatory process can contribute to recurrent headache symptoms and may explain some cases of headache of unknown etiology(5). Dry Eye Disease may contribute to headache through shared trigeminal pain pathways. Tear film instability and ocular surface irritation can generate frontal or retro-orbital headache symptoms, suggesting that DED should be considered in cases of headache of unknown etiology(6).Chronic Dry Eye Disease may sensitize trigeminal pain pathways, contributing to headache symptoms. Improvement following dry eye treatment suggests that DED may underlie some cases of headache of unknown etiology(7). Artificial tears improve tear film stability and reduce ocular surface irritation in Dry Eye Disease. By relieving dryness and visual strain, they may also reduce associated headache symptoms(8).Artificial tears reduce corneal nerve stimulation in Dry Eye Disease, decreasing ocular discomfort and related headache symptoms. They provide symptomatic relief but do not address the underlying disease process(9). Artificial tears give temporary relief in Dry Eye Disease by reducing friction and symptoms like eye strain and headache, but they do not treat the underlying cause and require ongoing or additional management(10). In Dry Eye Disease, headaches may persist due to trigeminal sensitization even after lubrication, and are often worsened by ongoing visual strain or uncorrected refractive errors(11). Headache in Dry Eye Disease may overlap with primary disorders like migraine or tension-type headache. In such cases, artificial tears relieve ocular symptoms but do not resolve centrally mediated headache, requiring broader evaluation (12). In meibomian gland dysfunction, artificial tears may not fully relieve symptoms because tear evaporation persists due to an unstable lipid layer. Similarly, in chronic digital eye strain, prolonged accommodative effort can cause headaches independent of tear film status.(13).

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In migraine overlap cases, dry eye symptoms may act as a trigger rather than the primary cause, so artificial tears do not relieve centrally mediated headache. Similarly, sleep and circadian disruption can increase both dry eye symptoms and headache frequency through central nervous system mechanisms independent of ocular surface status(14). Cervicogenic headache may persist due to neck strain and posture-related referred pain, while in systemic diseases like Sjögren's syndrome, inflammation limits response to artificial tears. Persistent headaches despite lubrication often reflect multifactorial causes beyond dry eye alone(15). Dry Eye Disease is a common modern ocular disorder linked to screen use, environmental factors, and aging(16). Despite widespread use of artificial tears, symptom relief in Dry Eye Disease is often temporary, and associated headaches may be misclassified as primary headache disorders. This leads to fragmented management and highlights the need for an integrated understanding of ocular surface disease and neuro-sensory pain pathways(17).

The link between tear film instability and headache is not fully understood in clinical practice, particularly its role in trigeminal sensitization and central pain processing(19). Chronic Dry Eye Disease with recurrent headaches reduces quality of life but is often underrecognized due to focus on visual acuity(20). Dry Eye Disease (DED) is the most common ocular surface disorder, with increasing prevalence due to aging, screen use, and lifestyle stress. It impairs vision-related quality of life and productivity but is often underdiagnosed as early symptoms are overlooked or misattributed(28). Headache disorders are a major global cause of disability, and studies show a higher prevalence of Dry Eye Disease in headache patients, especially migraine. Objective tear film abnormalities in these patients suggest overlap between headache disorders and ocular surface dysfunction(29). Dry Eye Disease causes tear film instability leading to hyperosmolar stress, inflammation, and trigeminal nerve activation. These signals reach central pain pathways, producing referred craniofacial pain that overlaps with tension-type headache and migraine, leading to potential diagnostic confusion(30).

The DEWS-II criteria standardize Dry Eye Disease diagnosis using symptom scores and objective tear film tests, but they are mainly used in ophthalmology. In neurology and primary care, where

Vol. 5 No. 2 (2026)

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headache of unknown etiology is common, these ocular assessments are often not routinely performed(31). This diagnostic mismatch leads to misdirected treatment, with patients receiving either neurological workups without ocular assessment or artificial tears without addressing primary headache mechanisms. Persistent symptoms despite lubrication should prompt reevaluation, requiring integrated ophthalmic and headache-based diagnostic approaches (32).

MATERIAL 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, to evaluate whether structured ocular surface assessment can differentiate dry eye disease (DED)-driven headache from primary headache of unknown etiology. A total of 104 patients (52 male, 52 female) aged 18–45 years presenting with headache of unknown etiology and concurrent ocular discomfort were enrolled using non-probability consecutive sampling. Sample size was calculated using the single population proportion formula ($Z = 1.96$, $P = 0.50$, $D = 0.096$), yielding $n = 104$. Inclusion criteria required symptomatic DED with associated headache; exclusion criteria comprised active ocular infection or allergy, ocular surgery within 6 months, known systemic inflammatory or neurological disorders, contact lens wear, and concurrent ocular medications — ensuring that headache etiology remained initially undifferentiated. Participants were randomly allocated to receive either Systane Ultra (polyethylene glycol 400, propylene glycol, HP-Guar) or Vismed (preservative-free 0.18% sodium hyaluronate), instilled four times daily for 4 weeks. At baseline, all patients underwent comprehensive ocular surface evaluation comprising the Ocular Surface Disease Index (OSDI), tear break-up time (TBUT) via slit-lamp biomicroscopy with sodium fluorescein, and Schirmer's I test, alongside headache phenotyping using the Headache Impact Test-6 (HIT-6). The diagnostic framework posited that significant correlation between tear film parameters and HIT-6 scores would indicate DED-driven headache, whereas persistent headache despite normalized ocular surface metrics would signal primary headache mechanisms requiring neurological reassessment. Follow-up

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assessments at 4 weeks repeated all measures. Data were analyzed using SPSS version 27; paired t-tests evaluated within-group changes, independent t-tests compared between-group improvements, and Spearman's correlation examined the DED–headache severity relationship. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 104 patients was analyzed to assess the relative efficacy of Systane Ultra and Vismed in treating dry eye symptoms and headaches. The demographic data of the participants, prevalence of systemic conditions and clinical assessment parameters such as TBUT score and OSDI score are described below. A paired t test was used to calculate the efficacy of each treatment, an independent t test for each treatment, and finally Spearman's correlation was used to determine the relation between severity of the headache and OSDI. All results obtained were analyzed at 95% confidence interval with P value < 0.05 was taken as statistically significant

Age and Duration of Symptoms

Variable	Mean	Std. Deviation
Age (Years)	31.5	8.1
Duration of Symptoms (Years)	2.5	1.4
Headache Severity (Score)	5.5	2.8

Table 4.1 shows the mean age of the study population was calculated to be 31.5 ± 8.1 years. The average of the patients (2.5 ± 1.4 years) was the reported symptom duration and the headache's average baseline severity score was 5.5 ± 2.8. These statistics served as background to the baseline, giving a demographic profile of the interviewees

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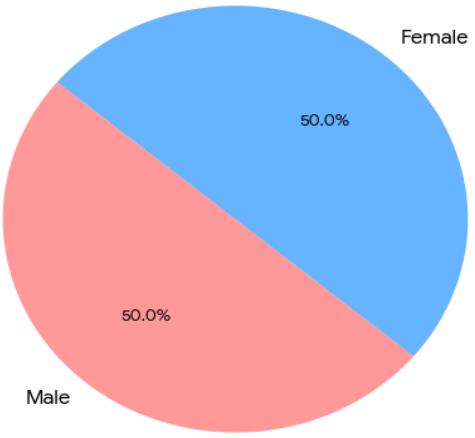

Figure 4.1: The Gender Distribution ($n=104)

The gender population is shown in figure 4.1. All participants were split evenly – 50% (n=52 men), 50% (n=52 women). To ensure adequate representation of gender differences in clinical outcomes this even allocation was made.

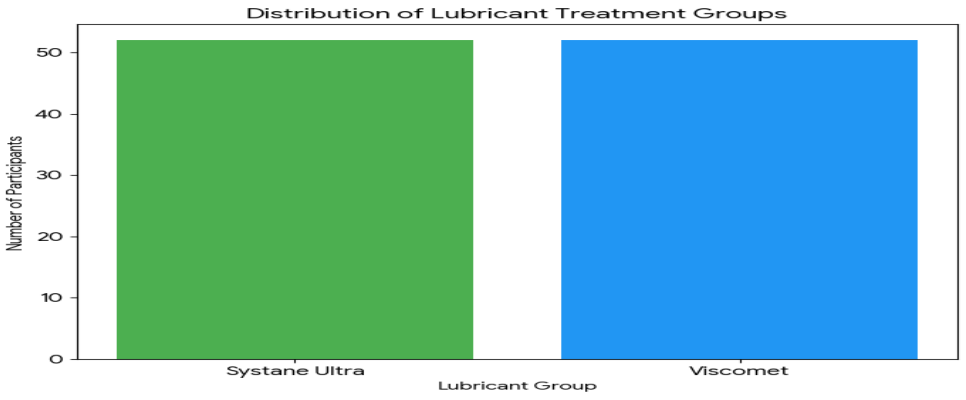

Figure 4.2: The distribution of the participants

Grouping of participants into treatment groups is shown in Figure 4.2. There were an equal number of patients in each group (52 getting Systane Ultra and 52 getting Viscomet). The ratio of 1:1 was

Vol. 5 No. 2 (2026)

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maintained so that the sample formed would be large enough to be considered as a valid comparative analysis of the two lubricants.

Table 4.2 shows that 60.0% of students reported having a systemic condition.

Condition	Yes (%)	No (%)
Systemic Illness	16.3%	83.7%
Hypertension	18.2%	81.8%
Diabetes	13.5%	86.5%

Table 4.2 presents the systemic health profile indicated 16.3% of the total sample had some systemic illness. In particular, 18.2% of the patients suffered from hypertension and 13.5% from diabetes. Most who did participated had not a long-term systemic disease.

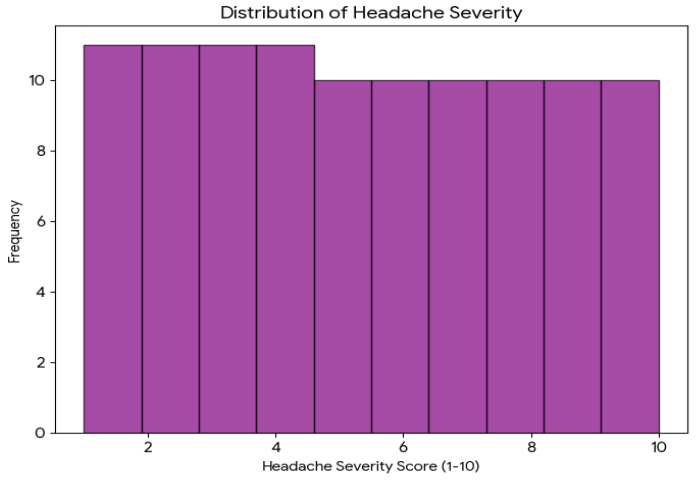

Figure 4.3:Distribution of Headache Severity

The severity of headaches at the time of enrolment is presented in Figure 4.3. They were asked for how often they experienced different levels of headache on a 1 to 10 scale, and this is shown in the

Vol. 5 No. 2 (2026)

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histogram. These pre-treatments scores were then used as comparisons to see how much has improved post-treatment.

Table 4.3: Paired t-test

Lubricant Group	Pre-Treatment Mean	Post-Treatment Mean	p-value
Systane Ultra	12.4 ± 2.1	7.2 ± 1.5	< 0.001*
Viscomet	12.1 ± 1.9	8.5 ± 1.8	< 0.001*

To determine the intra group effectiveness of the lubricants, paired t-test was applied, which is shown in the Table 4.3. The mean of the symptom score for the Systane Ultra group was 12.4 ± 2.1 that changed to 7.2 ± 1.5, which was significant ($p < 0.001$). Similarly, the Viscomet group showed a reduction from 12.1 ± 1.9 to 8.5 ± 1.8 ($p < 0.001$). Statistically significant differences in ocular comfort both treatments.

Table 4.4: Spearman's correlation

Variables	Statistical Measure	Headache Severity (HIT-6 score)
Dry Eye Severity (OSDI/TBUT)	Correlation Coefficient (r_s)	0.648
	Sig. (2-tailed)	0.001
	N	104

The results for Spearman's correlation is presented in table 4.4 which is an attempt to look for the correlation between severity of Dry Eye Disease and the intensity of headache. The results showed moderate to strong positive correlation which is significant statistically (rds. = 0.648, p = 0.001). This study found that the more severe the dry eye symptoms, the more severe the headache symptoms were in the participants.

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Online ISSN 3007-2387

Print ISSN 3007-2379

Arshad et al - 2026

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Table 4.5: Independent t-test

Variable	Group	Mean Improvement	Std. Deviation	t-value	p-value
Symptom Relief Score	Systane Ultra	5.2	1.1	2.45	0.016*
	Viscomet	3.6	1.4		

An Independent t test was used to check if there was a difference between the mean improvement of the two treatment protocols. The mean improvement score was higher in the Systane Ultra group (5.2 ± 1.1) compared to the Viscomet group (3.6 ± 1.4). The difference between the two was significantly different (p = 0.016), showing that Systane Ultra was more effective in decreasing the severity of symptoms than Viscomet in this study population.

DISCUSSION

The present study demonstrated a significant positive correlation between Dry Eye Disease (DED) severity and headache burden (r = 0.648, p = 0.001), indicating that worsening tear film dysfunction is associated with greater headache-related disability. These findings are consistent with Liu et al. (2022) and Ismail et al. (2019), who reported a strong association between DED and headache disorders, particularly migraine.

The observed relationship may be explained by shared trigeminovascular and neuroinflammatory pathways. Tear film instability and ocular surface inflammation can stimulate trigeminal nerve endings, resulting in referred pain that manifests as headache. Similar mechanisms have been described by Baksh et al. (2021), supporting the concept that DED may contribute to headache generation rather than simply coexist with it.

Both treatment groups showed significant improvement after four weeks of therapy; however, Systane Ultra produced greater symptomatic relief compared to Vismed (p = 0.016). This superior

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effect may be related to its HP-Guar-based formulation, which provides prolonged ocular surface protection and enhanced tear film stability.

These findings highlight the importance of evaluating dry eye in patients presenting with headache of unknown etiology. Early identification and treatment of DED may reduce headache burden, improve quality of life, and prevent unnecessary neurological investigations. Therefore, integrated ophthalmic and neurological assessment is recommended for patients with recurrent unexplained headaches.

CONCLUSION

This study demonstrated a significant positive association between Dry Eye Disease (DED) severity and headache burden, indicating that ocular surface dysfunction may be an important and often overlooked contributor to headaches of unknown etiology. The significant improvement in headache-related disability following treatment with polyethylene glycol 400, propylene glycol, and HP-Guar, as well as 0.18% sodium hyaluronate, suggests that headache symptoms in some patients may originate from tear film instability and ocular surface inflammation rather than primary neurological causes. These findings highlight the value of comprehensive dry eye assessment in patients presenting with unexplained headaches and support the incorporation of ocular surface evaluation into routine headache workups. Distinguishing DED-related headache from primary headache disorders may improve diagnostic accuracy, reduce misdiagnosis, and facilitate more targeted patient management.

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