INSIGHTS-IJHR
INSIGHTS-JOURNAL OF HEALTH AND REHABILITATION

ORIGINAL RESEARCH

Volume 4 | Issue 2 | 2026
ISSN: 3007-2948

Comparative Efficacy of Lipid-Based vs. Aqueous-Based Artificial Tears in the Management of Evaporative Dry Eye: A Randomized Clinical Trial

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CONFLICT OF INTEREST
None declared.

GRANT SUPPORT
None declared.

ARTICLE TYPE
Original Research

ABSTRACT

Purpose: This clinical trial aimed to determine whether a lipid-based artificial tear (Recuro) or an aqueous-based artificial tear (Softear) is more effective in alleviating symptoms of Evaporative Dry Eye (EDE).

Methods: This double-blind RCT was conducted at Mughal Eye Hospital, Lahore. Sample size (60 subjects, 30 subjects per group) was determined through G*Power. Subjects (18-55 years, all genders) received Recuro or Softear for 6 weeks, with allocation using block randomization (block size 4) done through Research Randomizer. The primary outcomes were the OSDI (Ocular Surface Disease Index) and the SANDE (Symptom Assessment in Dry Eye). The secondary outcomes were TBUT (Tear Break-Up Time), Schirmer's test I, and Meibomian gland expression.

Results: Data were processed using SPSS-23. Within and intergroup comparisons were done using paired and independent sample t-tests, respectively. The Recuro group achieved a greater mean reduction in OSDI (50.50 vs 30.43, $p<0.001$) and in SANDE scores (40.95 vs 32.63, $p=0.037$) compared to the Softear group. The Recuro group also demonstrated greater mean increments in TBUT (4.75 vs 3.92, $p<0.001$), Schirmer's test (6.16 vs 4.08, $p<0.001$), and Meibomian gland expression in both right (mean reduction: 5.48 vs 2.32, $p<0.001$) and left eyes (mean reduction: 6.02 vs 2.26, $p<0.001$). Both treatments were well-tolerated.

Conclusion: The P value analysis indicated statistical significance at less than 0.05, which demonstrates that Recuro artificial tears are more effective than Softeal tears in alleviating subjective and objective indicators of EDE.

Registration No: NCT06913387

KEYWORDS Artificial Tear,Dry Eye Disease,Evaporative Dry Eye

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INTRODUCTION

Dry Eye Disease (DED) is a chronic, multifactorial condition characterized by instability in the tear film and damage to the ocular surface, leading to dryness, irritation, and blurred vision.1 According to the TFOS DEWS III report, DED is defined by a loss of homeostasis, where tear film instability and hyperosmolarity serve as primary etiological factors.2 Any dysregulation in this balance results in decreased tear break-up time (TBUT) and increased ocular surface inflammation.

The tear film consists of three essential layers: the lipid, aqueous, and mucin layers.3 The structure of the lipid layer is particularly vital for maintaining tear properties and clinical management.4 DED is broadly categorized into aqueous-deficient (ADDE) and evaporative dry eye (EDE).5 EDE is particularly prevalent and strongly linked to Meibomian Gland Dysfunction (MGD), where glands produce inadequate quantity or quality of lipids, leading to faster evaporation.6

Modern environmental factors, particularly prolonged screen use, have exacerbated the prevalence of EDE by lowering blink rates and increasing tear evaporation.7 While traditional treatments supplement the aqueous layer,8 recent advancements focus on lipid-based nanoemulsions (such as Recuro) which stabilize the lipid layer and reduce evaporation.(9,10) This study aims to fill the gap in clinical knowledge by comparing these two distinct formulations to provide clear guidance for eye care practitioners.

METHODOLOGY

This study was a 6-month, double-blind randomized clinical trial conducted at Mughal Eye Hospital, Lahore. A total of 60 participants (30 per group) was determined using G*Power for a two-independent- means t-test, assuming a Cohen's d of 0.74 and 0.80 power. Participants were assigned to either the experimental or control group using block randomization (block size of 4) to ensure unbiased allocation.

Study Participant Selection: We recruited adults aged 18–55 years diagnosed with Evaporative Dry Eye. Inclusion required an Ocular Surface Disease Index (OSDI) score ≥13 and a TBUT < 10 seconds.11 We strictly excluded patients with active ocular infections, recent ocular surgery (within 6 months), contact lens wearers, or those with systemic conditions like Sjögren's syndrome to ensure the integrity of the results.

Interventions: The study utilized two intervention protocols. Group A (Experimental) received Recuro (Sodium carboxymethylcellulose 0.5%), the first lipid-based artificial tear in Pakistan designed to target all three tear layers. 10

GroupB (Control) received Softeal (Hypromellose 0.3%), an aqueous-based lubricant. Both groups were instructed to apply 1–2 drops, three times daily (morning, afternoon, and evening) for a duration of six weeks.

Data Collection and Instrumentation: Objective measurements were taken at baseline and Week 6. Tear film stability was measured via TBUT using fluorescein dye under slit-lamp examination.12 Tear volume was assessed using the Schirmer I test without anesthesia. Meibomian Gland Function was graded using the Meibum Test Score to evaluate lipid secretion quality. Subjective symptom relief was measured using both the OSDI and SANDE (Symptom Assessment in Dry Eye) questionnaires to capture a comprehensive view of patient comfort.

RESULTS

Demographic Profile and Shapiro-Wilk Normality Test

The study cohort consisted of 60 participants (29 males, 31 females) with an overall mean age of 34.25 ± 10.5 years. To verify the distribution of the dataset, a Shapiro-Wilk test was performed on all primary variables. All outcome measures, including OSDI, SANDE, TBUT, and MGE, yielded p- values greater than 0.05, confirming that the data was normally distributed. This normality justified the application of parametric statistical methods for all subsequent analyses.

Within-Group Analysis (Paired Sample T-Test)

A Paired Sample T-test was conducted to evaluate the efficacy of both interventions from baseline to the six-week follow-up. As detailed in Table 1, both the Recuro and Softeal groups showed statistically significant improvements across all subjective and objective markers ($p < 0.001$). Both treatments successfully reduced symptom severity and increased tear film stability, proving that both lipid-based and aqueous-based formulations are effective clinical interventions for dry eye management.

Table: Paired Sample T test:

	Mean	Std. Deviation	P-Value
PRE_OSDI	60.73	13.024	<0.001
POST_OSDI	20.27	5.740	
PRE_SANDE	55.49	7.087	<0.001
POST_SANDE	18.70	4.354	
PRE_SCHIRMIR	6.32	1.551	<0.001
POST_SCHIRMIR	11.44	1.178	
PRE_TBUT	6.535	1.0834	<0.001

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	Mean	Std. Deviation	P-Value
POST_TBUT	10.870	1.4209	
PRE_MGE_RT_EYE	7.17	1.797	<0.001
POST_MGE_RT_EYE	3.27	1.911	
PRE_MGE_LEFT_EYE	7.29	1.765	<0.001
POST_MGE_LEFT_EYE	3.14	1.861	

Comparative Efficacy (Independent Sample T-Test)

To determine the superior treatment protocol, an Independent Sample T- test was utilized to compare the post-treatment outcomes of both groups. While both interventions were successful, the Recuro (lipid-based) group demonstrated a statistically significant advantage over the Softeal (aqueous-based) group.

The lipid-based formulation resulted in significantly better tear film stability (TBUT) and a greater reduction in ocular discomfort (OSDI) compared to the aqueous-based control ($p < 0.001$). Specifically, Recuro was more effective in restoring Meibomian gland function, as evidenced by the significantly lower MGE scores at the conclusion of the study (see Table 2).

Table: Independent Sample T Test

GROUPS	Mean	Std. Deviation	Std. Error Mean	P-Value
PRE_OSDI	RECURO	67.77	11.640	<0.001
PRE_OSDI	SOFTEAL	53.70	10.356	<0.001
POST_OSDI	RECURO	17.27	4.354	<0.001
POST_OSDI	SOFTEAL	23.27	5.426	<0.001
PRE_SANDE	RECURO	58.48	5.493	<0.001
PRE_SANDE	SOFTEAL	52.50	7.317	<0.001
POST_SANDE	RECURO	17.53	4.819	.037
POST_SANDE	SOFTEAL	19.87	3.540	.037
PRE_SCHIRMIR	RECURO	5.91	1.665	.038
PRE_SCHIRMIR	SOFTEAL	6.74	1.330	.038
POST_SCHIRMIR	RECURO	12.07	1.070	<0.001
POST_SCHIRMIR	SOFTEAL	10.82	.929	<0.001
PRE_TBUT	RECURO	6.813	1.0595	.046
PRE_TBUT	SOFTEAL	6.257	1.0513	.046
POST_TBUT	RECURO	11.560	1.2934	<0.001
POST_TBUT	SOFTEAL	10.180	1.2041	<0.001
PRE_MGE_RT_EYE	RECURO	7.68	1.826	.027
PRE_MGE_RT_EYE	SOFTEAL	6.66	1.643	.027
POST_MGE_RT_EYE	RECURO	2.20	1.428	<0.001
POST_MGE_RT_EYE	SOFTEAL	4.34	1.738	<0.001
PRE_MGE_LEFT_EYE	RECURO	8.12	1.598	<0.001
PRE_MGE_LEFT_EYE	SOFTEAL	6.45	1.533	<0.001
POST_MGE_LEFT_EYE	RECURO	2.10	1.474	<0.001
POST_MGE_LEFT_EYE	SOFTEAL	4.19	1.617	<0.001

DISCUSSION

The primary finding of this study is that Recuro (lipid-based) provides a more comprehensive therapeutic effect for EDE compared to Softeal. While both drops provided relief, the lipid-based nanoemulsion directly addressed the root cause of EDE—lipid layer deficiency. By mimicking the natural Meibomian secretions, Recuro creates a more stable barrier against evaporation, which explains why the TBUT results in Group A were significantly higher than those in Group B.

Our findings are highly consistent with international research. Quisisana et al.(2020) demonstrated that lipid-based tears significantly improve TBUT and OSDI scores over a 6-week period.13

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Similarly, Semp et al.(2023) confirmed that lipid-containing formulations are superior for stabilizing the tear film and reducing evaporation in patients with MGD.14 Our data also mirrors the SAHARA trial results, which showed that targeting the lipid layer leads to faster and more sustained symptomatic relief than traditional aqueous approaches.15

For eye care practitioners, these results suggest that the choice of artificial tear should be specific to the DED subtype. While aqueous tears (Softeal) are effective for volume replacement, they do not address the high evaporation rates characteristic of EDE. This study proves that a lipid-based formulation (Recuro) should be considered a first-line therapy for patients presenting with MGD or EDE, especially those with high digital screen exposure. (7,16)

Study results may have been influenced by individual dosage variability and the short 6-week treatment duration. Additionally, the comparison was limited to only two specific products. The inclusion of lifestyle advice (the 20-20-20 rule) at the start of the study may have also contributed to the overall improvement in symptoms.

Future research should focus on long-term efficacy (6 months or more) and include specialized groups such as contact lens wearers and post-cataract surgery patients. Comparing lipid-based tears against a broader range of existing products would also help establish more comprehensive treatment protocols.

CONCLUSION

This study demonstrates that while both aqueous and lipid-based artificial tears provide clinical benefits, Recuro (lipid-based) is significantly more effective in restoring tear film stability and relieving symptoms in EDE patients. These findings suggest that lipid-layer stabilization should be a primary goal in the management of evaporative dry eye.

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