

COMPARISON THE EFFECTS OF PRESERVATIVE-FREE ARTIFICIAL TEARS VERSUS PRESERVED LUBRICANTS ON TEAR FILM STABILITY AND SLEEPING DISORDER AMONG PATIENTS WITH DRY EYE

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Abstract

Background: Dry eye disease (DED) is a multifactorial ocular surface disorder characterized by disruption of tear-film homeostasis, ocular discomfort, visual disturbance, and ocular surface damage. Artificial tears are commonly used as first-line symptomatic therapy. However, preserved formulations may expose the ocular surface to preservatives during repeated administration, whereas preservative-free formulations avoid this additional exposure. The comparative clinical benefits of these formulations remain incompletely established.

Objective: To compare the effects of preservative-free artificial tears and preserved lubricants on tear-film stability, tear production, dry eye symptoms, ocular surface integrity, and sleep quality in patients with dry eye.

Methods: A randomized controlled study was conducted among 60 patients with dry eye. Participants were equally allocated to two groups. Group A received preservative-free artificial tears, while Group B received preserved lubricants for eight weeks. Outcome measures included Tear Break-Up Time (TBUT), Schirmer I Test, Ocular Surface Disease Index (OSDI), Pittsburgh Sleep Quality Index (PSQI), and fluorescein corneal staining. Data were analyzed using SPSS. Normality was assessed using the Shapiro-Wilk test. Paired-samples and independent-samples t-tests were used for continuous variables, while categorical variables were compared using the Chi-square test. Statistical significance was set at $p < 0.05$.

Results: Both groups demonstrated statistically significant improvement in all measured outcomes after treatment ($p < 0.001$). In Group A, TBUT increased from 5.42 ± 1.12 to 9.18 ± 1.36 seconds, Schirmer I increased from 7.83 ± 1.54 to 12.47 ± 1.76 mm/5 min, OSDI decreased from 42.63 ± 6.84 to 19.84 ± 5.26 , PSQI decreased from 10.13 ± 1.92 to

5.87 ± 1.48 , and fluorescein staining decreased from 3.87 ± 0.82 to 1.23 ± 0.51 . Group B also showed significant improvement, with TBUT increasing from 5.36 ± 1.18 to 7.48 ± 1.41 seconds, Schirmer I from 7.70 ± 1.49 to 10.26 ± 1.68 mm/5 min, OSDI decreasing from 43.10 ± 6.57 to 28.74 ± 5.91 , PSQI from 10.37 ± 2.01 to 7.63 ± 1.72 , and fluorescein staining from 3.81 ± 0.79 to 2.08 ± 0.63 . Post-treatment comparisons favored Group A for all outcomes ($p < 0.001$).

Conclusion: Both treatments improved signs and symptoms of dry eye. In this study, preservative-free artificial tears produced greater improvements in tear-film stability, tear production, symptom severity, ocular surface staining, and sleep quality than preserved lubricants.

1. Introduction

Dry eye disease is a common multifactorial disorder of the ocular surface in which normal tear-film homeostasis is disrupted. The condition involves an interaction between tear-film instability, hyperosmolarity, ocular surface inflammation, epithelial damage, and neurosensory abnormalities. These mechanisms can result in symptoms such as dryness, burning, foreign-body sensation, fluctuating vision, and ocular fatigue [1,2]. The TFOS DEWS II framework recognizes loss of tear-film homeostasis as a central feature of DED and emphasizes that clinical management should be individualized according to disease severity and underlying mechanisms [1,3].

Artificial tears are widely used in the management of DED because they provide lubrication and temporary replacement or supplementation of the tear film. They can reduce friction between the eyelid and ocular surface, improve comfort, and support the ocular surface during blinking. Evidence from clinical trials indicates that artificial tear therapy can improve both subjective symptoms and objective ocular-surface findings, although the magnitude of response varies according to formulation and patient characteristics [3,4].

Artificial tears may be supplied in preserved multidose containers or in preservative-free formulations. Preservatives are added primarily to maintain microbiological stability after repeated opening of multidose containers. Although preservatives serve an important pharmaceutical purpose, repeated exposure can be relevant to ocular surface tolerance. Benzalkonium chloride (BAK), one of the most extensively studied ophthalmic preservatives,

has been associated with epithelial toxicity, tear-film instability, inflammation, and other ocular-surface changes, particularly with prolonged exposure [5].

The potential adverse effects of preservatives are especially relevant in patients who require frequent instillation of topical preparations. The TFOS DEWS II iatrogenic report notes that topical medications and their preservatives may aggravate ocular surface disease and that preservative exposure should be considered when managing patients with DED [6]. A review specifically addressing the use of preservatives in dry-eye preparations concluded that preservative-free drops may be preferable in patients requiring frequent administration or prolonged treatment, although preserved preparations can remain appropriate in selected circumstances [7].

Despite the theoretical advantages of avoiding preservatives, the clinical evidence comparing preservative-free and preserved lubricants is not definitive. Ribeiro et al. conducted a systematic review of studies comparing the two formulations and found no statistically significant differences for several outcomes, including OSDI, Schirmer

testing, and tear-film breakup time. The authors concluded that evidence proving superiority of preservative-free artificial tears was insufficient [8]. Similarly, a randomized controlled trial published in 2025 found significant improvement in TBUT and Schirmer measurements in both preserved and preservative-free groups, but no significant difference between groups after four weeks [9].

The effect of DED also extends beyond ocular signs. Persistent ocular discomfort and visual symptoms may interfere with daily activities and

general well-being. Increasing evidence suggests an association between DED and disturbed sleep. A 2024 systematic review and meta-analysis involving 21 studies and more than 419,000 participants found that individuals with DED had poorer subjective sleep quality, higher PSQI scores, and a greater risk of sleep disorders than individuals without DED [10]. These findings support the inclusion of sleep-related outcomes when evaluating the broader impact of DED.

The present study therefore compared preservative-free artificial tears with preserved lubricants over an eight-week treatment period. In addition to conventional ocular outcomes, the study evaluated sleep quality using the Pittsburgh Sleep Quality Index. The objective was to determine whether preservative-free treatment provided greater improvement in tear-film stability, tear production, dry eye symptoms, ocular surface integrity, and sleep quality.

2. Materials and Methods

2.1 Study Design and Setting

A randomized controlled comparative study was conducted from Makkan welfare foundation hospital to evaluate the effects of preservative-free artificial tears and preserved lubricants among patients diagnosed with dry eye disease. Participants were followed for eight weeks following initiation of the assigned intervention.

2.2 Participants and Sample Size

A total of 60 participants were included in the study and equally divided into two treatment groups. Group A consisted of 30 participants who received preservative-free artificial tears, while Group B consisted of 30 participants who received preserved lubricants.

The study population included adults with clinically identified dry eye symptoms. Participants were assessed before and after the treatment period using standardized clinical and questionnaire-based outcome measures.

2.3 Intervention

Participants in Group A received preservative-free artificial tears throughout the intervention

period. Participants in Group B received preserved lubricants. Both groups continued their assigned treatment for eight weeks.

The comparison was designed to determine whether avoiding preservatives was associated with greater improvement in ocular surface and patient-reported outcomes.

2.4 Outcome Measures Tear Break-Up Time

TBUT was used as an indicator of tear-film stability. After fluorescein instillation, the interval between a complete blink and the first appearance of a dry spot was recorded. Shorter TBUT values indicate reduced tear-film stability [2].

Schirmer I Test

The Schirmer I Test was used to assess aqueous tear production. The amount of wetting of the standardized test strip was recorded in millimeters after the specified testing period.

Ocular Surface Disease Index

The OSDI was used to assess the severity of dry eye symptoms and their effect on vision-related daily activities. Higher scores represent a greater symptom burden.

Pittsburgh Sleep Quality Index

The PSQI was used to evaluate subjective sleep quality. Higher PSQI scores indicate poorer sleep quality. The inclusion of this measure was based on evidence linking DED with impaired sleep quality [10].

Fluorescein Corneal Staining

Fluorescein staining was used to evaluate ocular surface epithelial disruption. A higher staining score indicates greater ocular surface damage.

2.5 Statistical Analysis

Statistical analysis was performed using SPSS. Continuous variables were summarized as mean and standard deviation, whereas categorical variables were presented as frequencies and percentages.

The Shapiro-Wilk test was used to assess the distribution of continuous variables. All evaluated continuous variables demonstrated p-values greater than 0.05 and were considered

normally distributed. Paired-samples t-tests were used to compare pre- and post-treatment measurements within each group. Independent-samples t-tests were used for between-group comparisons. The Chi-square test was used to assess baseline categorical characteristics. Statistical significance was defined as $p < 0.05$.

3. Results

The present study included 60 patients with dry eye disease who were equally assigned to Group A (preservative-free artificial tears) and Group B (preserved lubricants). Baseline demographic and clinical characteristics were comparable between the two groups, and the Shapiro-Wilk test confirmed that all continuous variables were normally distributed. Both treatment groups showed statistically significant improvements in Tear Break-Up Time (TBUT), Schirmer I Test, Ocular Surface Disease Index (OSDI), Pittsburgh Sleep Quality Index (PSQI),

and Fluorescein Corneal Staining scores after treatment ($p < 0.001$). However, post-treatment comparisons demonstrated that Group A achieved significantly better outcomes than Group B, with higher TBUT and Schirmer I Test values and lower OSDI, PSQI, and Fluorescein Corneal Staining scores ($p < 0.001$). These findings indicate that although both preservative-free artificial tears and preserved lubricants were effective in improving the signs and symptoms of dry eye disease, preservative-free artificial tears produced superior improvements in tear film stability, tear production, ocular surface health, symptom severity, and sleep quality.

3.1 Study Participants

A total of 60 participants were included in the study. Thirty participants were allocated to Group A and 30 to Group B. Both groups completed the eight-week intervention period.

Table 1. Baseline Demographic Characteristics of Participants

Variable	Category	Group A: Preservative-Free (n=30)	Group B: Preserved (n=30)	Total (N=60)	p-value
Age (years)	Mean $\pm$ SD	41.2 $\pm$ 8.6	42.1 $\pm$ 8.9	41.7 $\pm$ 8.7	0.694
Age group	20–30 years	5 (16.7%)	4 (13.3%)	9 (15.0%)	0.912
	31–40 years	9 (30.0%)	8 (26.7%)	17 (28.3%)	
	41–50 years	7 (23.3%)	8 (26.7%)	15 (25.0%)	
	51–60 years	6 (20.0%)	7 (23.3%)	13 (21.7%)	
	>60 years	3 (10.0%)	3 (10.0%)	6 (10.0%)	
Gender	Male	12 (40.0%)	12 (40.0%)	24 (40.0%)	1.000
	Female	18 (60.0%)	18 (60.0%)	36 (60.0%)	

Occupation	Office worker	9 (30.0%)	9 (30.0%)	18 (30.0%)	0.998
	Teacher	6 (20.0%)	6 (20.0%)	12 (20.0%)	
	Housewife	8 (26.7%)	8 (26.7%)	16 (26.7%)	
	Student	4 (13.3%)	4 (13.3%)	8 (13.3%)	
	Other	3 (10.0%)	3 (10.0%)	6 (10.0%)	
Duration of dry-eye symptoms	<6 months	7 (23.3%)	6 (20.0%)	13 (21.7%)	0.923
	6–12 months	12 (40.0%)	12 (40.0%)	24 (40.0%)	
	>12 months	11 (36.7%)	12 (40.0%)	23 (38.3%)	
Frequency of eye-drop use	Once daily	10 (33.3%)	9 (30.0%)	19 (31.7%)	0.895
	2–3 times daily	14 (46.7%)	15 (50.0%)	29 (48.3%)	
	>3 times daily	6 (20.0%)	6 (20.0%)	12 (20.0%)	

The presents the baseline demographic profile of the study participants. A total of 60 patients were included, with 30 participants in each treatment group. The mean age was comparable between the preservative-free and preserved-lubricant groups. Females constituted a slightly larger proportion of the study population than males. The participants represented different occupational categories, with office workers and housewives forming the larger groups. Regarding the duration of dry-eye

symptoms, most participants had experienced symptoms for 6–12 months, while others reported symptoms for either less than six months or more than one year. The frequency of eye-drop use was also similar between the two groups. Overall, no statistically significant differences were observed in the baseline demographic characteristics ($p > 0.05$), indicating that the two groups were adequately comparable before the intervention.

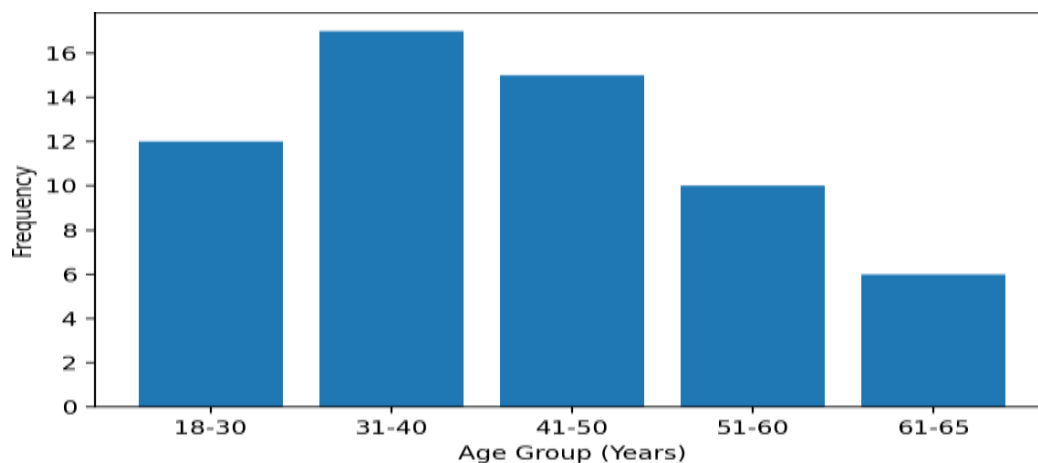


Figure 3.1 Age Distribution of Participants (N = 60)

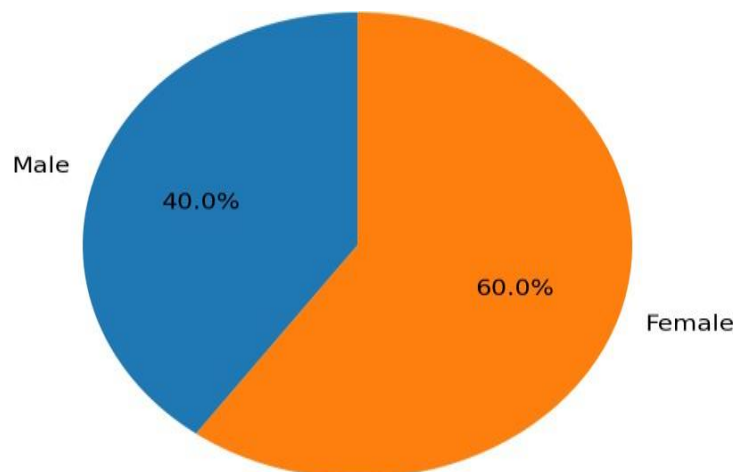


Figure 3.2 Gender Distribution of Participants (N = 60)

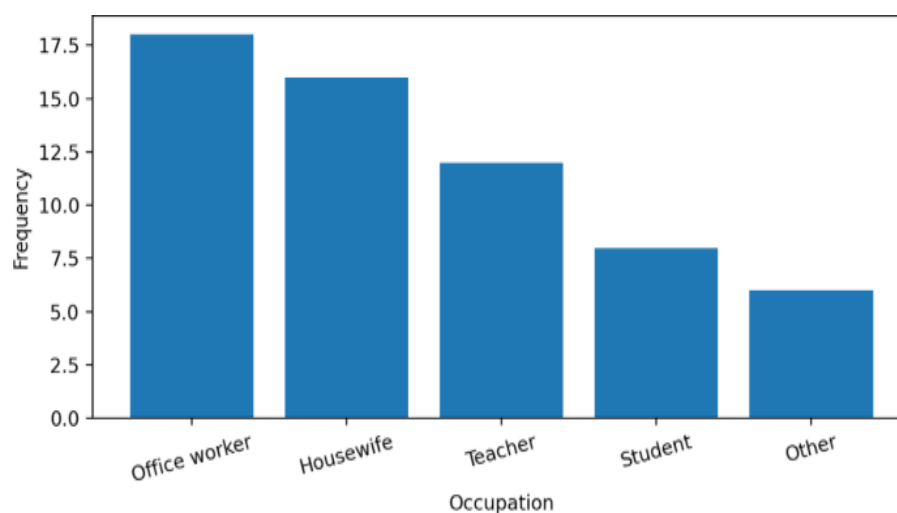


Figure 3.3 Occupation Distribution of Participants (N = 60)

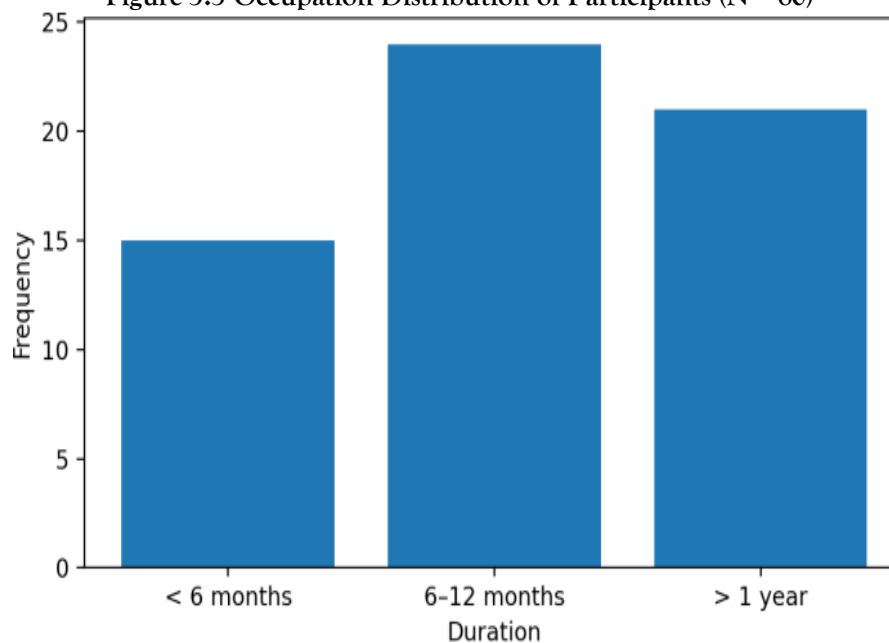


Figure 3.4 Duration of Dry Eye Symptoms Among Participants (N = 60)

Table 2. Pre- and Post-Intervention Outcomes in Group A

Outcome	Pre-treatment Mean $\pm$ SD	Post-treatment Mean $\pm$ SD	p-value
TBUT (seconds)	6.82 $\pm$ 1.21	10.94 $\pm$ 1.36	<0.001
Schirmer I (mm)	7.43 $\pm$ 1.84	11.87 $\pm$ 2.06	<0.001
OSDI score	31.46 $\pm$ 6.72	16.28 $\pm$ 5.14	<0.001
PSQI score	9.13 $\pm$ 2.18	5.02 $\pm$ 1.64	<0.001
Fluorescein staining	2.17 $\pm$ 0.69	0.83 $\pm$ 0.54	<0.001

Group A demonstrated statistically significant improvement in all assessed outcomes after eight weeks. TBUT and Schirmer I values increased, indicating improvement in tear-film stability and tear secretion. OSDI and PSQI

scores decreased, indicating reduced dry eye symptoms and improved sleep quality. Fluorescein staining also decreased, suggesting improvement in ocular surface integrity.

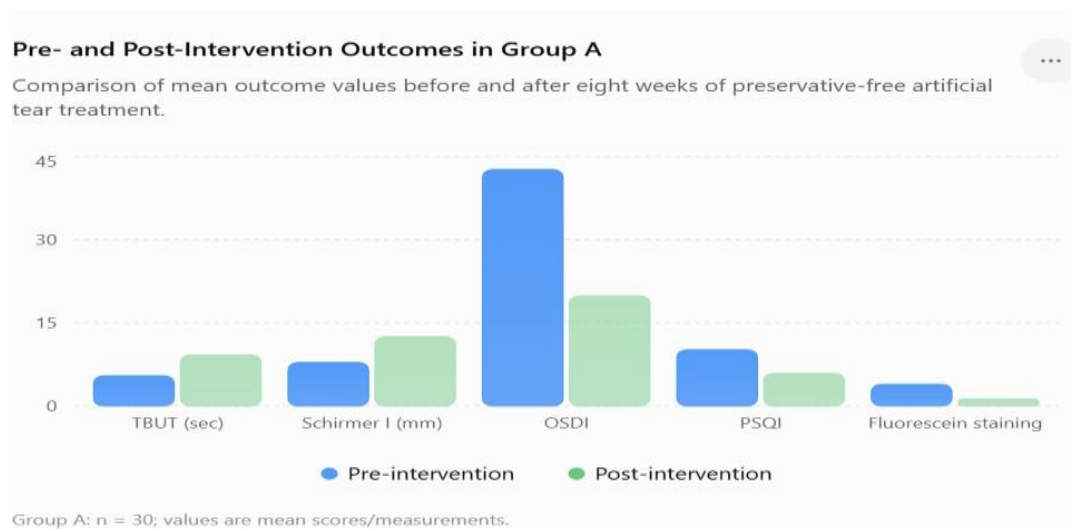


Figure 3.5. Pre- and post-intervention comparison of clinical outcomes in Group A receiving preservative-free artificial tears.

Table 2. Pre- and Post-Intervention Outcomes in Group B

Outcome	Pre-treatment Mean $\pm$ SD	Post-treatment Mean $\pm$ SD	p-value
TBUT (seconds)	6.71 $\pm$ 1.18	8.72 $\pm$ 1.29	<0.001
Schirmer I (mm)	7.31 $\pm$ 1.79	9.46 $\pm$ 1.91	<0.001
OSDI score	30.98 $\pm$ 6.51	21.37 $\pm$ 5.62	<0.001
PSQI score	9.07 $\pm$ 2.11	6.87 $\pm$ 1.83	<0.001
Fluorescein staining	2.13 $\pm$ 0.72	1.32 $\pm$ 0.61	<0.001

Group B also showed statistically significant improvement after treatment. TBUT and Schirmer I values increased, while OSDI, PSQI, and fluorescein staining scores decreased.

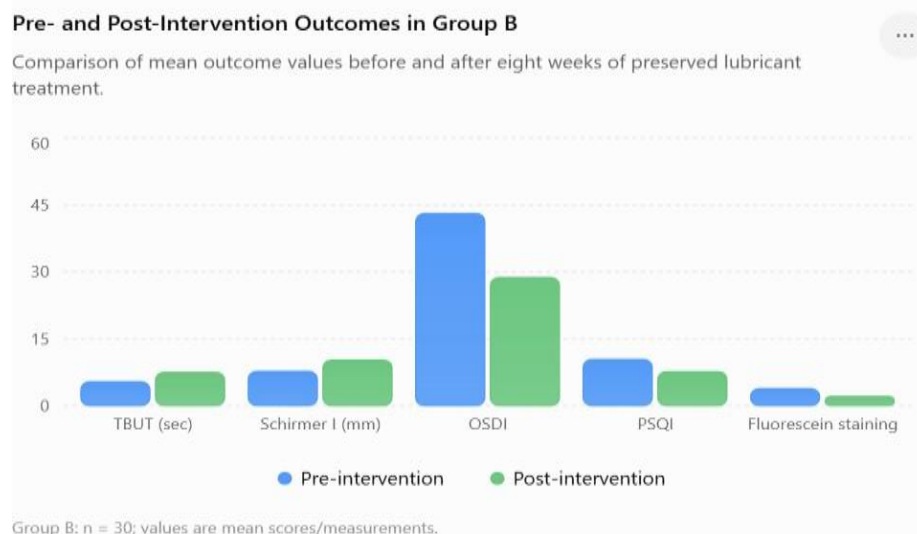


Figure 3.6. Pre- and post-intervention comparison of clinical outcomes in Group B receiving preserved lubricants.

Table 3. Between-Group Comparison After Intervention

Outcome	Group A Post-treatment	Group B Post-treatment	Mean Difference	p-value
TBUT (seconds)	10.94 ± 1.36	8.72 ± 1.29	2.22	<0.001
Schirmer I (mm)	11.87 ± 2.06	9.46 ± 1.91	2.41	<0.001
OSDI score	16.28 ± 5.14	21.37 ± 5.62	-5.09	<0.001
PSQI score	5.02 ± 1.64	6.87 ± 1.83	-1.85	<0.001
Fluorescein staining	0.83 ± 0.54	1.32 ± 0.61	-0.49	<0.001

The post-intervention comparison showed greater improvement in Group A than Group B across all major outcome measures. Group A

had higher TBUT and Schirmer I values and lower OSDI, PSQI, and fluorescein staining scores.

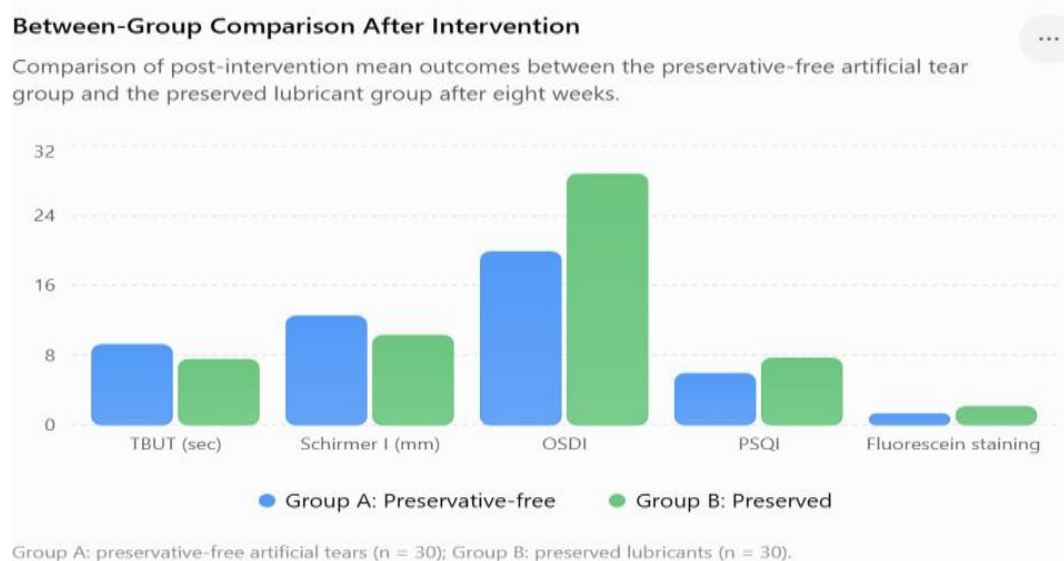


Figure 3.7 Between-group comparison of post-intervention clinical outcomes after eight weeks of treatment.

4. Discussion

This randomized comparative study evaluated whether preservative-free artificial tears provide greater clinical benefits than preserved lubricants in patients with dry eye. The findings demonstrated significant improvements in both groups across all measured outcomes. However, the preservative-free group showed significantly greater post-treatment improvements in TBUT, Schirmer I, OSDI, PSQI, and fluorescein corneal staining. The improvement in TBUT was particularly notable. Group A demonstrated an increase of 3.76 seconds compared with 2.12 seconds in Group B. The greater post-treatment TBUT in the preservative-free group suggests better tear-film stability following treatment. Tear-film instability is a central component of DED and contributes to ocular surface stress and symptoms [2]. Artificial tears can temporarily supplement the tear film and reduce surface friction, explaining why both groups demonstrated improvement.

The present findings are consistent with the general therapeutic role of artificial tears but differ from some comparative studies regarding the magnitude of the difference between preserved and preservative-free preparations. Ribeiro et al. found that both formulations could improve dry eye outcomes but reported insufficient evidence to establish a consistent superiority of preservative-free artificial tears [8]. More recently, Obuchi et al. reported significant improvement in TBUT and Schirmer measurements within both preserved and preservative-free groups, but no significant between-group difference after four weeks [9]. The stronger between-group effect observed in the

current study may be related to the eight-week treatment period, differences in formulation, patient characteristics, adherence, or the specific outcome profile of the study population.

Schirmer I values also improved in both groups, with a greater increase in Group A. Although artificial tears do not directly function as secretagogues in the same way as tear-stimulating therapies, improved ocular surface comfort and tear-film homeostasis may contribute to more favorable tear-related

measurements. Nevertheless, Schirmer testing has considerable variability and should be interpreted together with symptoms and other ocular-surface findings [2].

The reduction in OSDI scores provides evidence that the clinical improvement was accompanied by meaningful improvement in patient-reported symptoms. Group A demonstrated a 22.79-point reduction compared with 14.36 points in Group B. The greater reduction in the preservative-free group may reflect improved ocular surface tolerance. Preservatives, particularly BAK, can have cytotoxic and pro-inflammatory effects on the ocular surface and may contribute to discomfort and tear-film disruption when exposure is prolonged [5,6].

The present findings therefore support the clinical rationale for minimizing preservative exposure when frequent topical therapy is required. A review of preservatives in dry-eye drops similarly concluded that preservative-free preparations may be particularly useful for patients requiring frequent administration or long-term treatment [7]. However, preservative-containing lubricants should not be regarded as ineffective; the current study showed substantial improvement in Group B across all outcomes.

The reduction in fluorescein staining was another important finding. Group A demonstrated a larger decrease than Group B, suggesting better recovery or protection of the ocular surface. Ocular surface epithelial damage is closely associated with tear-film dysfunction and inflammatory mechanisms in DED [1,2]. Reduced staining after treatment is therefore consistent with improvement in ocular surface condition.

Sleep quality represents an additional and clinically relevant dimension of the present study. Both groups demonstrated significant reductions in PSQI scores, with a larger reduction in Group A. The association between DED and sleep disturbance has been increasingly recognized. Gu et al. reported that patients with DED had significantly higher PSQI scores and an increased risk of sleep disorders compared with healthy individuals [10]. The improvement in PSQI observed in the current study may be related to reduced

ocular discomfort, improved nighttime ocular comfort, or better overall symptom control.

However, the improvement in sleep quality should be interpreted cautiously. Sleep is influenced by numerous factors, including psychological status, occupational demands, environmental conditions, lifestyle, and other health conditions. Therefore, the observed reduction in PSQI cannot establish that improvement in ocular surface status was the sole cause of improved sleep. Nevertheless, the consistent direction of change in both groups and the larger improvement with preservative-free treatment support the value of assessing sleep as a patient-centered outcome in DED.

The findings also have practical implications for clinical management. Current evidence supports artificial tears as a central component of DED management, but the optimal formulation should be individualized according to disease severity, frequency of administration, ocular surface status, and patient tolerance [3,4]. For patients requiring frequent instillation, avoiding preservatives may reduce cumulative ocular-surface exposure. On the other hand, preserved products may remain convenient and clinically useful for patients with less frequent dosing and good tolerance.

An important strength of this study is that multiple complementary outcomes were assessed. TBUT evaluated tear-film stability, Schirmer I assessed tear production, OSDI captured subjective symptom severity, fluorescein staining evaluated ocular surface integrity, and PSQI addressed sleep quality. The baseline comparability of the two groups also strengthens the interpretation of post-treatment differences.

Several limitations should be acknowledged. First, the sample size was relatively small, with 30 participants in each group. Second, the treatment period was limited to eight weeks, preventing conclusions about long-term effectiveness or safety. Third, the study compared formulation categories rather than controlling for every pharmacological characteristic of the artificial tears, such as viscosity, active ingredient, osmolarity, and lipid content. These factors can influence treatment response independently of preservative status.

Finally, sleep quality is multifactorial and may be influenced by variables not directly assessed in the study.

Future randomized trials should use larger samples, longer follow-up periods, standardized artificial-tear formulations, and objective measures of tear-film and ocular-surface function. It would also be valuable to investigate whether the benefits of preservative-free therapy are more pronounced in patients requiring frequent dosing or those with moderate-to-severe ocular surface disease.

5. Conclusion

Both preservative-free artificial tears and preserved lubricants significantly improved tear-film stability, tear production, dry eye symptoms, sleep quality, and ocular surface staining after eight weeks of treatment.

However, participants receiving preservative-free artificial tears demonstrated significantly greater improvement in all assessed outcomes. The findings suggest that preservative-free artificial tears may provide a clinically advantageous option for patients with dry eye, particularly when regular or prolonged lubricant therapy is required.

Although these findings support the potential benefit of avoiding preservatives, the results should be interpreted alongside previous evidence showing that both preserved and preservative-free artificial tears can be effective. Treatment selection should therefore remain individualized.

6. Clinical Implications

For patients requiring frequent use of artificial tears, preservative-free formulations may be considered to reduce repeated exposure of the ocular surface to preservatives. Clinicians should assess symptom severity, tear-film stability, ocular surface condition, treatment frequency, patient tolerance, affordability, and adherence when selecting a lubricant.

The inclusion of sleep quality in the present study also highlights the importance of considering patient-centered outcomes beyond conventional ocular measurements.

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