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COMPARATIVE STUDY OF PRESERVATIVE-FREE AND PRESERVED LUBRICANTS ON TEAR FILM INTEGRITY AND SLEEP QUALITY IN PATIENTS WITH DRY EYES

Urooj Fatima[*1], Dr. Umara Shafiq[2], Amina[3], Muhammad Naveed Babar[4], Muhammad Ali[5]

*[*1,3]Ms. Rehabilitation Sciences (low vision) Superior University, Lahore*
[2]Consultant ophthalmologist and eye surgeon
[4]Dean of department of AHS in superior University
[5]Senior Orthoptist / Optometrist, MS Rehab.in Clinical optometry & Low Vision Sciences (SU), Jinnah hospital, Lahore

[*1]uroojfatimahh@gmail.com, [2]ummarashafiq@yahoo.com, [3]dramina12277@gmail.com, [4]naveed.babur@superior.edu.pk, [5]aliorthoptist@gmail.com

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Urooj Fatima

Abstract

Background: *Dry eye disease (DED) is a complex disorder of the ocular surface, which is associated with disruption of tear-film homeostasis, visual disturbance, discomfort and damage to the ocular surface. Artificial tears are frequently first line symptomatic treatment. But repeated use of preserved formulations can lead to exposure of the ocular surface to preservatives, while preservative-free formulations do not expose the surface to the preservatives of the formulation. It is not completely clear how these formulations compare to each other clinically.*

Objective: *To evaluate the tear-film integrity (tear-film stability and corneal staining) of preservative-free artificial tears compared to preserved lubricants, tear production, dry eye symptoms and subjective sleep quality in dry eye patients.*

Methods: *60 patients suffering from dry eye were included in a randomized controlled study. The participants were randomly divided into two groups. Preserved lubricants were given for 8 weeks to Group B, and preservative-free artificial tears were given to Group A. The following outcome measures were evaluated: Tear Break-Up Time (TBUT), Schirmer I Test, Ocular Surface Disease Index (OSDI), Pittsburgh Sleep Quality Index (PSQI), and fluorescein corneal staining. Data analysed using SPSS. Shapiro–Wilk test was used to assess normality. Continuous variables were compared using paired-samples or independent-samples t-test; categorical variables were compared using Chi-square test. A two-tailed p value of < 0.05 was considered statistically significant.*

Results: *The five outcomes reported were improved in both groups after eight weeks (reported within-group $p < 0.001$). In Group A (preservative-free), TBUT increased from 6.82 ± 1.21 to 10.94 ± 1.36 seconds and Schirmer I from 7.43 ± 1.84 to 11.87 ± 2.06 mm; OSDI decreased from 31.46 ± 6.72 to 16.28 ± 5.14, PSQI from 9.13 ± 2.18 to 5.02 ± 1.64, and fluorescein staining from 2.17 ± 0.69 to 0.83 ± 0.54. In Group B (preserved), corresponding changes were 6.71 ± 1.18 to 8.72 ± 1.29 seconds for TBUT, 7.31 ± 1.79 to 9.46 ± 1.91 mm for Schirmer I, 30.98*

± 6.51 to 21.37 ± 5.62 for OSDI, 9.07 ± 2.11 to 6.87 ± 1.83 for PSQI, and 2.13 ± 0.72 to 1.32 ± 0.61 for corneal staining. The comparisons after the treatment were reported to favor Group A ($p < 0.001$).

Conclusion: *Ocular and subjective sleep outcomes significantly improved in both treatment groups after 8 weeks. Preservative-free artificial tears were reported as the superior tear-film stability, corneal staining, sleep quality, and tear production, and as the superior assess of dry eye symptom burden. These results are related to subjective sleep quality, not sleep disorders.*

1. Introduction

Dry eye disease is a frequent, multifactorial ocular surface disease in which the normal tear-film homeostasis is disturbed. It is a vicious cycle of tear-film instability, hyperosmolarity, inflammation of the ocular surface, damage to the cornea's upper layer, and neurosensory abnormalities. These mechanisms may lead to symptoms of ocular fatigue, foreign-body sensation, fluctuating vision, and dryness (Craig et al., 2017; Wolffsohn et al., 2017).

Loss of tear-film homeostasis has been identified as a key component of DED in the TFOS DEWS II framework and a key consideration in clinical management should be to tailor the approach to the severity and underlying mechanisms of the disease (Craig et al., 2017; Jones et al., 2017).

Artificial tears are used extensively in the treatment of DED because they are used to lubricate and to temporarily replace and/or supplement the tear film. They can minimize the rubbing of the eyelid on the eye surface, make the eye surface more comfortable, and aid in the movement of the eye surface during blinking. Artificial tear therapy has been shown to have an effect on both subjective and objective measures of eye changes of the surface in clinical trials, but the response has been variable by formulation and patient (Craig et al., 2021; Jones et al., 2017).

Preserved multidose and preservative free artificial tears can be supplied. The main reason for adding preservatives is to preserve microbiological stability after multiple opening of multidose containers. Preservatives have a valuable pharmaceutical function but chronic exposure can be significant with regard to tolerance of the ocular surface. Benzalkonium chloride (BAK), one of the most widely studied ophthalmic preservatives, has been linked to changes in the eye's surface, such as epithelial toxicity, tear-film instability, inflammation and other changes, especially when used for longer periods (Baudouin, Labbé, Liang, Pauly, & Brignole-Baudouin, 2010).

Adverse effects of preservatives are particularly important in patients who use topical products on a frequent basis. The TFOS DEWS II iatrogenic report discusses how topical medications and preservatives can worsen OSD and the importance of avoiding preservatives when treating patients with DED (Gomes et al., 2017). A review on the topic of using preservatives in dry-eye preparations found that preservative-free formulations might be more suitable in those who need to apply their ocular drops more often or for longer, but preserved preparations could be useful in specific cases (Walsh & Jones, 2019).

While there are theoretical benefits to using preservative-free lubricants, there is not conclusive clinical evidence that can be used to compare preservative-free and preserved lubricants. In a systematic review of studies that compared the two formulations, Ribeiro et al. did not find a statistically significant difference between them for several outcomes such as OSDI, Schirmer testing, and tear-film breakup time. The authors found inadequate evidence of superiority of artificial tears without preservative (Ribeiro, Barbosa, Ribeiro, Sousa-Rodrigues, & Ribeiro, 2019). Likewise, the TBUT and Schirmer values improved in both preserved and preservative free groups in a 2025 randomized controlled trial, and there was no significant difference between the groups following 4 weeks (Obuchi, Ifeanyi, & Eghosasere, 2025).

DED also has an impact beyond ocular signs. Symptoms affecting the eye can cause long-term discomfort and impair vision, which can negatively affect a person's daily life and overall health. There is growing evidence that there is

a link between DED and disturbed sleep. The study by Roberts et al. (2024) was a systematic review and meta-analysis that included 21 studies, with over 419,000 participants, showing that DED had a significant impact on sleep quality, with higher PSQI scores and an increased risk of sleep disorders (Gu et al., 2024). The results confirm the need to consider sleep-related outcomes in assessing the overall impact of DED.

This study therefore compared preservative-free artificial tears with preserved lubricants in treatment for 8 weeks. This study also looked at sleep quality (using the Pittsburgh Sleep Quality Index), as well as the traditional eye-related outcomes. The aim of this study was to see if preservative-free treatment brought a greater improvement in the tear film stability, tear production, dry eye symptoms, and integrity of the ocular surface and sleep quality.

2. Materials and Methods

a. Study Design and Setting

Preservative free artificial tears versus preserved lubricants were compared through a randomized controlled comparative trial in Makkah welfare foundation hospital for dry eye patients. Participants were then followed up for eight weeks after initiation of intervention.

b. Participants and Sample Size

The total number of participants was 60 divided into two treatment groups. The first group (Group A) included 30 participants, and the second group (Group B) included 30 participants who were given preservative-free artificial tears. There were 30 participants in Group A, and 30 in the second group (Group B) who were given preserved lubricants.

This study targeted adult population with clinically diagnosed dry eye symptoms. Standardized clinical and questionnaire-based outcome measures were used to evaluate participants pre- and post-treatment.

c. Intervention

All subjects in Group A were given preservative free artificial tears during the intervention period. Conserved lubricants were provided for the participants of group B. All groups received the same treatment for 8 weeks. For 8 weeks both groups were treated as usual.

The comparison was used to see if there was an association between the use of preservative-free and higher levels of OME and higher levels of patient-reported outcomes.

d. Outcome Measures Tear Break-Up Time

The tear-film stability was used as an indicator of TBUT. The time lapse from a full blink to the first spot of dryness was measured after instillation of fluorescein. A shorter TBUT will reflect less stability of the tear film (Wolffsohn et al., 2017).

Schirmer I Test

The Schirmer I Test was used to assess aqueous tear production. The test results were measured as a number of millimeters of wetting of the standardized test strip after the set time.

Ocular Surface Disease Index

The OSDI was used to determine the severity of dry eye symptoms and how this impacts vision-related activities in the day-to-day world. A higher score indicates more burden of symptoms.

Pittsburgh Sleep Quality Index

Subjective sleep quality was assessed by using PSQI. Higher PSQI scores represent worse sleep quality. This measure was included based on research that related DED with poor sleep quality (Gu et al., 2024).

Fluorescein Corneal Staining

Fluorescein staining was used to evaluate ocular surface epithelial disruption. The more an eye is damaged, the higher the staining score.

e. Statistical Analysis

SPSS was used for statistical analysis. Data for continuous variables were described as mean and standard deviation while categorical data were described as frequencies and percentages.

The Shapiro–Wilk test was used to assess the distribution of continuous variables. None of the evaluated continuous variables had a p value < 0.05, and were therefore assumed to be normally distributed. Within group

comparisons of pre and post treatment measurements were performed using paired-samples t-tests. Independent-samples t-tests were used for between-group comparisons. The Chi-square test was used to assess baseline categorical characteristics. A p value < 0.05 was considered statistically significant.

3. Results

In the present study, 60 patients with the diagnosis of dry eye disease were equally divided into Group A (preservative-free artificial tears) and Group B (preserved lubricants). Both groups had similar baseline demographic and clinical data, and all continuous variables had a normal distribution (Shapiro–Wilk test). Post treatment statistically significant improvement was achieved in both treatment groups for Tear Break-Up Time (TBUT), Schirmer I Test, Ocular Surface Disease Index (OSDI), Pittsburgh Sleep Quality Index (PSQI) and Fluorescein Corneal Staining scores ($p < 0.001$). Post-treatment comparisons, however, showed that the Group A had significantly better scores than the Group B in terms of TBUT, Schirmer I Test and OSDI, PSQI and.

There was a greater degree of corneal staining with fluorescein ($p < 0.001$). These results revealed that both preservative-free artificial tears and preserved lubricants were effective in improving the signs and symptoms of dry eye disease, but that the preservative-free artificial tears led to greater improvement in tear film stability, tear production, in vivo assessment of ocular surface health, severity of symptoms, and sleep quality.

a. Study Participants

A total of 60 participants were studied. The eight-week intervention period was completed by 30 participants in Group A and 30 in Group B.

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 ± SD	41.2 ± 8.6	42.1 ± 8.9	41.7 ± 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 Presentations provide the basic demographic information about the participants in the study. There were 30 patients in each of the treatment groups and a total of 60 patients were included. There was no significant difference between the two groups with respect to the mean age. There were slightly more females than males in the study population. The working group consisted of various categories of occupations, of which the main groups were office work and housewives. Concerning the length of dry eye symptoms, most participants reported 6–12 months of symptoms, and others reported either < 6 months or > 1 year. There was no difference in the frequency of eye-drops use also between the two groups. The overall data showed no statistical difference ($p > 0.05$) in the baseline demographic characteristics, which means that the two groups were sufficiently comparable prior to the intervention.

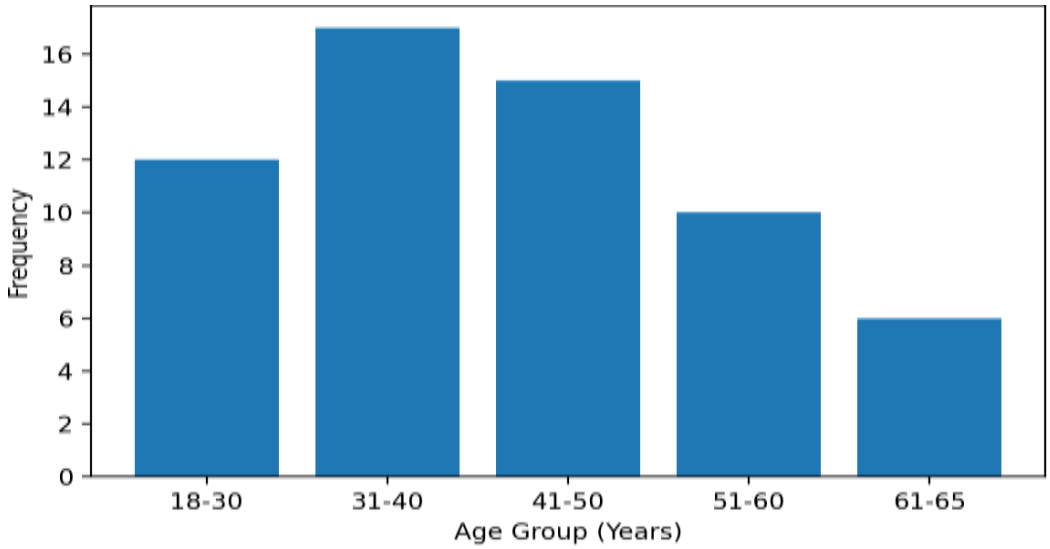


Figure 3.1 Age Distribution of Participants (N = 60)

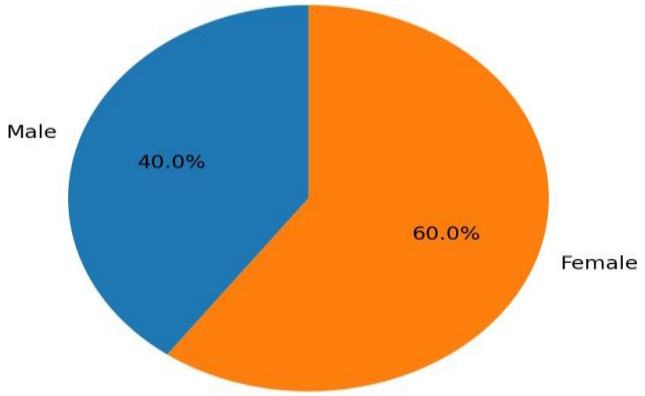


Figure 3.2 Gender Distribution of Participants (N = 60)

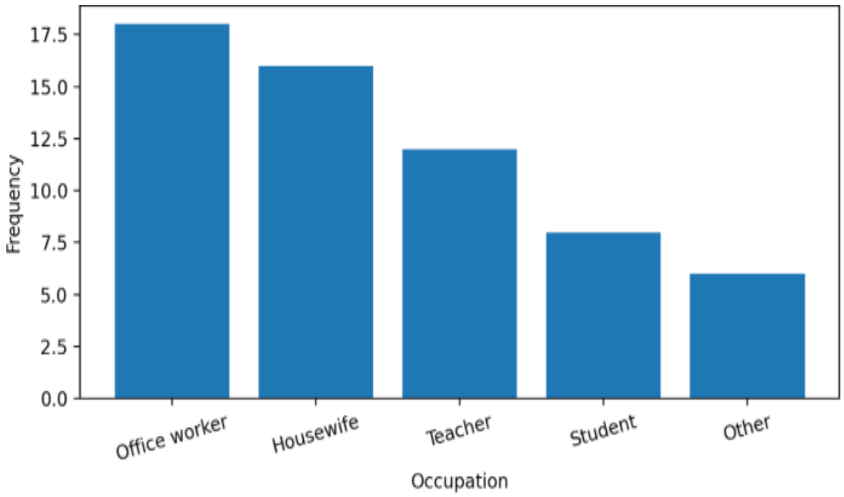


Figure 3.3 Occupation Distribution of Participants (N = 60)

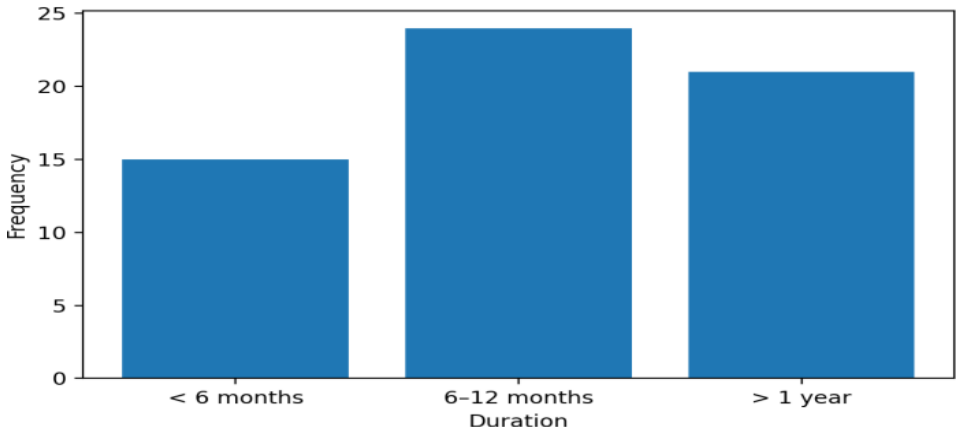


Figure 3.4 Duration of Dry Eye Symptoms Among Participants (N = 60)

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

Outcome	Pre-treatment Mean ± SD	Post-treatment Mean ± SD	p-value
TBUT (seconds)	6.82 ± 1.21	10.94 ± 1.36	<0.001
Schirmer I (mm)	7.43 ± 1.84	11.87 ± 2.06	<0.001
OSDI score	31.46 ± 6.72	16.28 ± 5.14	<0.001
PSQI score	9.13 ± 2.18	5.02 ± 1.64	<0.001

Fluorescein staining	2.17 ± 0.69	0.83 ± 0.54	<0.001

Group A had statistically significant improvement in all outcomes at 8 weeks. An improvement in tear-film stability and tear secretion was determined by increases in TBUT and Schirmer I values. There was a reduction in OSDI, PSQI scores which were used to monitor dry eye symptoms and sleep quality. The staining of fluorescein was also reduced indicating an improvement in the integrity of the ocular surface.

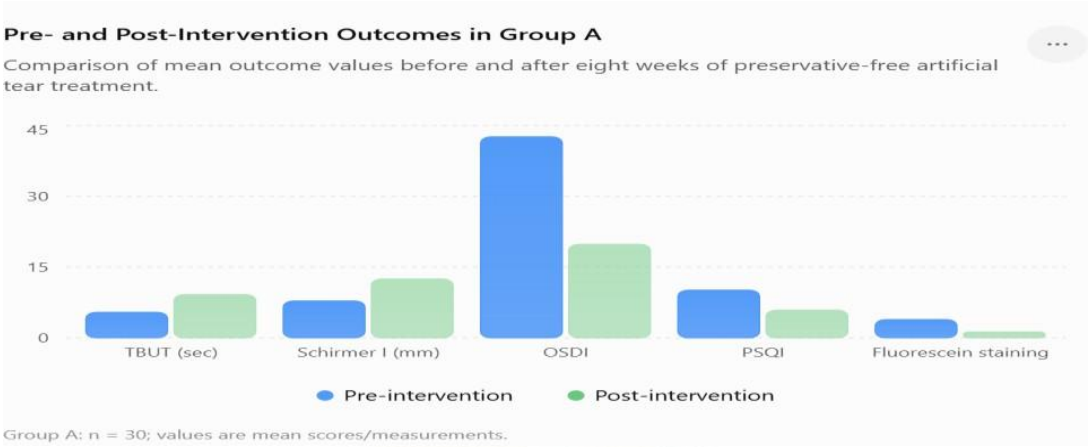


Figure 3.5. Pre- and post-intervention comparison of clinical outcomes in Group A receiving preservative-free artificial tears.

Table 3. Pre- and Post-Intervention Outcomes in Group B

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

There was also a statistically significant difference in group B after treatment. The TBUT and Schirmer I values had a positive change, whereas the OSDI, PSQI and fluorescein staining scores had a negative change.

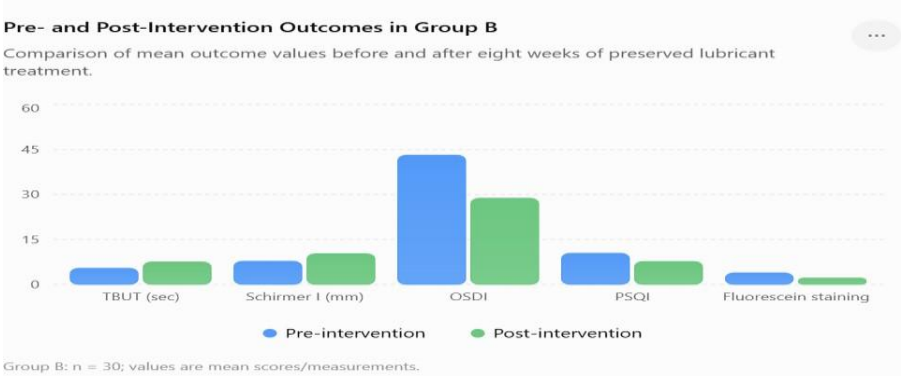


Figure 3.6. Pre- and post-intervention comparison of clinical outcomes in Group B receiving preserved lubricants.

Table 4. 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 revealed higher gains in the group A than group B in all major outcome measures. Group A had higher TBUT and Schirmer I values and lower OSDI, PSQI and fluorescein staining scores. The pre-to-post mean changes for Group A and Group B, respectively, were: TBUT +4.12 versus +2.01 seconds, Schirmer I +4.44 versus +2.15 mm, OSDI −15.18 versus −9.61 points, PSQI −4.11 versus −2.20 points, and fluorescein staining −1.34 versus −0.81 points. No separate significance tests of the differences in change scores are reported.

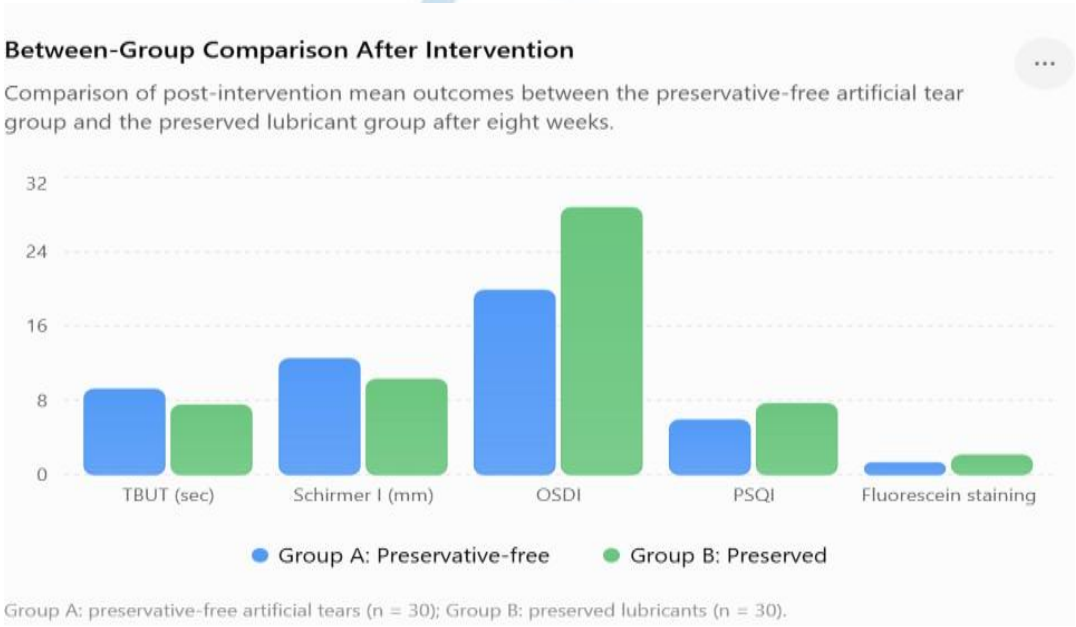


Figure 3.7 Between-group comparison of post-intervention clinical outcomes after eight weeks of treatment.

4. Discussion

Preservative-free artificial tears were compared to preserved lubricants in the management of dry eye in this randomized comparative trial. The results showed substantial gains for both groups on each of the measures. The preservative-free group, however, had significantly better post-treatment improvements in TBUT, Schirmer I, OSDI, PSQI and fluorescein corneal staining.

A change in integrity of the tear film was specifically pertinent to the study objective. Mean TBUT increased by 4.12 seconds in Group A (10.94 minus 6.82) and 2.01 seconds in Group B (8.72 minus 6.71). This equates to a descriptive difference of 2.11 seconds between groups with respect to mean pre to post change. Tear-film instability is one of the main features of DED and it is a key factor in inducing stress and symptoms of the ocular surface (Wolffsohn et al., 2017). The groups showed improvement because both were able to temporarily replace the tear film with artificial tears to minimize surface friction.

These change values were calculated from the reported group means and are not additional independently tested outcomes.

The current observations do not change the overall impression of the artificial tears' therapeutic use but do not agree with certain comparative studies as to the degree of difference between preserved and preservative-free formulations. Ribeiro et al. concluded that there is not enough evidence regarding the superiority of preservative-free artificial tears, but both formulations had the potential to improve the outcomes of dry eye (Ribeiro et al., 2019). More recently, Obuchi et al. have found that the TBUT and Schirmer measurements significantly improved in both preserved and preservative-free groups after four weeks, with no significant difference between the two groups after 4 weeks (Obuchi et al., 2025). Strong between group effect in the present study might be related to the treatment period (8 weeks), to formulation, patient characteristics, adherence, or to the outcome profile of the study population.

The values for Schirmer I also showed improvement in both groups, more so in Group A. While artificial tears are not per se secretagogues, they can increase comfort and tear-film homeostasis which can lead to better tear-related measurements. However, there is considerable variation in the Schirmer test, so it should be used in conjunction with clinical symptoms and other ocular surface abnormalities (Wolffsohn et al., 2017).

The decrease in OSDI scores implies that the clinical improvement was also paralleled by a decrease in patient-reported symptoms. Based on the results tables, Group A demonstrated a 15.18-point reduction (31.46 to 16.28), compared with 9.61 points (30.98 to 21.37) in Group B. The higher descriptive reduction seen in Group A might be due to better tolerability of the ocular surface. Preservatives, especially BAK, can be cytotoxic and pro-inflammatory at the ocular surface, and may cause discomfort and tear-film disruption if used for extended periods of time (Baudouin et al., 2010; Gomes et al., 2017).

Thus, the present results confirm the clinical need to reduce the amount of preservative exposure when topical treatment is necessary on multiple occasions. A study of dry-eye eye drops preservatives also found that preservative-free formulations could be especially beneficial when a person needs to use the drops often or for long periods of time (Walsh & Jones, 2019)

Preservative containing lubricants are not to be considered ineffective, however, significant improvements were seen in Group B in all outcomes in the current study. The second indicator of tear-film/ocular surface integrity measured in this analysis was corneal fluorescein staining, which dropped by 1.34 points in Group A (2.17 to 0.83), but only by 0.81 points in Group B (2.13 to 1.32). This descriptive difference of 0.53 points is in line with the improvement of the ocular surface epithelial condition. Tear-film dysfunction and inflammatory mechanisms play a role in ocular surface damage associated with DED (Craig et al., 2017; Wolffsohn et al., 2017). Staining scale and grading protocol should be defined in the methods prior to submitting.

The subjective part of this study is the subjective sleep quality. There was a descriptive difference in improvement of 1.91 between the two groups (Group A to 4.11; Group B to 2.20) with a mean PSQI score decrease in both groups. Sleep quality was evaluated in this study using PSQI but not clinically diagnosed sleep disorders were confirmed or resolved.

The link between DED and insomnia has been growing. Gu et al. found that the sleep quality scores (PSQI) for DED patients were higher and their risk of sleep disorders was higher than healthy controls (Gu et al., 2024). In the current study, the changes in PSQI might be attributed to better ocular comfort or symptom control overall, but a direct investigatory of a causal mechanism was not performed.

But it should be taken with a grain of salt that the quality of sleep has improved. Various factors affect sleep, such as psychological status, job demands, environment, lifestyle, and other health factors. Thus, the reported decrease in PSQI cannot be considered as evidence that improved sleep was due to the improvement in the ocular surface. However, the direction of change in both groups and the greater change in the preservative-free group lend support to the benefit of evaluating sleep as a patient-centered outcome in DED.

The results further have therapeutic applications in clinical care. There is evidence that artificial tears are a key therapy for the management of DED, but the ideal formulation will need to be tailored on a case-by-case basis depending on the severity of the disease, frequency of use, state of the ocular surface, and the patient's tolerability (Craig et al., 2021; Jones et al., 2017). If the patients need to instill the drug often, there may be less cumulative exposure to the eye surface without preservative. However, for patients who need to take less often, and tolerate the medication well, preserved products can be useful and convenient.

This study has the strengths of complementary outcomes. TBUT and corneal staining with fluorescein were used to provide information on tear-film and ocular surface integrity, Schirmer I was used to assess aqueous tear production and OSDI was used to capture symptom burden, whereas PSQI was used to measure subjective sleep quality. The similarity of the groups as reported also contributes to the comparability of the groups, which should be documented through the adequacy of randomization and allocation procedures.

There are some caveats that should be noted. Firstly, the number of people in each group was small (n = 30). Second, the treatment period lasted only a maximum of 8 weeks, which meant that results of long-term effectiveness or safety could not be drawn. Third, the study did not attempt to control for all the pharmacological characteristics of the artificial tears, including viscosity, active ingredient, osmolarity and lipid content. The formulations, identity of the formulations, dose frequency of the formulations, random sequence and allocation concealment methods, and corneal staining grading scale can affect these factors, which can influence treatment. If these details are not provided, it is hard to separate the independent contribution of preservative status. Inferential statistics should be verified with patient level data response independent of preservative status. Thirdly, sleep quality is complex and could be affected by factors that were not measured in the study.

Larger sample sizes, longer follow-up periods, standardized formulations of artificial tears, and objective assessment of tear-film and ocular-surface function should be used in future RCTs. It would also be interesting to determine if the advantages of preservative-free therapy are greater in cases that need frequent dosing or in cases with moderate to severe OCD.

5. Conclusion

Preservative-free artificial tears and preserved lubricants were effective in the improvement of tear-film stability, tear production, dry eye symptoms, sleep quality and staining of the ocular surface after eight weeks of treatment.

More improvements were noted in all outcomes of participants assigned to the preservative free artificial tears, however. Results indicated that preservative free artificial tears could be valuable clinically in dry eye patients who are on a regimen of frequent or long-term lubrication.

These findings also suggest that preserving eye drops are not necessary, but must be interpreted in the context of previous studies which have demonstrated the efficacy of both preserved- and preservative-free artificial tears. Treatment options should thus be tailored.

6. Clinical Implications

Preservative free artificial tears might be used to minimize repeated exposure of the ocular surface to preservatives in patients who use artificial tears often. Clinicians should evaluate the severity of symptoms, tear-film stability and ocular surface dryness.

When choosing a lubricant, consider factors such as condition, treatment frequency, patients' tolerance, cost, and adherence.

Sleep quality was also included in the present study, emphasizing the need to look beyond traditional ocular parameters and consider patient-centered outcomes.

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