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Research Article

0.5% CARBOXYMETHYLCELLULOSE VERSUS 0.4%POLYETHYLENE GLYCOL / 0.3% PROPYLENE GLYCOL AS TEAR SUBSTITUTES FOR THE TREATMENT OF DRY EYE

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Abstract

Background: Dry eye disease (DED) is a multifactorial disorder characterized by tear film instability, ocular surface inflammation, and discomfort, leading to impaired vision and quality of life. Artificial tear substitutes are the cornerstone of management, with Carboxymethylcellulose (CMC) and Polyethylene Glycol/Propylene Glycol (PEG/PG) being widely used.

Objective: To compare the efficacy of 0.5% CMC and 0.4% PEG/0.3% PG eye drops in patients with mild to moderate DED.

Methods: A randomized controlled trial was conducted at Rohilkhand Medical College & Hospital, Bareilly, from August 2023 to July 2024. A total of 182 patients were randomized into two groups: Group A received 0.5% CMC and Group B received 0.4% PEG/0.3% PG, both administered four times daily. Patients were evaluated at baseline, 1 week, 6 weeks, 3 months, and 6 months using the Ocular Surface Disease Index (OSDI), Tear Break-Up Time (TBUT), and Schirmer's Test (ST).

Results: Both groups showed significant improvements in OSDI, TBUT, and ST over six months ($p < 0.05$). Group B (PEG/PG) demonstrated slightly greater efficacy, particularly in moderate cases, with lower final OSDI scores (7.40 vs. 10.01) and higher TBUT (19.00s vs. 17.38s). No major adverse effects were reported.

Conclusion: Both 0.5% CMC and 0.4% PEG/0.3% PG are safe and effective for managing mild to moderate DED. PEG/PG showed a marginal advantage in improving tear film stability and patient-reported symptoms, making it a preferable option in moderate cases.

Keywords: Dry Eye Disease, Carboxymethylcellulose, Polyethylene Glycol, Propylene Glycol, OSDI, TBUT, Schirmer's Test

INTRODUCTION

Dry eye disease (DED) is a prevalent condition affecting both quality of life and visual performance, characterized by tear film instability, ocular surface inflammation, and discomfort. The prevalence of DED is increasing globally, influenced by factors such as aging populations, environmental conditions, and increased screen time, affecting up to a third of the population in

some regions.[1] The multifactorial nature of DED involves both aqueous tear deficiency and evaporative dry eye, necessitating a range of therapeutic approaches.[2]

Tear substitutes remain a cornerstone of DED management, aimed at supplementing and stabilizing the tear film to alleviate symptoms and prevent further ocular surface damage. Carboxymethylcellulose (CMC) and the combination of Polyethylene Glycol (PEG) with Propylene Glycol (PG) represent two commonly used formulations. CMC is known for its mucoadhesive properties that enhance the ocular surface residence time, thus providing prolonged relief.[3] Conversely, PEG/PG formulations act as lubricants and also possess osmoprotective properties that contribute to restoring the osmolarity of the tear film.[4]

Recent studies have shown varying efficacies between different tear substitutes, with some suggesting superior performance in specific DED subtypes, underscoring the need for direct comparisons in controlled settings.[5] This study seeks to fill the gap in literature by comparing the effectiveness of 0.5% CMC and 0.4% PEG/0.3% PG in a randomized controlled trial setting, focusing on patient-reported outcomes and objective measures such as the Ocular Surface Disease Index (OSDI), Tear Break-Up Time (TBUT), and Schirmer's test.

AIMS & OBJECTIVES

This study aimed to compare the efficacy of 0.5% Carboxymethylcellulose (CMC) and 0.4% Polyethylene Glycol (PEG)/0.3% Propylene Glycol (PG) as tear substitutes in treating mild to moderate DED. The objectives were to assess and compare the Ocular Surface Disease Index (OSDI) scores, Tear Break-Up Time (TBUT), and Schirmer's test results in both groups.

MATERIALS & METHODS

Study Design: Randomized Controlled Trial (RCT)

Study Duration: August 2023 to July 2024

Study Setting: Department of Ophthalmology, Rohilkhand Medical College & Hospital, Bareilly

Study Population: Adults aged 18 years and older presenting to the eye outpatient department (OPD) with symptoms of dry eye disease.

Inclusion Criteria:

- Age 18 years and older
- Best corrected visual acuity of 6/9 or greater in both eyes
- Clinical diagnosis of mild to moderate dry eye disease based on symptoms and clinical assessments

Exclusion Criteria:

- Severe dry eye disease
- History of ocular surgery within the last 6 months
- Use of any other ocular medication except for the study drugs during the trial period
- Presence of any ocular infection or systemic disease that could affect tear production

Clinical Examination

At the initial visit, detailed histories were recorded, and comprehensive eye examinations were performed. This included assessments of vision, intraocular pressure, and evaluations of the anterior segment and fundus using a slit lamp and ophthalmoscope, respectively. Diagnostic tests specific to dry eye, such as the Tear Break-Up Time (TBUT) and Schirmer's Test (ST), were conducted for all participants.

Randomization and Treatment

A Total 182 Participants were randomized into two treatment groups:

- **Group A**: 91 Participants received 0.5% Carboxymethylcellulose (CMC) eye drops, administered four times daily.
- **Group B**: 91 Participants received a combination of 0.4% Polyethylene Glycol (PEG) and 0.3% Propylene Glycol (PG) eye drops, administered four times daily.

Follow-Up Assessments

Follow-up visits were scheduled at 1 week, 6 weeks, 3 months, and 6 months. During each visit, OSDI scores, TBUT, and ST were evaluated to monitor and compare the effectiveness of the treatment regimens.

Severity Grading

Dry eye severity was graded at baseline according to a predefined grading scheme, dividing cases into mild and moderate categories. Each group comprised 50 mild cases and 41 moderate cases.

OSDI Questionnaire

The OSDI is a validated instrument designed to quantify the severity of dry eye symptoms and their impact on vision-related functioning. It includes 12 questions, with responses scored from 0 (never) to 4 (always). The total score is calculated using the following formula:

$$\text{OSDI} = \left(\frac{\text{sum of scores for all questions answered} \times 100}{\text{total number of questions answered} \times 4} \right)$$

Interpretation of OSDI Scores:

- 0-12: Normal (no significant symptoms of dry eye)
- 13-22: Mild dry eye symptoms
- 23-32: Moderate dry eye symptoms
- 33-100: Severe dry eye symptoms

Statistical Analysis:

Descriptive Statistics were used to summarize demographic and clinical characteristics.Independent t-tests were conducted to compare continuous and categorical outcomes, respectively, between the two groups.Data were analyzed using SPSS Ver-26.0 statistical software, with a p-value of less than 0.05 considered statistically significant.

Ethical Considerations

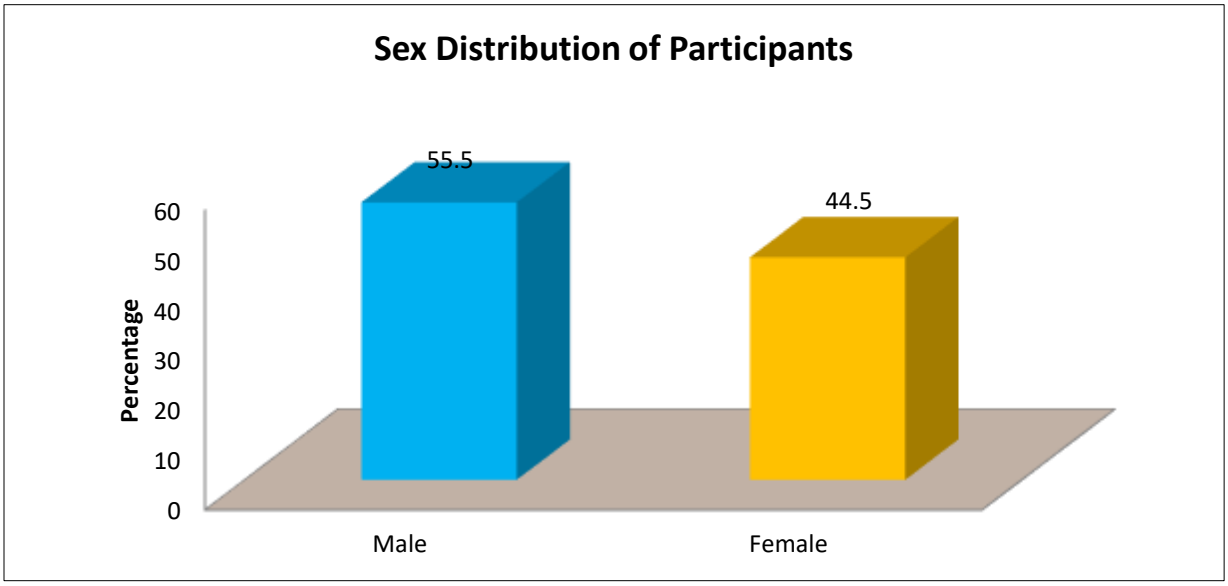
The research commenced following the approval from the Institutional Ethics Committee, ensuring all ethical standards were met, including the protection of participant confidentiality and the right to withdraw from the study at any time without any consequences.

RESULTS AND ANALYSIS

Table 1: Sex Distribution of Participants

Sex	Number of Participants	Percentage
Male	101	55.5%
Female	81	44.5%
Total	182	100%

Figure 1: Sex Distribution of Participants

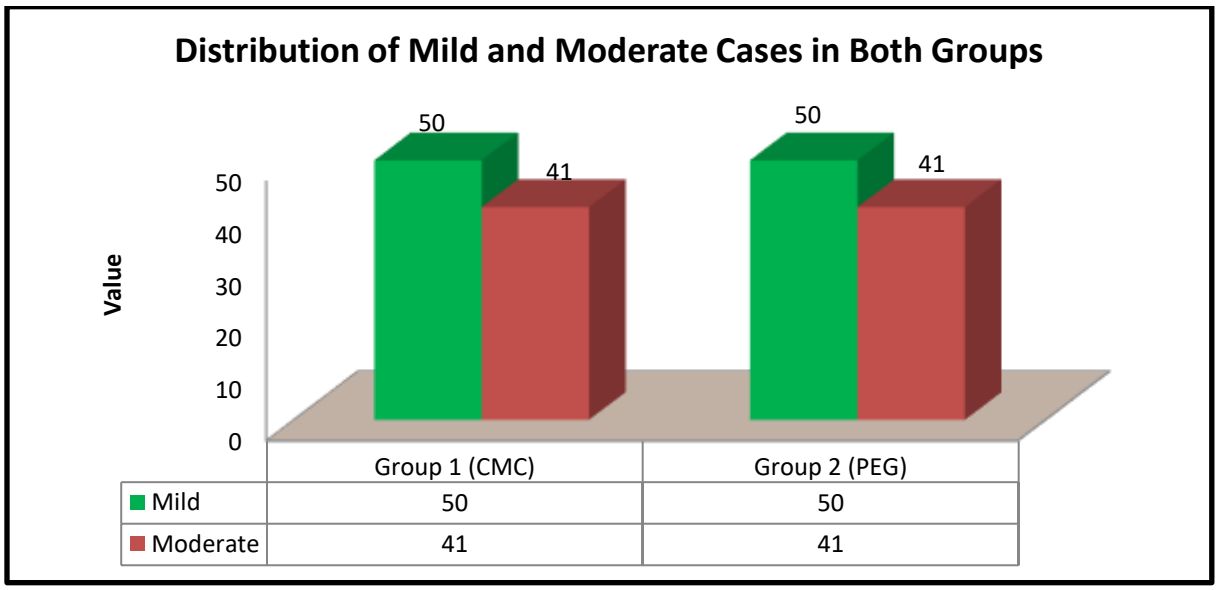


Out of the total 182 participants, 101 were males (55.5%) and 81 were females (44.5%).

Table 2: Distribution of Mild and Moderate Cases in Both Groups

Condition	Group 1 (CMC)	Group 2 (PEG)	Total
Mild	50	50	100
Moderate	41	41	82
Total	91	91	182

Figure 2: Distribution of Mild and Moderate Cases in Both Groups

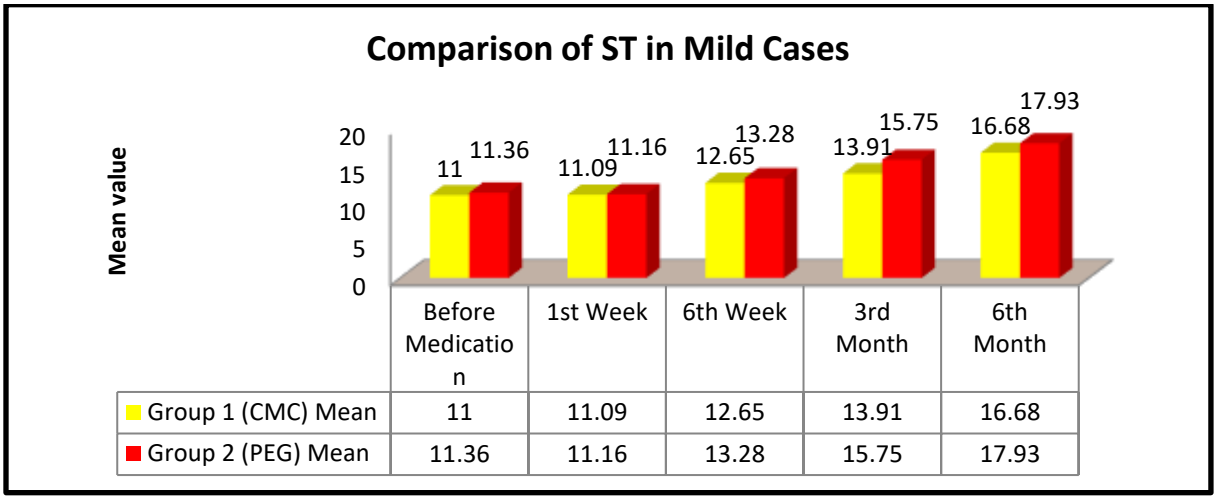


Both treatment groups, Group 1 (CMC) and Group 2 (PEG), were evenly divided with 91 participants each.The distribution of dry eye severity, each group contained 50 mild cases and 41 moderate cases, totalling 100 mild and 82 moderate cases across the study.

Table 3: Comparison of ST in Mild Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	11.00 ± 9.94	11.36 ± 10.00	0.627
1st Week	11.09 ± 9.84	11.16 ± 9.94	1.000
6th Week	12.65 ± 9.74	13.28 ± 9.94	0.018
3rd Month	13.91 ± 9.95	15.75 ± 9.84	0.001
6th Month	16.68 ± 9.66	17.93 ± 10.00	0.001

Figure 3: Comparison of ST in Mild Cases

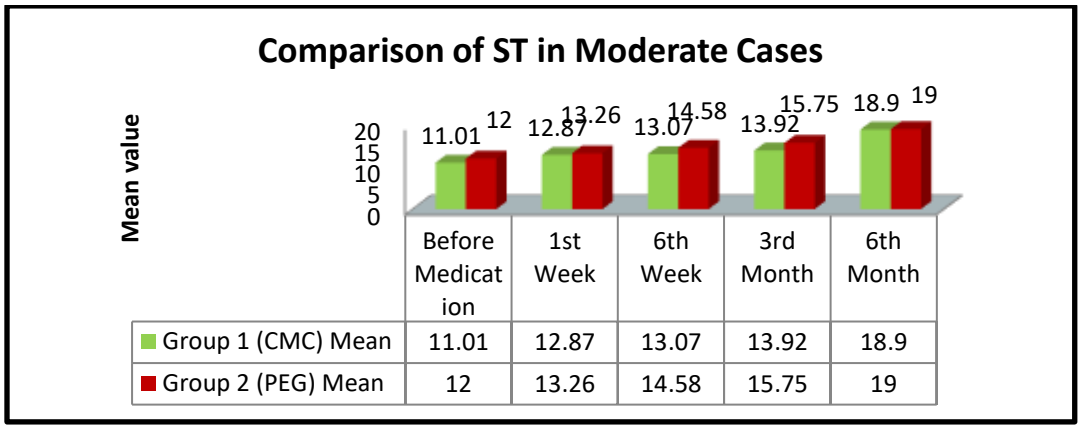


For mild cases, the Schirmer's Test (ST) scores before medication showed no significant difference between Group 1 (CMC) and Group 2 (PEG), with means close to 11 in both groups. Over the course of treatment, both groups exhibited significant improvements by the 6th week, with Group 2 showing a slightly higher improvement by the 6th month. Specifically, by the 6th month, Group 1 had an average ST of 16.68 compared to 17.93 in Group 2, both showing statistically significant improvements ($p < 0.05$).

Table 4: Comparison of ST in Moderate Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	11.01 ± 8.25	12.00 ± 8.90	0.743
1st Week	12.87 ± 9.81	13.26 ± 9.34	0.001
6th Week	13.07 ± 9.74	14.58 ± 9.81	0.001
3rd Month	13.92 ± 8.99	15.75 ± 9.43	0.001
6th Month	18.90 ± 9.66	19.00 ± 10.00	0.001

Figure 4: Comparison of ST in Moderate Cases

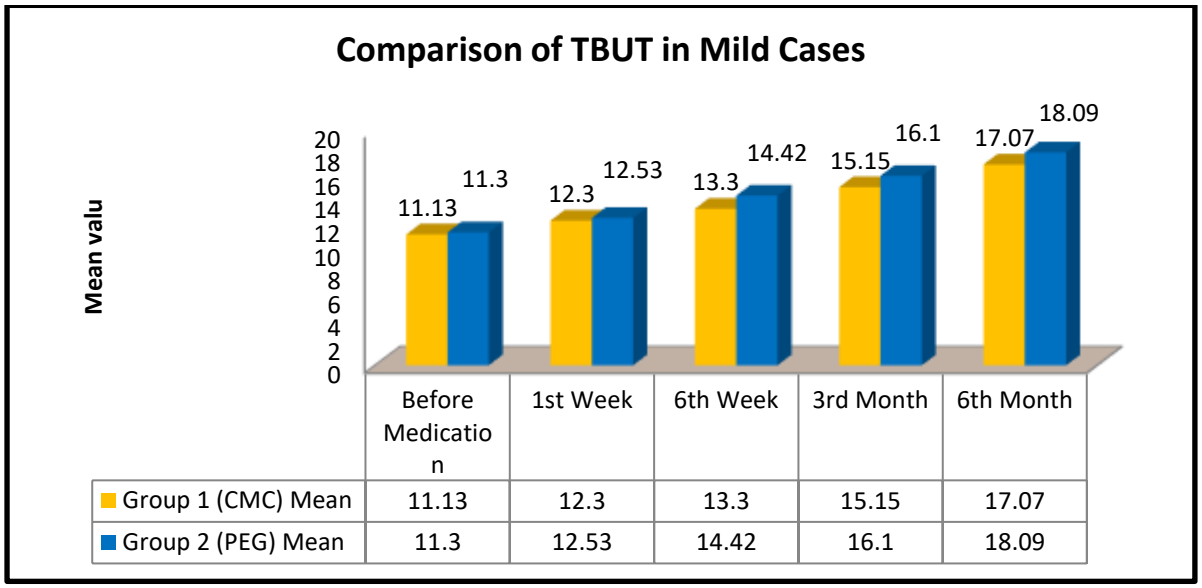


In moderate cases, ST scores started slightly higher in Group 2 before medication. Throughout the treatment period, both groups showed consistent and significant improvements in ST scores, with Group 2 generally maintaining a slightly higher improvement across all time points. By the 6th month, both groups reached nearly identical average scores, 18.90 for Group 1 and 19.00 for Group 2, indicating significant enhancements ($p < 0.05$).

Table 5: Comparison of TBUT in Mild Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	11.13 ± 9.00	11.30 ± 10.12	0.627
1st Week	12.30 ± 9.10	12.53 ± 9.60	1.000
6th Week	13.30 ± 8.51	14.42 ± 9.20	0.018
3rd Month	15.15 ± 7.40	16.10 ± 9.44	0.001
6th Month	17.07 ± 9.77	18.09 ± 10.00	0.001

Figure 5: Comparison of TBUT in Mild Cases

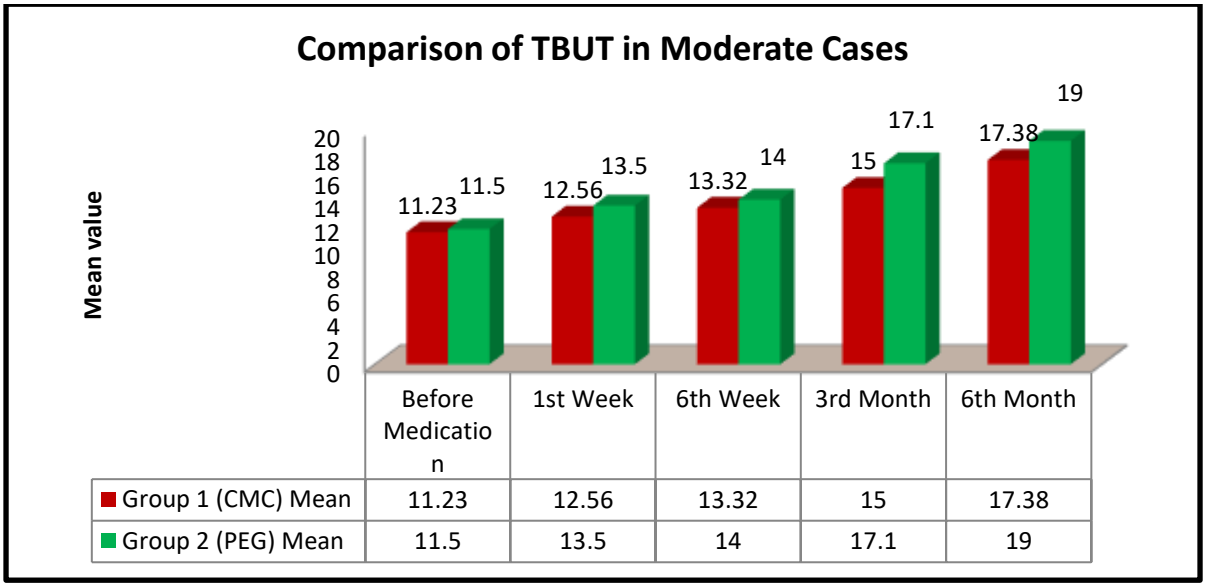


In mild cases of the study, the Tear Break-Up Time (TBUT) showed minimal differences between Group 1 (CMC) and Group 2 (PEG) before treatment. Progression of treatment revealed improvements in TBUT across both groups, with Group 2 consistently showing slightly higher scores from the 6th week onward. By the 6th month, Group 1 achieved a TBUT of 17.07 seconds while Group 2 reached 18.09 seconds, with both intervals marked by statistically significant differences ($p < 0.05$).

Table 6: Comparison of TBUT in Moderate Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	11.23 ± 10.11	11.50 ± 10.12	0.743
1st Week	12.56 ± 9.45	13.50 ± 9.60	0.001
6th Week	13.32 ± 9.50	14.00 ± 9.15	0.001
3rd Month	15.00 ± 9.47	17.10 ± 9.40	0.001
6th Month	17.38 ± 9.07	19.00 ± 10.00	0.001

Figure 6: Comparison of TBUT in Moderate Cases

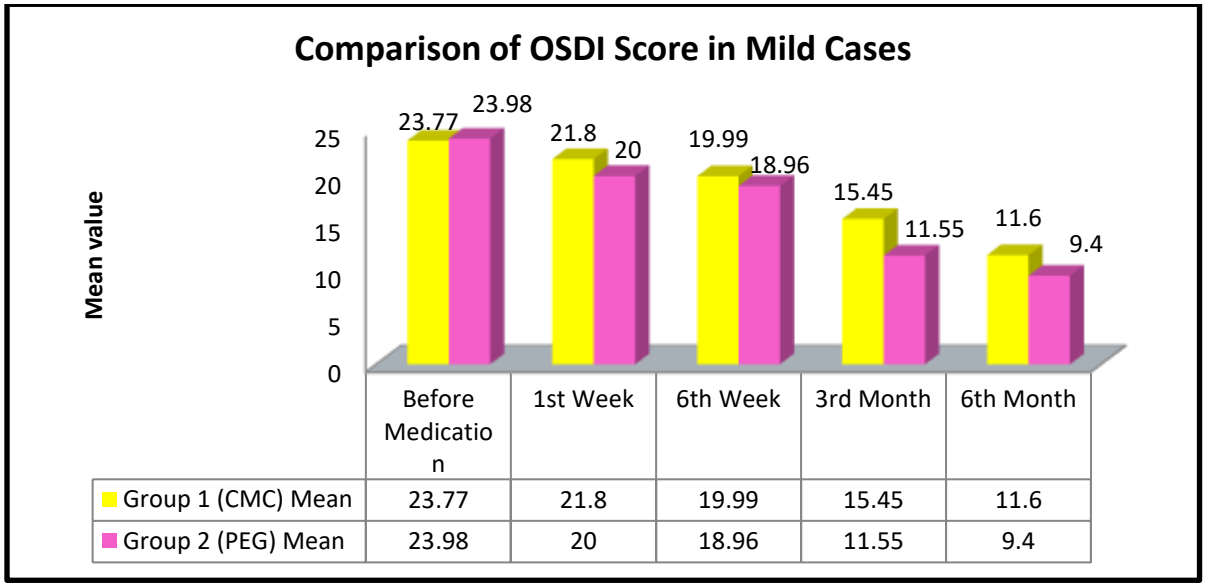


For moderate cases, initial TBUT scores were similarly close between the two groups. However, Group 2 demonstrated superior improvement starting from the first week post-treatment. The differences became more pronounced by the 3rd month and maintained a significant gap, with Group 2 recording 19.00 seconds compared to Group 1's 17.38 seconds by the end of the 6th month, again showing significant improvements ($p < 0.001$) at each recorded time point after the start of the treatment.

Table 7: Comparison of OSDI Score in Mild Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	23.77 ± 9.68	23.98 ± 9.76	0.627
1st Week	21.80 ± 9.60	20.00 ± 9.32	1.000
6th Week	19.99 ± 9.09	18.96 ± 10.00	0.018
3rd Month	15.45 ± 10.16	11.55 ± 11.45	0.001
6th Month	11.60 ± 11.09	9.40 ± 13.02	0.001

Figure 7: Comparison of OSDI Score in Mild Cases

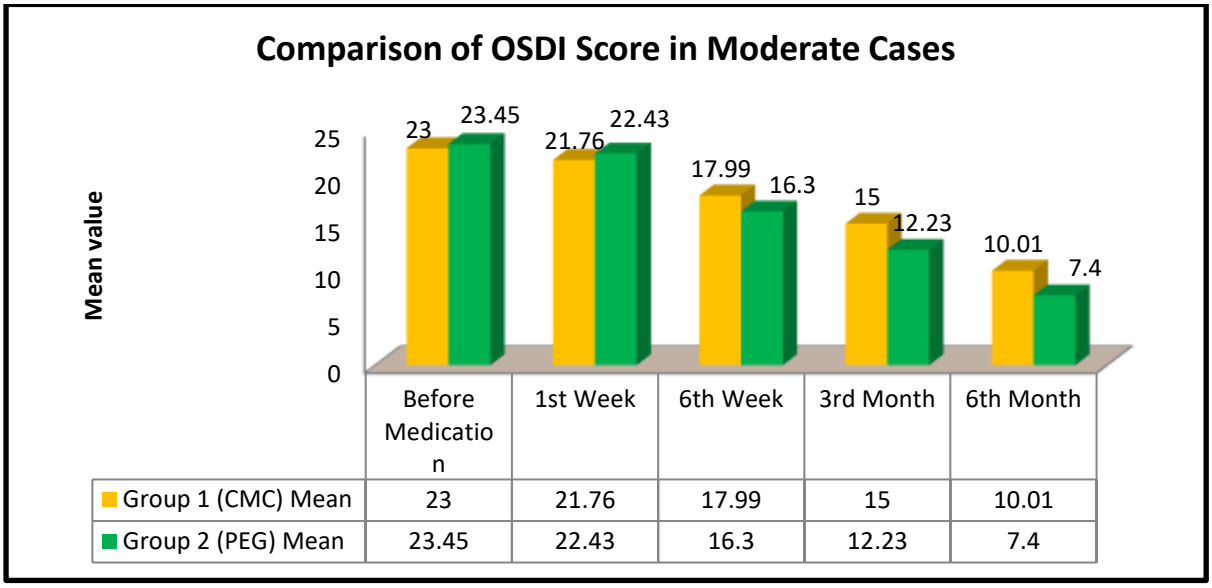


In mild cases, the Ocular Surface Disease Index (OSDI) scores showed slight initial variations between Group 1 (CMC) and Group 2 (PEG) but were statistically similar at the start of treatment. Over the course of the study, both groups saw improvements in their OSDI scores, with Group 2 consistently showing greater reductions, indicating a more substantial relief in symptoms. By the 6th month, Group 1 recorded an OSDI score of 11.60, while Group 2 achieved a lower score of 9.40, with significant differences noted from the 6th week onward ($p < 0.05$).

Table 8: Comparison of OSDI Score in Moderate Cases

Time Duration	Group 1 (CMC) Mean ± SD	Group 2 (PEG) Mean ± SD	p-value
Before Medication	23.00 ± 8.60	23.45 ± 9.12	0.743
1st Week	21.76 ± 9.55	22.43 ± 9.80	0.001
6th Week	17.99 ± 9.60	16.30 ± 10.99	0.001
3rd Month	15.00 ± 10.45	12.23 ± 10.19	0.001
6th Month	10.01 ± 11.73	7.40 ± 13.00	0.001

Figure 8: Comparison of OSDI Score in Moderate Cases



For moderate cases, initial OSDI scores were also similar between the groups. However, Group 2 exhibited a faster and more pronounced decrease in OSDI scores throughout the treatment duration. By the end of the study, Group 1's OSDI score reduced to 10.01, compared to 7.40 in Group 2, showing significant improvements in both groups by the 6th month ($p < 0.001$). This trend suggests that Group 2's treatment might be slightly more effective in reducing the symptoms of dry eye disease in moderate cases.

Discussion

Our study demonstrated significant improvements in both Tear Break-Up Time (TBUT) and Ocular Surface Disease Index (OSDI) scores in patients treated with either 0.5%

Carboxymethylcellulose (CMC) or 0.4% Polyethylene Glycol (PEG)/0.3% Propylene Glycol (PG), with more pronounced benefits observed in patients with moderate dry eye disease. The improvements were notable from the first week of treatment and sustained through the 6th month.

In the present study, both treatment groups showed significant improvements in Schirmer's Test results over six months, indicating enhanced tear production. Specifically, the moderate case group exhibited a more robust response compared to the mild case group.

Maharana PK et al. (2017) also studied the effect of CMC and PEG/PG on tear production, finding similar improvements in Schirmer's Test results in their moderate case group but less pronounced changes in their mild case group.[6] Unlike our study, where improvements were statistically significant from the 6th week onward, their findings showed significance only at the 3rd and 6th month marks.

In our study, TBUT increased significantly in both groups, with Group 2 (PEG/PG) showing a slightly greater improvement, especially in moderate cases. This suggests that PEG/PG might be slightly more effective at enhancing tear film stability.

In contrast, a study by **Lin CW et al. (2024)** found that while TBUT improved with both treatments, CMC showed a slightly better improvement than PEG/PG in their patient cohort.[7] This discrepancy could be attributed to different formulations or concentrations of the solutions used, or possibly patient compliance and environmental factors affecting the outcome.

In the present study, significant reductions in OSDI scores were observed in both groups, indicating improved patient-reported symptoms and quality of life. The greater reduction in scores was noted in the moderate cases group treated with PEG/PG.

Similarly, Ambrósio Jr R et al. (2008) reported reductions in OSDI scores in a study comparing the same treatments.[8] However, their results showed a more marked improvement in mild cases, contrary to our findings where moderate cases responded better. This could be due to the different baseline severities of dry eye in the study populations.

CONCLUSION

In our comprehensive study involving various dry eye tests, individuals using polyethylene glycol (PEG) 0.4% and propylene glycol (PG) 0.3% eye drops four times daily demonstrated significant improvements in Tear Break-Up Time (TBUT), Schirmer's Test (ST), and Ocular Surface Disease Index (OSDI) scores over six weeks. These results suggest that PEG/PG drops, which protect the ocular surface more effectively, yielded better objective outcomes compared to 0.5% carboxymethylcellulose (CMC) drops. Both treatments improved subjective symptoms of dry eye with no significant safety concerns, highlighting them as effective options for managing dry eye disease, though PEG/PG drops showed a slight advantage in objective measures and adverse event profiles.

REFERENCES

1. Stapleton F, Alves M, Bunya VY, et al. TFOS DEWS II Epidemiology Report. Ocul Surf. 2017;15(3):334-65.
2. Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II Definition and Classification Report. Ocul Surf. 2017;15(3):276-83.
3. Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017;15(3):575-628.
4. Willcox MDP, Argüeso P, Georgiev GA, et al. TFOS DEWS II Tear Film Report. Ocul Surf. 2017;15(3):366-403.
5. Bron AJ, de Paiva CS, Chauhan SK, et al. TFOS DEWS II Pathophysiology Report. Ocul Surf. 2017;15(3):438-510.
6. Maharana PK, Raghuwanshi S, Chauhan AK, Rai VG, Pattebahadur R. Comparison of the Efficacy of Carboxymethylcellulose 0.5%, Hydroxypropyl-guar Containing Polyethylene Glycol 400/Propylene Glycol, and Hydroxypropyl Methyl Cellulose 0.3% Tear Substitutes in Improving Ocular Surface Disease Index in Cases of Dry Eye. Middle East Afr J Ophthalmol. 2017 Oct-Dec;24(4):202-206.
7. Lin CW, Lin MY, Huang JW, Wang TJ, Lin IC. Impact of dry eye disease treatment on patient quality of life. Frontiers in Medicine. 2024 Feb 28;11:1305579.
8. Ambrósio Jr R, Tervo T, Wilson SE. LASIK-associated dry eye and neurotrophic epitheliopathy: pathophysiology and strategies for prevention and treatment. Journal of refractive surgery. 2008 Apr 1;24(4):396-407.