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A COMPARATIVE STUDY ON EFFICACY OF CARBOXYMETHYLCELLULOSE 0.5% VS POLYETHYLENE GLYCOL 0.4% / PROPYLENE GLYCOL 0.3% AS A TEAR SUBSTITUTE FOR OCULAR SURFACE DISORDER AND TEAR-FILM INSTABILITY IN POST CATARACT SURGERY PATIENTS.

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ABSTRACT

BACKGROUND: Ocular surface disorder and tear-film instability are one of the most common post-cataract surgery complications, affecting patient comfort and visual outcomes. Artificial tear substitutes like Carboxymethylcellulose (CMC) 0.5% and Polyethylene Glycol (PEG) 0.4% / Propylene Glycol (PG) 0.3% are essential for managing these conditions.

OBJECTIVE: This study aims to compare the efficacy of Carboxymethylcellulose 0.5% and Polyethylene Glycol 0.4% / Propylene Glycol 0.3% as tear substitutes in managing ocular surface disorder and tear-film instability in patients following cataract surgery.

MATERIALS AND METHODS: A prospective randomized comparative study was conductedin the Department of Ophthalmology, Saveetha Medical College and Hospital, Chennai. The study comprised 40 individuals who underwent cataract surgery over a period 6 months. A dry eye workup, including Schirmer's test (ST1), tear film breakup time (TBUT), and Ocular Surface Disease Index (OSDI) scoring will be carried out for all patients before and after the surgery. Patients will be separated into two groups and randomly assigned to be treated with a specific lubricant using stratified random sampling. Following cataract surgery, patients in groups 1 and 2 started receiving carboxymethyl cellulose 0.5% and polyethylene glycol 0.4%/propylene glycol 0.3%, respectively.

RESULTS: The outcomes of our study demonstrate that polyethylene glycol 0.4%/propylene glycol 0.3%, is more successful in promoting tear-film stability in those who have had cataract surgery than carboxymethylcellulose 0.5%.

CONCLUSION: Our results emphasize the importance of using artificial tears in patients who have undergone cataract surgery. It also demonstrates how to prevent and reduce clinical complications after

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the treatment. The symptomatology improved after surgery.

KEYWORDS:

Carboxymethylcellulose, Dry eye, Ocular Surface Disease Index, polyethylene glycol, post cataract surgery, tear - film

INTRODUCTION

Dry eye is a multifactorial ocular surface disease characterized by loss of tear film homeostasis and accompanied by ocular symptoms such as discomfort, visual disruption, irritation, and possibly even ocular surface damage, in which tear film instability and hyperosmolarity, ocular surface inflammation, and neurosensory abnormalities all play important roles. Dry eye is one of the most common causes of vision issues among patients who visit the outpatient ophthalmology clinic (1). One of the most intricate tissues in the body is the ocular surface. Its stability ensures protection and serves as a crucial refractive medium for high-quality vision. Therefore, any condition that disrupts the stability and function of the tear film can lead to the ocular surface disease and dry eye syndrome (2).

It is unknown how common DED occurs following cataract surgery. Extended use of antibiotic and steroid eye drops, decreased tear film break-up time because of irregularities in the incision made at surgical site, decreased conjunctival mucin production as a result of the incision placement, reduced corneal sensation at the surgical incision, which disrupts the cornea-lacrimal gland loop and reduces the tear secretion. Additionally, surgically induced ocular inflammation and exposure to the operating microscope light can lead to poor tear film production and stability resulting in DED post cataract surgery (3).

The primary goal of this study is to identify the incidence of the ocular surface disorder and the tear-film instability following post cataract surgery patients. Secondary goals include treating these patients with two drugs – Carboxymethyl cellulose and Polyethylene glycol and comparing the response to the treatment and outcome between the 2 groups.

MATERIALS AND METHODOLOGY

A prospective randomized comparative study was carried out in the Department of Ophthalmology, Saveetha Medical College and Hospital, Chennai. A total of 40 patients undergoing cataract surgery over a period of 6 months from June 2023 to November 2023, were included in the study considering the inclusion and exclusion criteria. The patients with age-related cataract scheduled for surgery, with no previous history of ocular surgery or eye disease were included in the study. The patients willing to comply with the study protocol and follow-up visits and who provide informed consent to participate in the study were also included in the study. Patients with a history of ocular trauma and inflammation, pre-existing ocular surface disease (e.g., Sjogren's syndrome), or a systemic condition that may influence the ocular surface (e.g., rheumatoid arthritis, diabetes), Patients taking topical or systemic drugs that may impact the ocular surface (e.g., antihistamines,

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antidepressants) Patients with corneal or conjunctival abnormalities that may affect tear film stability (e.g., pterygium, corneal opacity), those who are unable to complete the study protocol or attend follow-up visits, and those who have undergone previous ocular surgeries (e.g., LASIK) were excluded from the study. Once the study was designed, it was presented to the institutional research board and got approval from the ethics committee, then the study was initiated. The primary investigator will screen patients who meet the above-mentioned inclusion criteria and are having cataract surgery at our facility after outlining the aims and objectives of the study. The informed consent of the patients was obtained. Dry eye workup including Schirmer's test (ST1), Tear film breakup time (TBUT) and Ocular Surface Disease Index (OSDI) scoring will be performed for all patients pre-operatively, so that pre-existing ocular surface disorders can be excluded. Post-operatively, all the patients will be enrolled for the above-mentioned dry eye workup. Following this, the patients will be divided into 2 groups and will be randomly assigned to be treated by a particular lubricant by stratified random sampling. Group 1 and group 2, patients were started on Carboxymethyl cellulose 0.5% and polyethylene glycol 0.4%/propylene glycol 0.3%respectively following the cataract surgery. Schirmer's test (ST1), Tear film breakup time (TBUT) and Ocular Surface Disease Index (OSDI) scoring will be performed on Day 7, Day 14 and Day 28 post operatively. The data obtained will be analyzed and interpreted.

STATSTICAL ANALYSIS

The data was entered into MS Excel 2019 version and further analyzed using SPSS (version 26.0; SPSS Inc Chicago IL, USA). For descriptive analysis, the categorical variables will be analyzed by using frequency and percentages and the continuous variables will be analyzed by calculating mean ± Standard Deviation. For inferential analysis, the numerical data were analyzed using the Paired "t"-test. The categorical data were analyzed using Chi square test, will be applied and "p" <0.05 will be considered as statistically significant.

RESULTS

A total of 40 patients were included in this study and were divided into 2 groups. Each group contains 20 patients. In group 1 and group 2, patients were started on Carboxymethyl cellulose 0.5% and Polyethylene glycol 400/propylene glycol respectively following the cataract surgery.
Demographic information, including age and sex, was documented. Measurements such as the OSDI, the Schirmer test (ST) and the tear film breakup time (TBUT) were taken at day 0 (before to the initiation of treatment), day 7, day 14 and day 28. At each follow-up, a comparison of the group's improvements in TBUT, ST and OSDI scores were conducted.

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Figure 1: Number of patients in each group

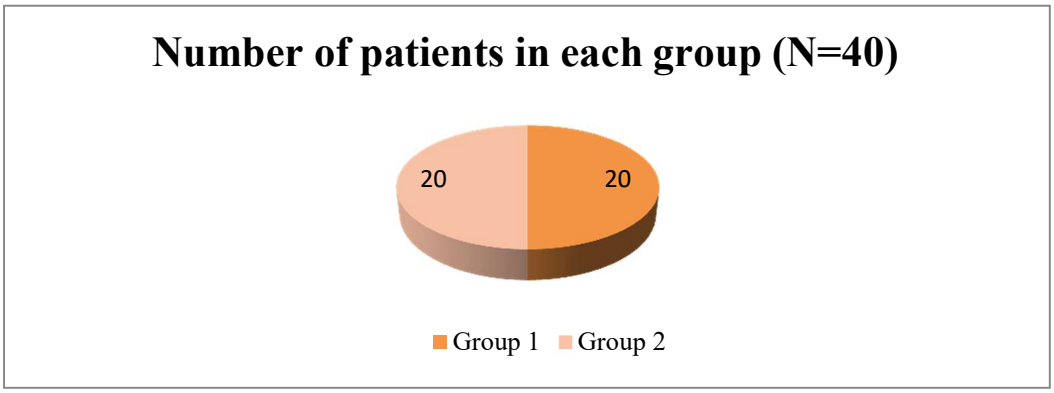

Table 1: Mean age in groups

Age	Mean ± SD
Group 1	58.9±7.16
Group 2	63.1±10.35

Table 1 shows one of the demographic data of patients that is age. The mean age of group 1 (carboxymethyl cellulose 0.5%) is 58.9±7.16, group 2 (polyethylene glycol 400/propylene glycol) is 63.1±10.35.

Figure 2: Gender distribution in groups

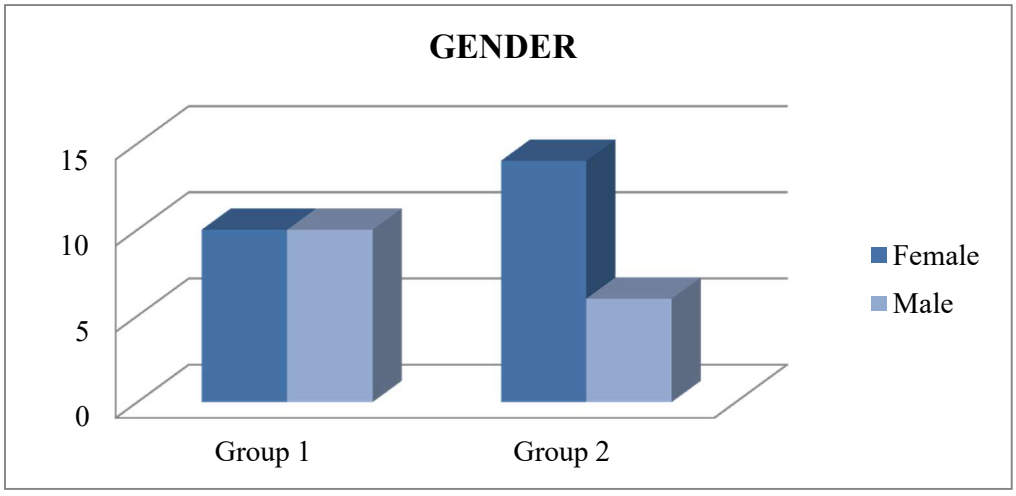

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Table 2: Gender distribution in groups

Gender	Group 1 n (%)	Group 2 n (%)
Female	10 (50%)	14 (70%)
Male	10 (50%)	6 (30%)

Table 2 shows major demographic information of our study population. Overall study population female patients are majority in our study. Most of the female patients (70%) and least male patients (30%) in our study fall under group 2.

Table 3: Laterality of eye in groups

Laterality	Group 1 n (%)	Group 2 n (%)
Left eye	9 (45%)	13 (65%)
Right eye	11 (55%)	7 (35%)

Table 3 shows, In the first group of our study on laterality of the eye, 45% of patients had cataract surgery on their left eye and 55% on their right. Group 2 patients experienced similar outcomes. The majority of patients in our study had right eye cataract surgery.

Table 4: Type of surgery

Surgery	Group 1 n (%)	Group 2 n (%)
PHACO	3 (15%)	1 (5%)
SICS	17 (85%)	19 (95%)

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(PHACO -Phacoemulsification, SICS-Small incision cataract surgery)

Table 4 shows Fifteen percent of the patients in groups one had phacoemulsification, and eighty-five percent had small incision cataract surgery. Just 5% of the patients in group 2 had phacoemulsification; the rest patients all had small incision cataract surgery. This indicates that there is a discrepancy in the distribution of surgical procedures performed across all groups. This could lead to a bias in the results.

Table 5: Comparison between the pre-op values OSDI and Day 7 OSDI with group of the subjects

Variable		OSDI		'p' value
		Mean	SD	
Group (1)	Pre-op	5	2.9	<0.0001*
	Day 7	47.9	3.6	
Group (2)	Pre-op	6.9	2.9	<0.0001*
	Day 7	45.8	2.6	

Table 5 shows the comparison between the pre-op values (baseline score) OSDI and Day 7 OSDI with group of the subjects. The mean baseline score of OSDI in group 1 is 5±2.9, and in group 2 is 6.9±2.9. Decrease in the mean value indicates improvement. At day 7 the mean score of OSDI in group 1 is 47.9±3.6 and in group 2 is 45.85±2.6. Compared to the group 1, group 2's OSDI mean score was considerably lower. p value showed significant difference in both the groups when compared with baseline score.

Table 6: Comparison between the pre-op values OSDI and Day 14 OSDI with group ofthe subjects

Variable		OSDI		'p' value
		Mean	SD	
Grou	Pre-op	5	2.9	<0.0001*

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p(1)	**Day 14**	37.9	3.3	
Grou p(2)	**Pre-op**	6.9	2.9	**<0.0001***
	Day 14	34.6	1.9	

Table 6 shows the comparison between the pre-op values (baseline score) OSDI and Day 14 OSDI with group of the subjects. The mean baseline score of OSDI in group 1 is 5±2.9 and in group 2 is 6.9±2.9. At day 14 the mean score of OSDI in group 1 is 37.9±3.3 and ingroup 2 is 34.6±1.9. Similar to the initial follow-up, group 2's OSDI score was noticeably lower. In both the groups p value showed significant difference when compared with baseline score.

Table 7: Comparison between the pre-op values OSDI and Day 28 OSDI with group of the subjects

Variable		**OSDI**		**'p' value**
		Mean	**SD**	
Group (1)	**Pre-op**	5	2.9	**<0.0001***
	Day 28	28.7	3.3	
Group (2)	**Pre-op**	6.9	2.9	**<0.0001***
	Day 28	23	2.0	

Table 7 shows the comparison between the pre-op values (baseline score) OSDI and Day 28 OSDI with group of the subjects. The mean baseline score of OSDI in group 1 is 5±2.9 and in group 2 is 6.9±2.9. At day 28, the mean score of OSDI in group 1 is 28.7±3.34 and in group 2 is 23±2.0. P value showed noteworthy result when compared with baseline score.

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Table 8: Comparison between the pre-op values TBUT and Day 7 TBUT with group of the subjects

Variable		TBUT		'p' value
		Mean	SD	
Group (1)	Pre-op	14.9	2.5	<0.0001*
	Day 7	8.8	0.8	
Group (2)	Pre-op	15.2	2.7	<0.0001*
	Day 7	9.0	0.6	

Table 8 shows the comparison between the pre-op values TBUT and Day 7 TBUT with group of the subjects. The mean baseline score of TBUT in group 1 is 14.9±2.5 and in group 2 is 15.2±2.7. The higher mean score indicates progress. At day 7, the mean score of TBUT in group 1 is 8.8±0.8 and in group 2 is 9.0±0.6. In group 2 it shows better improvement. In both the groups statistically showed significant result when compared with baseline score.

Table 9: Comparison between the pre-op values TBUT and Day 14 TBUT with group of the subjects

Variable		TBUT		'p' value
		Mean	SD	
Group (1)	Pre-op	14.9	2.5	<0.0001*
	Day 14	9.6	0.4	
Group (2)	Pre-op	15.2	2.7	<0.0001*

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	Day 14	9.5	0.5	

Table 9 shows the comparison between the pre-op values TBUT and Day 14 TBUT with group of the subjects. The mean baseline score of TBUT in group 1 is 14.9±2.5 and in group 2 is 15.2±2.7. At day 14, the mean score of TBUT in group 1 is 9.6±0.4 and in group 2 is 9.5±0.5. TBUT mean score in all the two groups shows almost similar. In both the groups statistically showed significant result when compared with baseline score.

Table 10: Comparison between the pre-op values TBUT and Day 28 TBUT with group of the subjects

Variable		**TBUT**		**'p' value**
		Mean	**SD**	
Group (1)	**Pre-op**	14.9	2.5	**<0.0001***
	Day 28	10.4	0.5	
Group (2)	**Pre-op**	15.2	2.7	**<0.0001***
	Day 28	10.6	0.5	

Table 10 shows the comparison between the pre-op values TBUT and Day 28 TBUT with group of the subjects. The mean baseline score of TBUT in group 1 is 14.9±2.5 and in group 2 is 15.2±2.7. At day 28, the mean score of TBUT in group 1 is 10.4±0.5 and in group 2 is 10.6±0.51. Almost similar mean score in two groups. In both the groups statistically showed significant result when compared with baseline score.

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Table 11: Comparison between the Preop values ST-1 and Day 7 ST-1 with group of thesubjects

Variable		ST-1		'p' value
		Mean	SD	
Group (1)	Pre-op	27.6	3.1	<0.0001*
	Day 7	20.7	2.0	
Group (2)	Pre-op	24.1	4.6	0.0007*
	Day 7	20.0	2.8	

Table 11 shows comparison between the preop values ST-1 and Day 7 ST-1 with group of the subjects. The mean baseline score of Schirmer's in group 1 is 27.6±3.1 and in group 2 is 24.1±4.6. Good tear function is indicated by a higher mean score. At day 7, the mean score of Schirmer's test score in group 1 is 20.7±2.05 and in group 2 is 20±2.8. The mean score for all two groups was close to identical. In both the groups statistically showed significant result when compared with baseline score.

Table 12: Comparison between the pre-op values ST-1 and Day 14 ST-1 with group ofthe subjects

Variable		ST-1		'p' value
		Mean	SD	
Group (1)	Pre-op	27.6	3.1	<0.0001*
	Day 14	20.8	2.3	
Group (2)	Pre-op	24.1	4.6	0.0023*
	Day 14	21.1	2.7	

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Table 12 shows comparison between the pre-op values ST-1 and Day 14 ST-1 with group of the subjects. The mean baseline score of Schirmer's in group 1 is 27.6±3.1 and in group 2 is 24.1±4.6. At day 14 the mean score of Schirmer's test in group 1 is 20.8±2.3 and in group 2 is 21.1±2.7. In both the groups statistically showed significant result when compared with baseline score.

Table 13: Comparison between the pre-op values ST-1 and Day 28 ST-1 with group ofthe subjects

Variable		ST-1		'p' value
		Mean	SD	
Group (1)	Pre-op	27.6	3.1	<0.0001*
	Day 28	22.8	2.4	
Group (2)	Pre-op	24.1	4.6	0.001*
	Day 28	28.7	2.83	

Table 13 shows comparison between the pre- op values ST-1 and Day 28 ST-1 with group of the subjects. The mean baseline score of Schirmer's in group 1 is 27.6±3.1 and in group 2 is 24.1±4.6. At day 28, the mean score of Schirmer's in group 1 is 22.8±2.4 and in group 2 is 28.7±2.8. The mean score in group 2 is considerably higher than the group 1. In both the groups statistically showed significant result when compared with baseline score.

DISCUSSION

Dry eye disease (DED) is a prevalent ocular disorder that greatly lowers quality of life, affecting 6-34% of the world's adult population (4). Since there are no effective traditional therapy options for cataracts (such as drops), surgery is the only option. A minimally invasive procedure, cataract extraction surgery is typically carried out. The majority of patients have a brief, uneventful recuperation period. After the surgical procedure, the patient needs to be given drops that reduce inflammation caused by the surgery and speed up the healing of their eyes. The main goals of the postoperative regimen are to avoid endophthalmitis, corneal oedema and macular oedema, regardless of the precise active components (5). Tear substitutes are a vital component of the dry eye treatment regimen. The OSDI was originally used to diagnose dry eye. The OSDI score is arguably a more practical way to assess dry eye improvement from a patient's perspective (6). And it also indicates that patients with much superior break-up-time

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scores and significantly less subjective discomfort are those who also receive artificial tears as part of their surgical regimen.

The viscosity, retention duration and adherence to the ocular surface of artificial tears are all controlled by the polymers present in their aqueous solution. Nowadays, a variety of polymers are used, such as sodium hyaluronate, chondroitin sulphate, polyvinyl derivatives (such polyvinyl alcohol), hydroxypropyl methylcellulose (HPMC) and carboxymethylcellulose (CMC) (7,8).

In our study, we compared the effectiveness of carboxymethylcellulose 0.5 and polyethylene glycol 0.4%/propylene glycol 0.3% as tear substitutes for ocular surface disorder and tear-film instability in post-cataract surgery patients. Our study sample has a greater mean age compared to Maharana PK et al, (2017) study in Groups 1 and 2, which were 44.10 ± 17.82 and 42.58 ± 16.21 years, respectively. Their study group distribution was in group 1 (CMC 0.5%), group 2 (hydroxypropyl-guar containing PEG/PG) (6).

In our study both Phacoemulsification and Small incision cataract surgery are done for the patients. There is no equal distribution of patients among the groups in both the surgery. This indicates that there is a discrepancy in the distribution of surgical procedures performed across all groups. This could lead to a bias in the results.

In our study PEG applied group had better change in OSDI score than other groups. Similar results were showed in another study Aragona P et al (9). in which Significant improvements in OSDI score from baseline were observed within both two groups at Days 7, 30, 60, and 90 ($P<0.001$). Patients in Group 2 (PEG) had a significantly better percentage change in OSDI than those in Group 1; at 0–1 week ($P = 0.000$), 0–4 weeks ($P = 0.000$), and 1–4 weeks ($P = 0.000$).

From the patient's point of view, the OSDI grading is perhaps a more useful method to assess the improvement in dry eye. In this investigation, PEG 400/PG outperformed CMC 0.5% in terms of OSDI improvement, which was contrast to study Salim et al (10).

Daily PEG/PG use for at least 28 days in patients with dry eye has been shown in clinical studies to be consistently associated with a significant decrease in conjunctival and/or corneal staining, an increase in invasive or non-invasive TBUT, a significant increase in patient-assessed parameters (ocular comfort, drop comfort and dry eye symptoms) and a significantly greater ocular protection index which was contrast to study Aragona P et al. there was a clear trend in favour of CMC-HA UD for improving symptoms, TBUT and Schirmer scores (9).

Our study's findings are consistent with those of earlier investigations. Therefore, in comparison to CMC 0.5% tear replacements, it can be concluded that PEG/PG can result in early and persistent alleviation in both objective and subjective criteria.

CONCLUSION

Our study’s findings show that polyethylene glycol 0.4%/propylene glycol 0.3% is more effective in promoting tear-film stability in people who have had cataract surgery than carboxymethylcellulose 0.5%. It also highlights the significance of employing artificial tears in patients who have had cataract surgery. And it also shows how to prevent and reduce clinical problems following the procedure. The symptomatology following surgery improved. Clinical investigations have consistently shown a significantly decreased complications in patients with dry eye when PEG/PG is used regularly for at

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least 28 days.

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