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Role of Tear Substitutes on Ocular Comfort and Tear Film Stability after Phacoemulsification for Age-Related Cataract

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Abstract

Purpose: This study aimed to investigate the role of tear substitutes on ocular comfort and tear film parameters after phacoemulsification in age-related cataracts.

Patients and methods: A prospective, randomized, controlled, single-center interventional study was conducted. Forty-one candidates (28 men, 13 women) for unilateral cataract surgery at the Ibn-Alhaitham Eye Teaching Hospital between October 2020 and February 2021 with a mean age of 59.80 + 6.15 years were randomly assigned to one of three groups: group A, B, and C. Group A received a standard postoperative cataract regimen of steroid–antibiotics combination and high-viscosity tear substitutes q.i.d.; group B received low-viscosity tear substitutes q.i.d; and group C, the control group, only received standard therapy. For all patients, the tear film break-up time (TBUT), Schirmer's test without anesthesia, and ocular pain assessed by visual analog scale (VAS) were estimated at three points in time: before, at 1 week, and 1 month after surgery.

Results: The mean TBUT and Schirmer's wetting, both at 1 week (P=0.001 and 0.004, respectively) and 1 month (P<0.001 for both tests) after surgery in group A was statistically significantly higher than groups B and C, while groups B and C did not show any significant difference. The VAS score was significantly lower in group A than in group B, which also demonstrated significantly lower VAS scores than group C both at 1 week (P<0.001) and 1 month (P<0.001), postoperatively. Intragroup comparisons revealed that the mean TBUT and Schirmer's wetting improved over the preoperative baseline at 1 month in group A (P=0.001), returned to baseline in group B (P=0.33), and deteriorated in group C (P<0.001). Groups A and B had a reduction in VAS score from 1 week to 1 month after surgery (P=0.001 and 0.04, respectively); however, this was not observed in group C (P=0.56).

Conclusion: Tear substitutes are well tolerated and effective in reducing ocular discomfort after age- related cataract surgery with high-viscosity substitutes offering greater improvement. Further, tear film parameters were improved with the addition of high-viscosity substitutes to the standard post-cataract regimen.

Keywords: Dry Eye Disease; Tear Film Break-Up Time; Schirmer's Test; Visual Analog Scale; Cataract Surgery; Artificial Tears

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Introduction

Dry eye disease (DED) is defined as "a multifactorial disease of the ocular surface characterized by the loss of homeostasis of the tear film, accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles" according to the second report of the International Dry Eye Workshop from the Tear Film and Ocular Surface Society [1]. Meta-analytic studies revealed a prevalence ranging between 5% and 50% for symptomatic disease, regardless of the presence of clinical signs; however, this prevalence increased to 75% when it was based on the presence of signs alone [2].

Several risk factors have been identified, including female sex, older age, hormonal replacement therapy, collagen vascular disease, diabetes mellitus, vitamin A deficiency, certain diets, and medication, such as antihistamines, and antidepressants, and previous refractive and cataract surgeries [3-6]. Moderate and severe DED can significantly impair the quality of life and limit work productivity of patients [7]. Symptoms, such as grittiness, discomfort, foreign body sensation, and lacrimation, and signs of DED correlate poorly and yet there is no single diagnostic method [8]. A variety of questionnaires and clinical tests had been implemented to assess the disease, including the Ocular Surface Disease Index (OSDI) and Schirmer test, which reflects aqueous production, the tear break-up time (TBUT), which assesses tear film stability, measurement of tear osmolarity, and ocular surface staining [8,9]. The TBUT is defined as the interval between the

last complete blink and first appearance of a dry spot, or disruption in the tear film, an average score of 10 seconds or more is classified as normal. The Schirmer-1 test (without anesthesia) measures tear flow by inserting a Schirmer paper strip over the lower lid margin, midway between the middle and outer third of the eyelid. The wetness of the strip is measured 5 min after application. A wet area measuring 10 mm or less is regarded as diagnostic of DED [8-10]. Stepwise management algorithms for DED have been adopted, where tear substitutes are commonly prescribed and form the basis of treatment protocols [11].

Phacoemulsification surgery is the procedure of choice for cataract extraction, particularly in developed countries, and is commonly performed worldwide [12]. It is estimated that by 2050, there will be approximately 50 million people with cataracts in the United States alone compared to 100 million people with operable cataracts worldwide [13,14]. DED is exacerbated by cataract surgery, at least for those with meibomian gland dysfunction, and non-diabetic patients may be more susceptible to decreased tear production after cataract surgery [6,15]. Suggested pathophysiologic mechanisms include repeated drying and irrigation of the ocular surface during surgery, perioperative eye drops and their preservatives, phototoxicity, and surgical trauma from speculum to suction ring and ocular surface manipulation. All of which, along with incisional corneal nerve damage, can culminate in ocular surface trauma and DED [15]. DED symptoms peak around 1 week after surgery and persist for up to 3 months [16]. The standard postoperative regime of patients that undergo cataract extraction aims primarily at preventing endophthalmitis, postoperative uveitis, persistent corneal edema, and cystoid macular edema.

Unfortunately, this does not prevent symptoms of DED that many patients experience after cataract surgery [15,17]. Tear substitutes are gaining popularity as an addition to the standard postoperative cataract regime and promising results had been shown, including hyaluronic acid-based substitutes, which are commonly utilized for the treatment of DED because of their viscosifying and mucoadhesive properties [15,18, and 19].

Our study aimed to evaluate the efficacy of using tear substitutes to prevent ocular discomfort and tear film stability in eyes undergoing age-related cataract surgery with phacoemulsification.

Patients and Methods

This was a prospective, randomized, controlled, single-center, interventional study. Participants were candidates for unilateral cataract surgery at the Ibn-Al Haitham Teaching Eye Hospital Baghdad (Iraq) between October 2020 and February 2021. All patients were informed about the purpose of the study, which was approved by the institutional ethical committee of the respective hospital. Written informed consent was obtained from each patient, and the study followed the tenets of the Declaration of Helsinki. All patients underwent standard phacoemulsification surgery with an intraocular lens implant. The exclusion criteria were non-age-related cataract, moderate to severe dry eye (defined as TBUT <10 s before surgery), coexisting ocular surface disease, complicated cataract surgery (even putting a suture), other drugs not in the protocol such as anti-glaucoma treatment or systemic medications contributing to DED (e.g., drugs with anticholinergic activity and diuretics), contact lens wearers, a history of previous eye surgery, and systemic diseases predisposing to dry eye (e.g., connective tissue diseases and diabetes). Patients who were noncompliant with the treatment protocol or who were lost to follow-up were also excluded.

One day before the operation, the TBUT and Schirmer-1 tests (without anesthesia) were performed. TBUT was done first, then after 5 min interval, Schirmer 1 test was carried out. Eligible patients were randomly assigned to one of three groups: group A, B, and C. Group A received the usual 4 weeks of antibiotic-steroid (AS) treatment consisting of 1% prednisolone acetate ophthalmic suspension (Pred Forte, Allergan, Inc., Irvine, CA) instilled every 2 hours in the first postoperative week, tapered gradually over the next 3 weeks, and 0.5% moxifloxacin hydrochloride ophthalmic solution (Vigamox, Novartis, AG) instilled every 2 hours in the first postoperative week and then decreased to every 4 hours for the next 2 weeks, plus a high-viscosity tear substitute eye drops (BLUgel A, Sooft, Italy). Group B received the usual AS treatment plus low-viscosity tear substitute eye drops (BLUyal, Sooft, Italy), and group C was the control group that received AS treatment only. Groups A and B were instructed to instill the tear substitutes four times daily for 4 weeks, at least 10 min after the AS eye drops.

Outcome Measures

The following outcome measures were assessed at two postoperative visits, at 1 week and 1 month: the TBUT, Schirmer-1 test without anesthesia, and visual analog scale (VAS) scale to grade their subjective pain levels. Patients were also asked about their compliance with medications. The VAS is scored on a scale from 0 to 10. A value of 0 represented "no pain" and a value of 10 represented "maximum pain." Patients were requested to indicate on the scale where they thought it would be representative of the severity of their discomfort and pain. The goal of this regimen of self-reporting was to determine whether and when maximum pain was experienced and to grade their subjective pain level.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as frequencies and percentages. The Shapiro-Wilk test and Levene's test were used to assess the normality of distribution and homogeneity of variance of data, respectively. Two group comparisons were conducted with either an independent sample t-test or Mann-Whitney U test, and multiple groups were compared using either the one-way analysis of variance or Kruskal-Wallis test according to fulfilled statistical assumptions. Similarly, intragroup comparisons involved either a paired t-test or Wilcoxon signed-rank test. Significance was considered at P-value ≤0.05. All statistical tests and calculations were performed using an updated version of the statistical software package (IBM SPSS Statistics for Windows, Version 26. Armonk, NY: IBM Corp).

Results

The study involved 41 patients who underwent unilateral cataract surgery. The mean age of the study participants was 59.80 + 6.15 years. Most patients were men (68.3%, n=28). Table 1 shows the preoperative data of the recruited patients. The preoperative VAS score was 0 for all the recruited patients.

At 1 week after surgery, summarized in Table 2, the mean TBUT was significantly higher in group A than in groups B and C (P=0.023 and 0.01, respectively); however, the mean TBUT did not differ significantly between groups B and C (P=0.378). The results of Schirmer's wetting were significantly higher in group A than in group B (P=0.005) and group C (P=0.003). There was no statistically significant difference in Schirmer's wetting between groups B and C (P=0.7). Group A demonstrated a lower mean VAS score than group

Table 1: Preoperative data of patients recruited.

	Group A (n= 12)	Group B (n= 14)	Group C (n= 15)	P-value
Age (years)	62.50±6.07	58.43±6.53	58.93±5.52	0.194
Male N (%)	9 (75%)	10 (71.5%)	9 (60%)	
Female N (%)	3 (25%)	4 (28.5%)	6 (40%)	
Tear film break- up time (seconds)	12.42±1.78	13.14±2.07	13.53±1.51	0.283
Schirmer's test without anesthesia before surgery (mm)	21.17±2.33	18.86±1.99	19.80±3.21	0.073
Values are expressed as mean±standard deviation. Group A: patients that used high-viscosity tear substitutes; Group B: patients that used low-viscosity tear substitutes, and Group C: control group				

Table 2: Comparison of the tear film break-up time, Schirmer's test, and visual analog scale score at 1 week and 1 month after surgery between patient groups.

		Group A (n=12)	Group B (n=14)	Group C (n=15)	P-value for three-group comparisons
At 1 week after surgery	**TBUT (seconds)**	13.25±1.60	12.21±2.12	10.20±2.04	**0.001**
	Schirmer's test (mm)	20.50±1.98	17.64±2.34	17.13±3.31	**0.004**
	VAS score	3.67±0.78	4.86±1.027	6.53±0.915	**<0.001**
At 1 month after surgery	**TBUT (seconds)**	14.50±1.68	13.00±2.25	9.93±1.75	**<0.001**
	Schirmer's test (mm)	22.42±2.07	18.50±2.25	16.80±3.21	**<0.001**
	VAS score	2.50±0. 91	4.29±0.73	6.67±0.98	**<0.001**
	Values are expressed as mean±standard deviation; TBUT: tear film break-up time; VAS: visual analog scale; Group A: patients that used high-viscosity tear substitutes; Group B: patients that used low-viscosity, tear substitutes; Group C: control group				

B (P=0.023). Meanwhile, group C had significantly higher VAS scores than the other groups (P<0.001 for group A; P=0.001 for group B).

At 1 month after surgery, summarized in Table 2, the mean TBUT was significantly higher in group A than in groups B and C (P<0.001 for both groups). There was no statistically significant difference in the mean TBUT between groups B and C (P=0.129). The same is true regarding Schirmer's wetting, which was significantly higher in group A than in groups B and C (P<0.001 for both groups), while both groups (B and C) showed no statistically significant difference in the amount of wetting (P=0.1). Group C had a significantly higher mean VAS score than groups A and B (P<0.001 for both groups), and group B also demonstrated a significantly higher mean VAS score than group A (P<0.001).

Table 3 and Figure 1 summarize the changes in the mean TBUT for each patient group at 1 week and 1 month after surgery in comparison to preoperative values. Only group A demonstrated an increase in the mean TBUT from the preoperative values both at 1 week and 1 month, which was statistically significant. Meanwhile, the mean TBUT significantly decreased at 1 week for groups B and C and also at 1 month only for group C, in comparison to preoperative values. Changes in the TBUT were significant for all groups at 1 week and 1 month postoperatively.

Mean Schirmer's wetting (Table 4, Figure 2) significantly decreased for both groups C and B at 1 week in comparison to the preoperative values. Group A did not show a statistically significant change in mean Schirmer's wetting at 1 week after surgery. However, there was a statistically significant increase in Schirmer's wetting at 1 month in comparison to preoperative values in group A. Group B showed no significant change at 1 month, while group C showed a significant decrease in Schirmer's wetting at 1 month in comparison to preoperative values. When comparing postoperative values at 1 week and 1 month (Table 4), groups A and B experienced a significant increase in Schirmer's wetting; meanwhile, group C did not show any significant change.

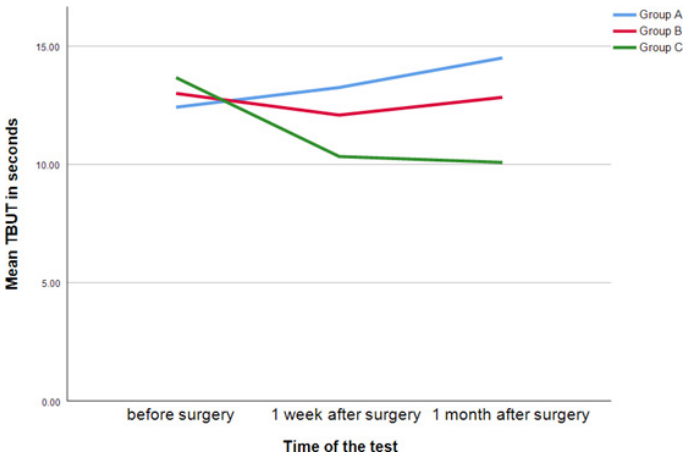

Figure 1: Changes in mean tear break-up time (TBUT) in seconds across patient groups. Group A: patients that used high viscosity tear substitutes, Group B: patients that used low viscosity tear substitutes, Group C: control group.

The mean VAS score significantly increased for all patients after surgery (P<0.001) in comparison to preoperative values, which was 0 for all patients before surgery. Table 5 summarizes the change in VAS score for each group from 1 week to 1 month. It is noteworthy to mention that group A demonstrated the greatest reduction in mean VAS score between 1 week and 1 month after surgery. Group C did not show any significant reduction in the mean VAS score between 1 week and 1 month postoperatively.

Discussion

Dry eye is associated with cataract surgery, either by reduction of tear production, particularly among non-diabetic patients, or by induction of tear film instability and ocular surface damage that is noticed among those with pre-existing meibomian gland dysfunction [5,16]. Regimes after cataract surgery are limited to AS combinations

Table 3: Intragroup comparisons of the tear film break-up time before, at 1 week, and 1 month after surgery.

		TBUT before surgery (seconds)	TBUT 1 week after surgery	Mean difference	P value
Before and 1 week after surgery	Group A (n=12)	12.42±1.78	13.25±1.60	0.83	**<0.001**
	Group B (n=14)	13.14±2.07	12.21±2.12	-0.93	**<0.001**
	Group C (n=15)	13.53±1.51	10.20±2.04	-3.33	**0.001**
Before and 1 month after surgery	Group A	12.42±1.78	14.50±1.68	2.08	**0.001**
	Group B	13.14±2.07	13.00±2.25	-0.14	0.336
	Group C	13.53±1.51	9.93±1.75	-3.6	**<0.001**
1 week and 1 month after	Group A	13.25±1.60	14.50±1.68	1.25	**<0.001**
	Group B	12.21±2.12	13.00±2.25	0.79	**<0.001**
	Group C	10.20±2.04	9.93±1.75	-0.46	**0.041**
	Values are expressed as mean±standard deviation; TBUT: tear film break-up time; Group A: patients that used high-viscosity tear substitutes; Group B: patients that used low-viscosity tear substitutes; Group C: control group				

Table 4: Intragroup comparisons of Schirmer's wetting before, 1 week, and 1 month after surgery.

		Schirmer's test before surgery (mm)	Schirmer's test 1 week after surgery	Mean difference	P value
Before and 1 week after surgery	Group A (n=12)	21.17±2.33	20.50±1.98	0.67	0.054
	Group B (n=14)	18.86±1.99	17.64±2.34	-1.22	**<0.001**
	Group C (n=15)	19.80±3.21	17.13±3.31	-2.67	**<0.001**
Before & 1 month after surgery	Group A	21.17±2.33	22.42±2.07	1.2500	**<0.001**
	Group B	18.86±1.99	18.50±2.25	-0.36	0.063
	Group C	19.80±3.21	16.80±3.21	-3.00	**<0.001**
1 week & 1 month after	Group A	20.50±1.98	22.42±2.07	1.92	**<0.001**
	Group B	17.64±2.34	18.50±2.25	0.86	**0.001**
	Group C	17.13±3.31	16.80±3.21	-0.33	0.063
	Values are expressed as mean±standard deviation; Group A: patients that used high-viscosity tear substitutes; Group B: patients that used low-viscosity tear substitutes; Group C: control group.				

in many clinical settings, with tear substitutes added in certain circumstances [15,17]. There is a paucity of studies investigating the role of tear substitutes in normal patients without evidence of DED undergoing standard uncomplicated phacoemulsification surgery for age-related cataract [18,20-23]. These account for the majority of patients undergoing cataract surgery in clinical practice. The objective of our study was to evaluate the efficacy of using tear substitutes to prevent ocular discomfort and improve tear film stability after cataract surgery in eyes with no evidence of DED.

At 1 week after surgery, patients in group A demonstrated higher mean TBUT values than those in groups B and C (P=0.023 and 0.01, respectively). Schirmer's wetting was also higher in group A than in groups B (P=0.005) and C (P=0.003). Caretti L, et al. (2019) [23], in support of our findings, demonstrated that the mean TBUT was significantly higher in the high-viscosity treatment group (trehalose) than in the low- viscosity (hyaluronic acid) and control groups at 1 week after surgery (P<0.001); however, Schirmer's wetting mean values showed no statistically significant improvement between the groups. These findings indicate that cataract surgery might induce postoperative dry eye and further suggest that the addition of high-viscosity tear substitutes could prevent the development or worsening of dry eye after surgery.

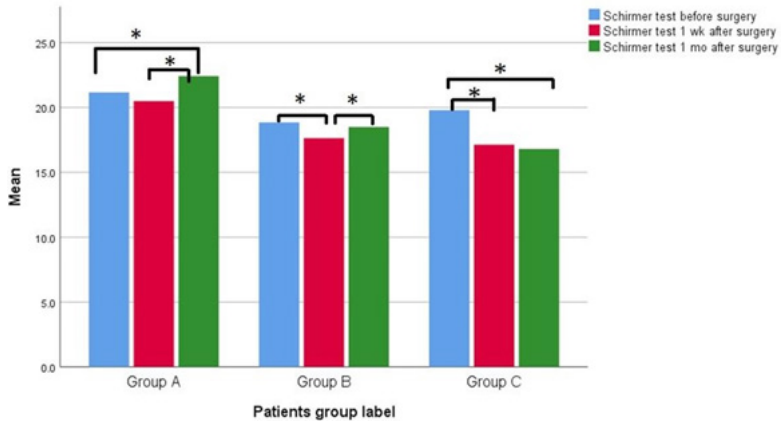

Figure 2: Comparison of mean Schirmer's wetting in mm (Mean) across patient groups, before, 1 week, and 1 month after surgery. Group A: patients that used high viscosity tear substitutes, Group B: patients that used low viscosity tear substitutes, Group C: control group. * Indicates a statistically significant change.

At 1 month after surgery, as compared to groups B and C, group A showed a higher mean TBUT (P<0.001 for both) and Schirmer's wetting (P<0.001 for both groups), while group B showed improvement to a lesser degree in mean values compared to group C (p=0.129). Sanchez MA, et al. (2010) [21], had comparable results with the use of a high-viscosity HP-Guar tear substitute. This can be explained by the fact that treating dry eyes with tear substitutes could reduce the expression of inflammatory markers that are elevated in the tear film of patients with dry eye after phacoemulsification. Moreover, the reduction could be because of increased stability of the tear film, followed by a reduction in hyperosmolarity that occurs upon increasing the TBUT that the lubricant treatment produces.

Caretti L, et al. (2019) [23], also showed that the TBUT values increased by a factor of 2.17 at 30 days after surgery in the high-viscosity (trehalose) group as compared to the control group, while the improvement was minor in the low-viscosity group. However, Schirmer's wetting mean values showed no statistically significant improvement between the groups. In contrast to our findings, Mencucci R, et al. (2015) [22], showed that low-viscosity tear substitutes (0.1% sodium hyaluronate and 0.5% carboxymethylcellulose) had statistically higher mean TBUT values in the study groups than in the control group. Yao K, et al. (2015) [24], demonstrated that the use of 1% low-viscosity carboxymethylcellulose sodium had statistically significant higher TBUT mean values in the study group than in control group, but not in case of Schirmer's wetting values, both at 1 week and 1 month after surgery, which could be attributed to the use of different formulations or the frequency of instillation used in these studies.

In accordance with our results, Caretti L, et al. (2019) [23], also showed that the mean TBUT improves with the use of high-viscosity tear substitutes from 1 week to 1 month after surgery. Meanwhile, the control group underwent a significant decrease in the mean TBUT over the same period.

Regarding patient satisfaction postoperatively, group A patients had a lower mean VAS score than group B (P=0.023), while group C showed a higher VAS score in comparison to the other groups (P<0.001 for group A; P=0.001 for group B at 1 week), (P<0.001 for both groups at 1 month) postoperatively. Sipos E, et al. (2011) [20], verified similar findings to our results and stated that low-viscosity tear substitutes showed minor substantial subjective benefits for the patients and patient satisfaction was highest with high- viscosity tear substitutes, which could be explained by the fact that high-viscosity drops have longer persistence in the tear film, good distribution over the cornea and conjunctiva, and clear consistency and cooling properties. Treatment with tear substitutes is also reported to improve vision [25]. Caretti L, et al. (2019) [23], used the OSDI scoring system to test patient satisfaction and found that the mean OSDI score decreased to 5.05 at 30 days from baseline in the high-viscosity (trehalose) group and to 11.24 in the low- viscosity group. Miyake K, et al. (2017) [26], and Baek J, et al. (2016) [27], evaluated pre- and postoperative symptoms using the OSDI score and reported that symptom relief did occur with the addition of tear substitutes to standard therapy.

Our study limitations include the short duration of the postoperative assessment and limited sample size, which was based on convenience.

Conclusion

Tear substitutes are well tolerated and effective in reducing ocular discomfort after cataract surgery with high-viscosity substitutes offering greater improvement. Further, tear film parameters were improved with the addition of high-viscosity substitutes to the standard post-cataract regimen. We recommend considering the addition of high-viscosity tear substitutes to standard AS therapy post age-related cataract surgery, even for patients with no evidence of DED before surgery.

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Disclosure

The authors report no conflicts of interest in this work.

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