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COMPARING THE EFFECT OF HYALURONIC ACID AND LIPID-COATED CARBOMER GEL ON DRY EYES AFTER PHACOEMULSIFICATION IN DIABETIC PATIENTS

Original Article

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ABSTRACT

Background: Dry eye disease (DED) is a prevalent complication following phacoemulsification surgery, especially among diabetic patients who are predisposed due to metabolic and vascular changes. Tear film instability, ocular inflammation, and delayed epithelial healing contribute to persistent postoperative discomfort and impaired vision. Identifying effective interventions is critical for enhancing visual rehabilitation and patient quality of life. This study compared the effectiveness of hyaluronic acid (HA) and lipid-coated carbomer gel (LCC) in improving tear film stability and alleviating dry eye symptoms in diabetic patients after cataract surgery.

Objective: To evaluate and compare the efficacy of HA and LCC in diabetic patients with postoperative DED using Tear Break-Up Time (TBUT) and Schirmer's Test.

Methods: A randomized clinical trial was conducted at Shaheen Welfare Hospital, Lahore, including 64 diabetic patients aged 50–70 years who developed DED after uncomplicated phacoemulsification. Participants were randomized into two equal groups: Group A received HA drops, and Group B received LCC gel for four weeks. Data were collected at baseline, 2 weeks, and 4 weeks using TBUT and Schirmer's Test. Randomization was computer-generated, blinding was maintained, and SPSS version 25 was used for statistical analysis. Mann–Whitney and Friedman tests determined between- and within-group differences, with significance set at $p<0.05$.

Results: At baseline and at the 2nd week, no significant difference was observed between groups in TBUT or Schirmer's Test ($p=1.000$). At the 4th week, LCC demonstrated significant superiority. Mean ranks for TBUT were 41.27 in the LCC group versus 23.73 in the HA group ($p=0.000$). For Schirmer's Test, LCC showed a mean rank of 46.63 compared to 18.38 for HA ($p=0.000$). Within-group analysis confirmed progressive improvement in both groups, though LCC achieved higher scores consistently by week 4.

Conclusion: Lipid-coated carbomer gel demonstrated superior efficacy over hyaluronic acid in improving tear film stability and tear secretion among diabetic patients with postoperative dry eye disease. These findings suggest LCC as a more effective and preferable option for managing moderate to severe DED after cataract surgery.

Keywords: Diabetes Mellitus, Dry Eye Disease, Hyaluronic Acid, Lipid-Coated Carbomer, Phacoemulsification, Schirmer Test, Tear Break-Up Time.

INTRODUCTION

Dry eye disease (DED) is a multifactorial disorder characterized by ocular discomfort, visual disturbances, and tear film instability that ultimately leads to inflammation and damage of the ocular surface (1,2). Among the many systemic conditions associated with DED, diabetes mellitus (DM) represents a major risk factor due to its combined metabolic, vascular, and neuropathic consequences. These mechanisms impair the lacrimal functional unit, reduce tear secretion, cause neuronal dysfunction, and increase tear osmolarity, all of which contribute to ocular surface compromise (3,4). This disruption, further aggravated by chronic inflammation, mechanical stress, and epithelial barrier damage, makes ocular surface rehabilitation especially challenging in individuals with diabetes, particularly following ocular surgeries such as phacoemulsification (5,6). Postoperative dry eye in diabetic patients has been reported to be more frequent and severe compared to non-diabetic individuals. This heightened vulnerability is linked to delayed corneal epithelial wound healing, persistent low-grade inflammatory reactions, and oxidative stress triggered by surgical trauma (7,8). Epidemiological data further support this association, showing that the prevalence of DED in diabetic patients ranges between 30% and 70%, significantly higher than in non-diabetic populations. Mechanistically, hyperglycemia, oxidative stress, microvascular damage, and chronic inflammation disrupt the tear film and ocular surface homeostasis (9,10).

In recent years, therapeutic approaches with artificial tears containing hyaluronic acid (HA) and lipid-coated carbomer formulations have shown encouraging outcomes. HA exerts beneficial effects by enhancing corneal epithelial repair, suppressing inflammatory responses, and stabilizing the tear film, while lipid-based carbomers primarily act by reducing evaporative loss and improving tear film stability, particularly in patients with Meibomian gland dysfunction (11–14). Despite promising evidence, limited research has specifically addressed the efficacy of these interventions in diabetic individuals undergoing cataract surgery, where ocular surface compromise may significantly hinder visual rehabilitation and patient comfort. Therefore, this study was designed to evaluate the comparative effectiveness of hyaluronic acid and lipid-coated carbomer-based artificial tears in managing postoperative dry eye symptoms among diabetic patients undergoing phacoemulsification. The objective was to determine whether these therapies could enhance ocular surface healing, reduce postoperative complications, and improve visual outcomes and quality of life in this high-risk patient group.

METHODS

The study was designed as a randomized clinical trial conducted at Shaheen Welfare Hospital, Lahore, over a duration of six months following the approval of the synopsis. The sample size was determined using G*Power version 3.1.9.2, with an effect size of 0.84 and a statistical power of 0.80, targeting significant differences based on Schirmer Test outcomes as the primary variable (10). To account for potential dropouts, a 20% attrition rate was added, resulting in a final required sample size of 64 participants, ensuring the adequacy of the study power. Participants were recruited using a non-probability convenient sampling technique. Eligible participants included patients aged 50–70 years (11), of both genders, with a confirmed diagnosis of type 2 diabetes mellitus for at least five years (12). Only those who had undergone uncomplicated phacoemulsification cataract surgery within the past four weeks (13) and presented with acute postoperative dry eye symptoms confirmed by clinical evaluation, including Schirmer test values ≤10 mm (14), were included. Patients with pre-existing chronic dry eye prior to cataract surgery (15), active ocular infections, glaucoma, uveitis, or ocular surface diseases unrelated to DED (16) were excluded. Similarly, individuals with a history of ocular surgery within the past six months (other than the index procedure) (2), uncontrolled systemic diseases such as advanced diabetic retinopathy or autoimmune disorders (3), recent contact lens use within two weeks, or those receiving systemic or topical medications influencing tear film stability within three months were not eligible (4). Additional exclusion criteria included known hypersensitivity to hyaluronic acid or lipid-coated carbomers (5) and significant intraoperative or postoperative complications, such as posterior capsular rupture or endophthalmitis (6).

Randomization was performed using a computer-generated method, ensuring equal allocation into two intervention groups. Group A received hyaluronic acid eye drops (Hylo®) for four weeks, while Group B was treated with lipid-coated carbomer eye drops (Visol® gel) for the same duration. Both patients and outcome assessors were blinded to treatment allocation, maintaining a double-blind study design. Data collection involved standardized ophthalmological assessments. The Tear Break-Up Time (TBUT) test and the Schirmer test were employed to evaluate tear film stability and aqueous tear secretion, respectively. Baseline readings were obtained prior to initiation of therapy. Follow-up evaluations were conducted after two weeks (mid-therapy) and four weeks (completion of therapy), allowing comparative assessment of treatment efficacy. Each measurement was repeated twice to ensure accuracy and consistency of data. Data were entered and analyzed using SPSS version 25. A normality test was applied to confirm the distribution of data. Depending

on normality, parametric or non-parametric statistical methods were planned for inter- and intra-group comparisons of treatment outcomes. A p-value <0.05 was considered statistically significant. Ethical approval was obtained from the Institutional Review Board (IRB) of Shaheen Welfare Hospital prior to commencement of the study. All participants provided informed written consent before enrollment. Ethical considerations such as confidentiality, anonymity, voluntary participation, and avoidance of harm were strictly maintained throughout the study.

RESULTS

A total of 64 participants were included in the trial. The age distribution showed that 31.3% of participants were between 50–55 years, 31.3% were aged 56–61 years, 20.3% were 62–66 years, and 17.2% were 67–70 years. With respect to body mass index (BMI), 3.1% were underweight, 15.6% had normal weight, 28.1% were overweight, and 53.1% were obese. Regarding height, 7.8% measured less than 4 feet, 51.6% were up to 5 feet, 37.5% were between 5.5–6 feet, and 3.1% were taller than 6 feet. In terms of body weight, 18.8% weighed less than 60 kg, 37.5% less than 80 kg, and 43.8% less than 100 kg. Between-group analysis demonstrated no significant differences at baseline or at the second week in either Tear Break-Up Time (TBUT) or Schirmer Test scores, with both groups presenting identical mean ranks and p-values equal to 1.000. However, at the fourth week, lipid-coated carbomer gel showed a marked improvement compared to hyaluronic acid. For TBUT, the mean rank was 41.27 in the carbomer group versus 23.73 in the hyaluronic acid group, with a statistically significant p-value of 0.000. Similarly, for Schirmer Test values at the fourth week, the lipid-coated carbomer group demonstrated a higher mean rank of 46.63 compared to 18.38 in the hyaluronic acid group, also with a highly significant p-value of 0.000. Within-group comparisons revealed consistent patterns of improvement across both groups. In the hyaluronic acid group, TBUT scores improved significantly from baseline to the fourth week (mean rank increasing from 2.17 at baseline to 2.83 at week 4, χ^2=59.042, p=0.000). Similarly, Schirmer Test values improved from a mean rank of 2.17 at baseline to 2.70 at week 4 (χ^2=52.297, p=0.000). In the lipid-coated carbomer group, TBUT scores showed progressive improvement from a mean rank of 2.00 at baseline to 3.00 at the fourth week (χ^2=64.000, p=0.000). Schirmer Test scores followed a similar trend, rising from 1.88 at baseline to 3.00 at week 4 (χ^2=60.800, p=0.000). Both interventions demonstrated clinical benefits over time; however, lipid-coated carbomer gel consistently produced greater improvement in TBUT and Schirmer Test scores by the fourth week, indicating superior efficacy in enhancing tear film stability and aqueous tear production in postoperative dry eye among diabetic patients.

Table 1: Demographic Distribution of all variables

Values	Frequency	Percent
Age		
50-55 Years	20	31.3
56-61 years	20	31.3
62-66 years	13	20.3
67-70 years	11	17.2
Total	64	100.0
BMI		
Under Weight	2	3.1
Normal Weight	10	15.6
Over Weight	18	28.1
Obesity	34	53.1
Total	64	100.0
Height		
less than 4 Feet	5	7.8
Up to 5 Feet	33	51.6
5.5-6 Feet	24	37.5
Above 6 Feet	2	3.1
Total	64	100.0
Weight		

Values	Frequency	Percent
Less than 60 KG	12	18.8
less than 80 KG	24	37.5
Less Than 100 KG	28	43.8
Total	64	100.0

Table 2: Between-group comparison of all variables (Man-Whitney)

	Group	N	Mean Rank	Mann-Whitney U	P-Value
Baseline Tear Break-Up Line Score	Hyaluronic Acid	32	32.50	512.000	1.000
	Lipid Coated Carbomer gel	32	32.50		
	Total	64			
Tear Break-Up Line Score 2nd Week	Hyaluronic Acid	32	32.50	512.000	1.000
	Lipid Coated Carbomer gel	32	32.50		
	Total	64			
Tear Break-Up Line Score 4th Week	Hyaluronic Acid	32	23.73	231.500	.000
	Lipid Coated Carbomer gel	32	41.27		
	Total	64			
Baseline Schirmer Test	Hyaluronic Acid	32	32.50	512.000	1.000
	Lipid Coated Carbomer gel	32	32.50		
	Total	64			
Schirmer Test 2nd Week	Hyaluronic Acid	32	32.50	512.000	1.000
	Lipid Coated Carbomer gel	32	32.50		
	Total	64			
Schirmer Test 4th Week	Hyaluronic Acid	32	18.38	60.000	.000
	Lipid Coated Carbomer gel	32	46.63		
	Total	64			

Table 3: Within-group comparison of all Variables (Fried man)

Ranks					
Group		Mean Rank	Chi-Square	df	P-Value
Hyaluronic Acid	Baseline Tear Break-Up Line Score	2.17	59.042	2	.000
	Tear Break-Up Line Score 2nd Week	1.00			
	Tear Break-Up Line Score 4th Week	2.83			
Lipid Coated Carbomer gel	Baseline Tear Break-Up Line Score	2.00	64.000	2	.000
	Tear Break-Up Line Score 2nd Week	1.00			
	Tear Break-Up Line Score 4th Week	3.00			
Hyaluronic Acid	Baseline Schirmer Test	2.17	52.297	2	.000
	Schirmer Test 2nd Week	1.13			
	Schirmer Test 4th Week	2.70			
Lipid Coated Carbomer gel	Baseline Schirmer Test	1.88	60.800	2	.000
	Schirmer Test 2nd Week	1.13			
	Schirmer Test 4th Week	3.00			

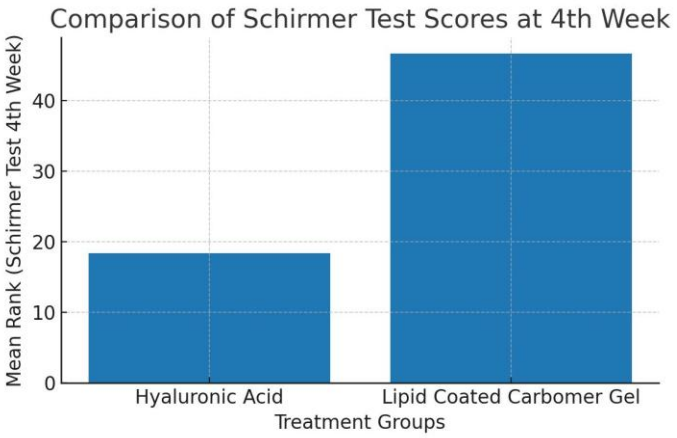

Figure 2 Comparison of Schirmer Test Scores at 4th Week

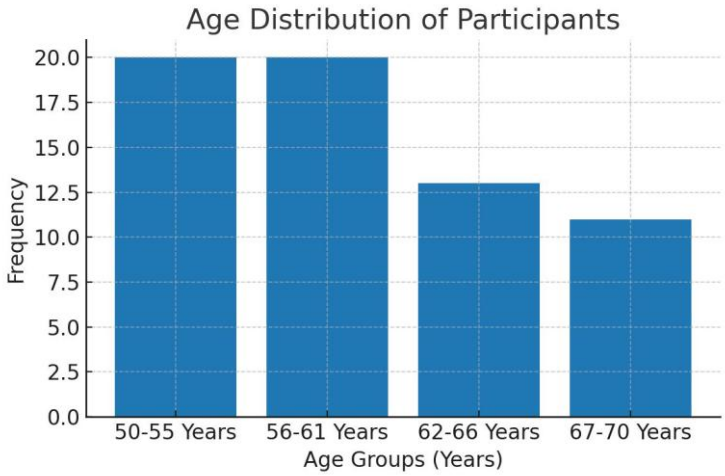

Figure 2 Age Distribution Participants

DISCUSSION

The findings of this randomized clinical trial demonstrated that both hyaluronic acid and lipid-coated carbomer gel improved dry eye disease parameters in diabetic patients following phacoemulsification surgery; however, lipid-coated carbomer gel produced superior outcomes by the fourth week. The improvement was particularly evident in Schirmer's Test and Tear Break-Up Time, where significant differences favored lipid-coated carbomer gel at week four. These results suggest that the lipid component of the formulation enhanced tear film stability and reduced evaporative loss more effectively, providing a more durable therapeutic effect. Comparison with earlier research highlights both consistencies and divergences. Some prior studies reported no significant differences between hyaluronic acid-based lubricants and other formulations over shorter durations, indicating comparable efficacy during early follow-up periods (15,16). In contrast, the present study identified a marked advantage of lipid-coated carbomer gel after four weeks, which may be attributed to the extended observation window that allowed differential effects to become clinically significant (17). Other investigations have shown beneficial effects of hyaluronic acid following ocular surgery, particularly in reducing postoperative complications and improving tear film integrity, findings that were partially corroborated in the present trial, as hyaluronic acid also improved outcomes but to a lesser degree (18). Evidence from other studies supports the role of carbomer-based formulations in enhancing corneal healing due to antioxidant properties, which may explain the superior long-term improvements seen with lipid-coated carbomer gel in this study (19,20). Additional reports have indicated that combination therapies, such as trehalose with hyaluronic acid or phospholipid-based multi-agent formulations, improved both objective and subjective outcomes of dry eye disease. While this trial did not explore combination regimens, its results reinforce the concept that augmenting tear substitutes with lipid or antioxidant components may provide enhanced therapeutic efficacy (21-23). Systematic reviews have also recognized hyaluronic acid as a reference standard in dry eye treatment, but the current evidence adds weight to the growing consideration of alternative or adjunct formulations, such as lipid-based carbomers, in certain patient populations (23).

The study holds several strengths, including its randomized double-blind design, use of standardized clinical measures, and inclusion of a homogeneous population of diabetic patients after cataract surgery—a cohort known to be at increased risk for dry eye disease. These features strengthened the reliability of the results and minimized potential bias. However, limitations must be acknowledged. The duration of follow-up was limited to four weeks, which restricts understanding of the long-term benefits or sustained efficacy of the interventions. The sample size of 64 participants, though statistically powered, may not adequately represent the wider population. The study relied only on Schirmer's Test and TBUT as outcome measures, without incorporating other relevant assessments such as corneal fluorescein staining, tear osmolarity, or patient-reported symptom scores, which could have provided a more comprehensive evaluation. Additionally, the study did not investigate the potential role of combination therapies, which remain a promising avenue for optimizing dry eye disease management. In terms of clinical implications, the results suggest that lipid-coated carbomer gel could represent a more

effective therapeutic option compared with hyaluronic acid, particularly in diabetic patients undergoing ocular surgery where tear film stability is further compromised. Its superior performance at the fourth week highlights its value in postoperative rehabilitation and symptom alleviation. Future research should focus on extending the follow-up period to determine sustained effects, expanding sample size for greater generalizability, and incorporating broader clinical measures to assess both structural and symptomatic improvement (24,25). Exploration of combination therapies integrating lipid-based carbomers with other protective or anti-inflammatory agents may also enhance efficacy. In conclusion, the study adds to the growing evidence that while hyaluronic acid remains a well-established therapy for dry eye disease, lipid-coated carbomer gel offers superior short-term efficacy in restoring tear film stability and improving ocular surface health. Its use may therefore be prioritized in moderate to severe cases, particularly among high-risk populations such as diabetic patients after cataract surgery.

CONCLUSION

This study concluded that lipid-coated carbomer gel provided greater therapeutic benefit than hyaluronic acid in managing dry eye disease among postoperative diabetic patients. Both treatments improved ocular surface stability and alleviated symptoms; however, the lipid-based formulation demonstrated superior efficacy, highlighting its potential as a more effective option for patients with moderate to severe disease. The findings underscore the importance of selecting therapies that not only relieve discomfort but also enhance long-term tear film stability, ultimately improving visual rehabilitation and quality of life. These results contribute meaningful evidence to clinical practice, suggesting that lipid-coated carbomer gel may serve as a preferred intervention, while further research on combination therapies and extended outcomes is warranted to maximize its clinical utility.

AUTHOR CONTRIBUTION

Author	Contribution
Shehzad Ahmad*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Saleh Shah	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Afaq Ahmad Khan	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Hafiz Zohaib Hassan	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Zara Arif	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Sibgha Naseem	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published

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