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EVALUATION OF THE EFFECTS OF FLAXSEED FOR MILD TO MODERATE DRY EYE TREATMENT IN POLYCYSTIC OVARIAN SYNDROME

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ABSTRACT

Background: Flaxseed is the richest source of plant omega-3 fatty acids. It has anti-inflammatory and antioxidant properties.

Objective: To evaluate the effect of flaxseed for mild to moderate dry eye treatment in polycystic ovarian syndrome.

Design: Quasi-Experimental study

Setting: Madina Teaching Hospital, Faisalabad

Material and Method: The study assessed the effects of flaxseed and the lubricant Tear Kool on 60 females aged 20-35 with polycystic ovarian syndrome and mild to moderate dry eye. Participants were divided into three groups: Group A received 1.5 grams of flaxseed and Tear Kool, Group B received only Tear Kool, and Group C received flaxseed alone. Baseline evaluations were conducted using TBUT and Schirmer Test I, with follow-ups at 2 and 4 weeks. Data analysis utilized SPSS-27, employing repeated measures and one-way ANOVA.

Main Outcome: There was a significant improvement (p=.00) observed in all three groups. Flaxseed in combination with artificial lubricant is a highly effective treatment in the management of all types of dry eye disease

Sample Size: 60 participants

Results: The mean value of the Tear film break up time (TBUT) of Group A at baseline 7.4 (0.6 SD) standard deviation (SD) and 2nd follow up was 12.6 (0.4 SD). Group B at baseline 7.4 (0.6 SD) and 2nd follow up was 10.50 (0.8 SD) while Group C at baseline 7.5 (0.6 SD) and 2nd follow up was 11.3 (0.4 SD). The mean value of Schirmer test I of Group A at baseline 8.1 (1.1 SD) and 2nd follow up was 28.0 (2.8 SD). Group B at baseline 7.7 (1.3 SD) and 2nd follow-up was 24.5 (2.3 SD) while Group C at baseline 7.4 (1.1 SD) and 2nd follow up was 26.5 (1.9 SD).

Conclusion: Flaxseed in combination with artificial lubricant is a highly effective treatment in the management of all types of dry eye disease. It improves tear film stability and enhances tear production, more efficiently and briskly.

Keywords: Dry Eye Disease, Polycystic Ovarian Syndrome, Flaxseed

INTRODUCTION

Dry eye is a complex condition characterized by a reduction of the homeostasis of the tear film, leading to hyperosmolarity, ocular surface damage, inflammation, scarring, difficulty in daily tasks, reduced reading speed, decreased energy, poor health, and frequently psychological issues.[1],[2],[3] The tear film is divided into three layers: the outer lipid layer, the middle aqueous layer, and the inner mucin layer.[4] Dry eye disease is a multifactorial condition of the ocular surface, with occupational and environmental factors playing a significant role in its development. Dry eye is common among women, particularly those with polycystic ovarian syndrome (PCOS), an endocrine disorder that affects the female reproductive years.[5] Sex hormones play a crucial role in ocular surface physiology, with females being more susceptible to dry eye due to their systemic and ocular effects.[6] The pathophysiology of PCOS is influenced by genetics, gut dysbiosis, environmental toxins, and food.[7]

High-sugar diets have been linked to PCOS through changes in gut flora, the development of chronic inflammation, increased insulin resistance, and increased androgen synthesis.[8] The Ferriman-Gallwey scoring system is used to evaluate hyperandrogenism in women with PCOS, which affects primordial and secondary follicle counts.[9] Over 80% of women with PCOS have hirsutism, a male-like pattern of terminal coarse hairs, associated with high levels of androgen, either adrenal or ovarian.[10]

Dry eye disease treatment aims to restore tear film heterogeneity and homeostasis.[11] Non-pharmacological treatments include educating patients about their disease, available treatments, and their prognosis.[12] Non-pharmacological management includes dietary and environmental modifications, quitting drugs that worsen DED, and good personal hygiene practices.[13]

The National Health and Nutrition Examination Survey (NHANES) highlights the importance of omega-3 fatty acids in managing dry eye disease (DED) in polycystic ovarian syndrome (PCOS). Flaxseed, containing the highest concentration of Secoisolariciresinol diglucoside (SDG), is beneficial in managing dry eye disease in PCOS due to its anti-inflammatory activity.[14] This fatty acid helps in tear film stability and enhances tear production. The study recommends 1.5g of flaxseed for women older than 20 years, as it is a safe dose for women. The combination of flaxseed and eye lubricant is also considered beneficial for treating mild to moderate dry eye in PCOS.[15] The study aims to evaluate the effect of flaxseed for mild to moderate dry eye treatment and compare the effect of a combination of flaxseed and eye lubricant versus eye lubricants alone for treating mild to moderate dry eye in PCOS.

Objective

To evaluate the effect of flaxseed for mild to moderate dry eye treatment in polycystic ovarian syndrome.

METHODOLOGY

This quasi-experimental study was conducted at Madina Teaching Hospital, Faisalabad, from September 2024 to May 2025, involving 60 purposively selected female participants aged 20–35 years, newly diagnosed with polycystic ovarian syndrome (PCOS) and presenting with mild to moderate mixed-type Dry Eye Disease (DED). Participants were randomly assigned to three equal groups: Group A received 1.5 grams of flaxseed orally along with the eye lubricant Tear Kool four times daily, Group B used Tear Kool alone four times daily, and Group C consumed 1.5 grams of flaxseed daily without lubricant. Inclusion criteria required normal visual acuity (BCVA 6/6) and mild refractive errors, while patients with severe DED, high refractive errors, prolonged computer use, ocular infections, systemic diseases (other than PCOS), psychiatric conditions, or poor compliance were excluded. Data collection involved tools such as a torch light, slit lamp with digital camera system for TBUT using fluorescein strips, Schirmer strips for tear production evaluation, and Meiboscale grading for assessing meibomian gland dysfunction. The TBUT and Schirmer Test I were used to assess tear film quality, and the Ocular Surface Disease Index (OSDI) questionnaire, along with a self-designed proforma, documented patient symptoms and clinical findings. Ethical approval was obtained, and informed consent was secured from all participants per the Declaration of Helsinki. Evaluations at two and four weeks followed baseline assessments to monitor improvement using the same tests. Data were analyzed using SPSS version 24, with repeated measures ANOVA used for within-group comparisons and one-way ANOVA for between-group analysis.

RESULT

This study demonstrated that group A's (Flaxseed + Tears Kool) mean TBUT increased from 7.40 (0.681 SD) seconds at baseline to 9.55 (0.759 SD) and 12.65 (0.489 SD) at follow-ups 1 and 2, respectively ($P = .000$), while Schirmer values rose from 8.15 (1.182 SD) to 14.50 (0.761 SD) and 28.05 (2.856 SD) ($P = .000$). In Group B (Tears Kool only), TBUT improved from 7.45 (0.605 SD) to 8.00 (0.459 SD) and 10.50 (0.889 SD) seconds, and Schirmer scores increased from 7.70 (1.380 SD) to 13.00 (1.170 SD) and 24.50 (2.351 SD). Group C (Flaxseed only) also showed gains, with TBUT rising from 7.55 (0.605 SD) to 8.65 (0.587 SD) and 11.30 (0.470 SD) seconds, and Schirmer values from 7.45 (1.146 SD) to 13.50 (1.051 SD) and 26.55 (1.932 SD). Post hoc comparisons revealed that Group A significantly outperformed both B and C at each follow-up ($P = .000$), indicating that combining Flaxseed with Tears Kool provides superior benefits in enhancing tear film parameters compared to either treatment alone.

Table 1

Group		N	Mean	Std. Deviation	Greenhouse Geisser (*P*)
Group A	**TBUT Baseline**	20	7.40	.681	.000
	TBUT Follow-up 1	20	9.55	.759	
	TBUT Follow-up 2	20	12.65	.489	
Group B	**TBUT Baseline**	20	7.45	.605	.000
	TBUT Follow-up 1	20	8.00	.459	
	TBUT Follow-up 2	20	10.50	.889	
Group C	**TBUT Baseline**	20	7.55	.605	.000
	TBUT Follow-up 1	20	8.65	.587	
	TBUT Follow-up 2	20	11.30	.470	

The table 1 shows the progression of Tear Break-Up Time (TBUT) across three groups (A, B, and C) at baseline, follow-up 1, and follow-up 2, each with 20 participants. In Group A, the mean TBUT improved significantly from 7.40 (0.681 SD) seconds at baseline to 9.55 (0.759 SD) at follow-up 1 and 12.65 (0.489 SD) at follow-up 2 (P=.000). Group B showed a similar trend, increasing from 7.45 (0.605 SD) to 8.00 (0.459 SD) and then to 10.50 (0.889 SD) (P=.000). Group C also demonstrated significant improvement from 7.55 (0.605 SD) to 8.65 (0.587 SD) and finally 11.30 (0.470 SD) (P=.000). These results indicate that all groups experienced a statistically significant enhancement in tear film stability over time, with Group A showing the most pronounced improvement, followed by Groups C and B.

Table 2

Group		N	Mean	Std. Deviation	Greenhouse Geisser (*P*)
Group A	Schirmer Test Baseline	20	8.15	1.182	.000
	Schirmer Test Follow up 1	20	14.50	.761	
	Schirmer Test Follow up 2	20	28.05	2.856	
Group B	Schirmer Test Baseline	20	7.70	1.380	.000
	Schirmer Test Follow-up 1	20	13.00	1.170	
	Schirmer Test Follow up 2	20	24.50	2.351	
Group C	Schirmer Test Baseline	20	7.45	1.146	.000
	Schirmer Test Follow up 1	20	13.50	1.051	
	Schirmer Test Follow up 2	20	26.55	1.932	

The table 2 presents Schirmer Test results for Groups A, B, and C at baseline, follow-up 1, and follow-up 2, each group consisting of 20 participants. In Group A, the mean Schirmer score increased significantly from 8.15 (1.182 SD) mm at baseline to 14.50 (0.761 SD) mm at follow-up 1 and further to 28.05 (2.856 SD) mm at follow-up 2 (*P*=.000), indicating a strong improvement in tear production. Group B also showed significant improvement, with scores rising from 7.70 (1.380 SD) mm at baseline to 13.00 (1.170 SD) mm and 24.50 (2.351 SD) mm at subsequent follow-ups (*P*=.000). Similarly, Group C improved from 7.45 (1.146 SD) mm to 13.50 (1.051 SD) mm and then to 26.55 (1.932 SD) mm (*P*=.000). All three groups demonstrated statistically significant increases in Schirmer values over time, reflecting enhanced tear secretion, with Group A achieving the highest final scores, followed by Group C and then Group B.

Table 3

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig. (*P*)
Follow-up 1	Group A	Group B	1.550	.194	.000
		Group C	.900	.194	
	Group B	Group A	-1.500	.194	.000
		Group C	-.650	.194	
	Group C	Group A	-.900	.194	.000
		Group B	.650	.194	
Follow up 2	Group A	Group B	2.150	.204	.000
		Group C	1.350	.204	
	Group B	Group A	-2.150	.204	.000
		Group C	-.800	.204	
	Group C	Group A	-1.350	.204	.000
		Group B	.800	.204	

This table 3 shows post hoc comparisons of mean differences in Schirmer Test values between Groups A, B, and C, at follow-up 1 and follow-up 2. At follow-up 1, Group A had a significantly higher mean value than Group B by 1.55 mm (*P*=.000) and higher than Group C by 0.90 mm, though the latter lacks a reported *P*-value. Group B scored significantly lower than Group A (–1.50 mm, *P*=.000) and also lower than Group C by –0.65 mm, with no *P*-value reported. Similarly, Group C was significantly lower than Group A (–0.90 mm, *P*=.000) and higher than Group B by 0.65 mm. At follow-up 2, Group A again showed significantly higher values compared to Group B (2.15 mm, *P*=.000) and Group C (1.35 mm). Group B remained significantly lower than Group A (–2.15 mm, *P*=.000) and also lower than Group C by –0.80 mm. Group C was significantly lower than Group A (–1.35 mm, *P*=.000) but higher than Group B by 0.80 mm. These results confirm that Group A consistently outperformed Groups B and C in tear secretion improvements, with all reported comparisons reaching statistical significance (*P*=.000).

DISCUSSION

Both the Patel et al. study and our current trial evaluated the role of nutritional therapy in dry eye disease (DED), focusing on flaxseed and omega-3 supplementation. Patel et al. found that both flaxseed and omega-3 capsules led to significant improvements in Schirmer test, TBUT, and OSDI scores over 12 weeks, with no statistically significant difference between the two groups (*P* = 0.018), indicating comparable efficacy. In contrast, our study demonstrated that the combination of flaxseed and Tears Kool (Group A) resulted in significantly greater improvements in Schirmer values (from 8.15 (1.182 to 28.05 (2.856 mm) and TBUT (from 7.40 (0.681 to 12.65 (0.489 s) compared to Tears Kool alone (Group B) and flaxseed alone (Group C), with all intergroup comparisons showing statistical significance (*P* = 0.000). These findings suggest that while flaxseed alone is effective, as supported by Patel et al., its combination

with lubricating eye drops produces a synergistic effect, offering superior therapeutic outcomes in the management of DED.[16]

The meta-analysis by Giannaccare et al., which included 17 randomized clinical trials with 3363 patients, demonstrated that omega-3 fatty acid (FA) supplementation significantly improved both subjective symptoms and objective signs of dry eye disease (DED), including increased tear breakup time (SDM = 0.905), Schirmer test values (SDM = 0.905), and reduced corneal fluorescein staining (SDM = 0.517), with greater benefits observed in Indian populations. In comparison, our study found that all treatment groups, Group A (flaxseed + Tears Kool), Group B (Tears Kool alone), and Group C (flaxseed alone), showed statistically significant improvement in TBUT and Schirmer scores over 12 weeks (p = 0.000), with Group A showing the highest improvement (e.g., TBUT from 7.40 (0.681 to 12.65 (0.489 seconds; Schirmer from 8.15 (1.182 to 28.05 (2.856 mm). While Giannaccare et al. confirmed the effectiveness of omega-3 FAs over placebo, our findings suggest that flaxseed, a plant-based omega-3 source, is similarly effective, and when combined with topical lubricants, offers superior therapeutic benefit, reinforcing the role of nutritional therapy, particularly in South Asian populations, in managing DED.[17]

The study by Downie et al. evaluated the efficacy and safety of OM3, a preservative-free nano-emulsion artificial tear containing carboxymethylcellulose (CMC), glycerin, flaxseed oil, castor oil, and trehalose, in comparison with Refresh Optive Advanced (ROA), which lacks trehalose and flaxseed oil. Over 90 days involving 242 dry eye patients, both treatments significantly improved OSDI scores, TBUT, and ocular staining; however, OM3 showed superior outcomes, particularly in reducing combined ocular staining at all timepoints, and in corneal and conjunctival staining at days 90 and 30, respectively. Moreover, OM3 had a lower incidence of treatment-related adverse events (6.7% vs. 9.8%). Comparatively, our study also demonstrated significant improvements in TBUT and Schirmer test scores across all groups ($P = 0.000$), with the combination therapy group (Group A: flaxseed + Tears Kool) showing the greatest benefit (e.g., TBUT increased from 7.40 (0.681 to 12.65 (0.489 s; Schirmer from 8.15 (1.182 to 28.05 (2.856 mm). Similar to Downie et al., our findings highlight the added value of flaxseed oil when combined with tear substitutes, suggesting enhanced efficacy through a multi-targeted mechanism. However, unlike Downie's focus on ocular staining, our study emphasized tear quantity and stability, offering complementary evidence that flaxseed-based combination therapies provide superior and well-tolerated relief in dry eye disease.[18]

CONCLUSION

In this study, all three treatment groups of mild to moderate dry eye with polycystic ovarian syndrome, Group A (Combination therapy of flaxseed with artificial lubricant), Group B (Tear Kool), and Group C (Flaxseed), showed marked improvement in Tear film breakup time and Schirmer test values in four weeks. But between group comparison showed that by using flaxseed with artificial lubricant showed fast recovery it reduces the inflammatory mediators of lacrimal and meibomian gland in short time interval and patient also report marked improvement in symptoms because alpha-linolenic acid of Flaxseed has anti-inflammatory, antioxidant properties that work well in conjunction with artificial lubricant to normalize the mebium of meibomian gland and aqueous production of Lacrimal gland, also it causes fast improvement in dry eye sign and symptoms then using flaxseed and artificial lubricant alone.

Limitations

- The study was conducted at a single center.
- Small sample size may affect the statistical power.
- Lack of a placebo or untreated control group makes it difficult to distinguish treatment effects from natural disease variability.
- Short follow-up duration (12 weeks) does not assess long-term efficacy or safety of the interventions.
- Ocular surface staining and inflammatory markers were not evaluated.
- Dietary variations and compliance with flaxseed supplementation were not objectively monitored.

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