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ORIGINAL ARTICLE

Comparison of autologous serum versus artificial tears in the management of dry eyes syndrome.

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ABSTRACT… Objective: To compare the reduction in ocular surface disease index (OSDI) score from baseline by using autologous serum and artificial tears in managing dry eye syndrome. **Study Design:** Quasi-experimental study. **Setting:** Department of Ophthalmology, Federal Government Polyclinic Hospital, Islamabad, Pakistan. **Period:** June-2025 to November-2025. **Methods:** A total of 70 patients with dry eye syndrome were included and divided into groups 1 and 2 without randomization in alternating fashion. Group-1 was given autologous serum eye drops for 3 months and Group-2 was given artificial tears for 3 months. Comparison of pre- and post-intervention median OSDI score within the groups was done using Wilcoxon signed rank test. Intergroup comparison of median OSDI score and median % reduction in OSDI score from baseline was done using Mann Whitney U-test. Analysis was done with SPSS software version 25. **Results:** Composite median age of DES sufferers was 41.50 (22.00) years. There were 41 (58.60%) male and 29 (41.40%) female patients. In Group-1, median pre-intervention OSDI, post-intervention OSDI score and % reduction in OSDI score from baseline was 61.00 (17.00), 32.00 (36.00) and 47.54 (44.76) % while in Group-2, these were 64.00 (15.00); (p = 0.400), 34.00 (12.00); (p = 0.184) and 52.50 (10.82) %; (p = 0.025), respectively. There was no significant difference of post-intervention DES severity among the study groups (p = 0.628). **Conclusion:** Autologous serum provides comparable results to artificial tears in dry eyes syndrome with significantly increased reduction in OSDI score.

Key words: Autologous, Dry Eye Syndrome, Lubricant Eye Drops, Serum.

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INTRODUCTION

Dry eye syndrome (DES) is a multifactorial ocular surface disorder characterised by an imbalance in tear film homeostasis, stemming from either tear deficiency or excessive tear evaporation that has a global prevalence of 11.59%.[1] This condition can occur either due to increased evaporation, aqueous-deficiency, decreased ocular moisture or by the combination of any of these factors.[2] To diagnose and assess the severity of DES, the Ocular Surface Disease Index (OSDI) is a simpler, faster and dependable diagnostic tool which is used by the clinicians globally.[3] In addition, there are various tests available to assess DES including Schirmer's test, slit lamp examination, meibomian gland imaging, lipid layer thickness assessment and optical coherence tomography (OCT).[4]

Management of DES primarily involves use of artificial tears. There are several types of artificial tears based on their composition compounds including polyvinyl alcohol, polyvinylpyrrolidone, carboxymethyl cellulose (CMC), dextran, carbomer 940, sodium hyaluronate, hydroxypropyl guar, hyaluronic acid, hydroxypropyl methylcellulose and polyethylene glycol.[5] These agents provide relief from the disease symptoms through adequate lubrication, ocular surface modulation and tear substitution.[6,7] One alternative novel treatment modality for managing this disease is autologous serum. It contains several epitheliotrophic factors like epidermal, transforming and platelet derived growth factors, similar to natural tears, which are hypothesised to be very effective in managing DES.[8] In this instance, a study compared efficacy of autologous serum versus artificial tears in the management of DES and reported that there was 50.95% decrease in OSDI score with autologous serum and only 22.19% decrease with artificial tears.[9]

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In the modern therapeutics, application of autologous serum is wide spread, however, in the management of DES there is still lack of concrete evidence regarding its efficacy. In addition, artificial tears have proven efficacy in the management of DES. Therefore, it is essential to conduct further studies in this regard. For this purpose, present studies being conducted with the aim to compare the reduction in OSDI score from baseline by using autologous serum and artificial tears in managing DES.

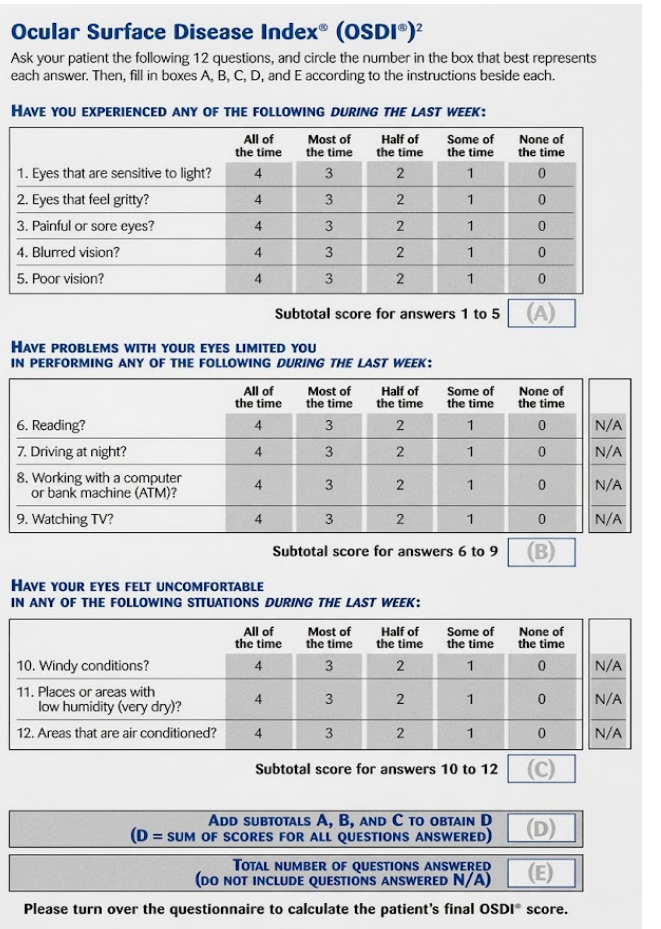
METHODS

This quasi-experimental study was held at Federal Government Polyclinic Hospital, Ophthalmology Department, Islamabad, Pakistan from June-2025 to November-2025 after ethical committee approval (FGPCI/12/2024-E-Committee). A sample size of 70 was calculated by inputting 5% level of significance, 70% power and anticipated frequency of decrease in OSDI score with autologous serum and artificial tears of 50.95% and 22.19%, respectively.[9] Calculation was done with OpenEpi sample size calculator software. Sample was selected consecutively, without randomization using non-probability technique. Before inclusion, it was ensured that all the patients gave their explicit informed consent in written form for which a dedicated pre-printed form was used.

Adult patients of either gender who presented with severe DES were included. Patients with the disease of the ocular surface other than the DES, inability to completely follow up, severe anaemia, previous use of autologous serum, topical steroids, or cyclosporine, medically uncontrolled cerebrovascular and cardiovascular disease and hypersensitivity to the proposed interventions, were excluded.

DES was evaluated with a standardised instrument - Ocular Surface Disease Index (OSDI score) more than 33 (Figure-1).

DES severity was labelled based on OSDI score as mild (score 13-22), moderate (score 23-32) and severe (score 33-100) while a score of 0-12 was considered normal.



Ocular Surface Disease Index® (OSDI®)[2]

Ask your patient the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

HAVE YOU EXPERIENCED ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5 (A)

HAVE PROBLEMS WITH YOUR EYES LIMITED YOU IN PERFORMING ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9 (B)

HAVE YOUR EYES FELT UNCOMFORTABLE IN ANY OF THE FOLLOWING SITUATIONS *DURING THE LAST WEEK*:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12 (C)

ADD SUBTOTALS A, B, AND C TO OBTAIN D (D = SUM OF SCORES FOR ALL QUESTIONS ANSWERED) (D)

TOTAL NUMBER OF QUESTIONS ANSWERED (DO NOT INCLUDE QUESTIONS ANSWERED N/A) (E)

Please turn over the questionnaire to calculate the patient's final OSDI® score.

Pre-intervention patient demographics and effect modifiers including age, gender, pre-intervention OSDI score and DES severity were documented. All patients underwent an ophthalmic examination which involved an external examination of the eyes, visual acuity by standard Snellen's chart, diffuse torch light examination, slit lamp examination for corneal and conjunctival fluorescein staining. After this, patients were divided into two groups without randomization in alternating order. Group-1 was given autologous serum (AS) eye drops to be instilled one drop of eye drops to each eye four times daily for 12 weeks and Group-2 was given artificial tears (AT), with a composition of polyethylene glycol and propylene glycol, to be instilled one drop of eye drops to each eye four times daily for 12 weeks.

For preparation of AS eye drops, 100ml of venous whole blood was extracted from each patient who was to be prescribed autologous serum therapy. Sample was centrifuged for 5 minutes at 1500 rpm. The obtained 20ml serum was carefully separated

in a sterile manner and diluted with saline solution to achieve a final serum concentration of 20%. The final preparation was aliquoted into 5ml vials with ultraviolet protection. Patients were advised to keep the vial that they were using in a refrigerator at 4 degrees celsius and to store the other vials in a freezer until required. Patients were instructed to instil one drop of eye drops to each eye four times daily for 12 weeks. Participants were advised against using any other eye drops or medications during the study period.

All the patients were followed up at 6 and 12 weeks after therapy initiation. Final assessment for efficacy was made at 12 weeks after therapy initiation through OSDI score assessment. Percentage reduction from baseline was calculated and documented. Calculation was done by using following formula [(pre-intervention OSDI – post-intervention OSDI / Pre-intervention OSDI) x 100]. In addition, post-treatment DES severity was also documented.

All the collected data was entered and analysed with SPSS version 25. Qualitative variables (gender and DES severity) were measured as frequency and percentage. Quantitative variables (age, OSDI score and % reduction in OSDI score from baseline) were measured as median interquartile range (IQR) since normality assessment by Shapiro-Wilk test revealed these to have non-normal distribution. Comparison of pre- and post-intervention median OSDI score within the groups was done using Wilcoxon signed rank test. Intergroup comparison of median OSDI score and median % reduction in OSDI score from baseline was done using Mann Whitney U-test. Intergroup comparison of post-intervention DES severity was done using Chi-square test. A p-value ≤ 0.05 was considered as significant.

RESULTS

In this study, 70 patients were included. Composite median age of DES patients was 41.50 (22.00) years with 33 (47.10%) patients aged < 40 years while 37 (52.90%) aged ≥ 40 years. There were 41 (58.60%) male and 29 (41.40%) female patients. Intergroup comparative analysis of pre-intervention patient characteristics is given in Table-I:

TABLE-I

Intergroup pre-intervention patient characteristics comparison (n = 70)

	Group-1 (n = 35)	Group-2 (n = 35)	P-Value
Median age (years)	43.00 (22.00)	40.00 (23.00)	0.707 [a]
Age group			
< 40 years	17 (48.57%)	16 (45.71%)	0.811 [b]
≥ 40 years	18 (51.43%)	19 (54.29%)	
Gender			
Male	19 (54.29%)	22 (62.86%)	0.467 [b]
Female	16 (45.71%)	13 (37.14%)	
DES severity			
Severe	30 (85.71%)	30 (85.71%)	1.000 [b]
Moderate	5 (14.29%)	5 (14.29%)	

DES = Dry eye syndrome, a = independent sample t-test, b = Chi-square test

In Group-1, median pre-intervention OSDI, post-intervention OSDI score and % reduction in OSDI score from baseline was 64.00 (15.00), 34.00 (12.00) and 52.50 (10.82) % while in Group-2, these were 47.54 (44.76); (p = 0.400), 32.00 (36.00); (p = 0.184) and 47.54 (44.76) %; (p = 0.025), respectively. There was no significant difference of post-intervention DES severity among the study groups (p = 0.628). Intergroup comparative analysis of 12-weeks post-intervention parameters is given in Table-II:

TABLE-II

Intergroup 12-weeks post-intervention parameters comparison (n = 70)

	Group-1 (n = 35)	Group-2 (n = 35)	P-Value
Median pre-intervention OSDI	64.00 (15.00)	61.00 (17.00)	0.400 [a]
Median post-intervention OSDI	34.00 (12.00)	32.00 (36.00)	0.184 [a]
	< 0.001 [b]	< 0.001 [b]	
Median % reduction in OSDI	52.50 (10.82) %	47.54 (44.76) %	0.025 [a]
DES severity			
Mild	8 (22.86%)	6 (17.14%)	0.628 [c]
Moderate	11 (31.43%)	9 (25.71%)	
Severe	16 (45.71%)	20 (57.14%)	

OSDI = Ocular Surface Disease Index, DES = Dry eye syndrome, a = Mann Whitney U-test, b = Wilcoxon signed rank test, c = Chi-square test

DISCUSSION

Present study focused on comparing a novel therapeutic agent (autologous serum) effectiveness in management of a highly common eye condition with the most commonly prescribed agent (the artificial tears). In the modern therapeutics, autologous serum has a lot of applications and is used for management of a wide variety of allergic and inflammatory diseases, particularly in the fields of dermatology and surgery.[10,11] However, its use in management of DES is quite new, particularly in the context of a developing country. To gauge the effectiveness of the two interventions in DES management, OSDI score was used which is a highly validated and widely used clinical scale in this regard and has been used by multiple researchers in the past for the same purpose.[12,13]

Upon analysis of the individual effectiveness of each intervention, it was observed that after 12 weeks of therapy, both the therapies were highly effective with significant improvement in the OSDI score compared to baseline with AT ($p < 0.001$) and AS eye drops ($p < 0.001$). As far as effectiveness of AT is concerned, substantial evidence exists indicating that any AT which has glycol compounds in its composition (as was the case in present study) can significantly improve the symptoms and the severity of DES.[14,15] For AS, this characteristic of improving symptoms and the severity of DES comes from its unique properties and composition similarities to the natural tears produced by the eyes.[16,17]

Upon comparison of the effectiveness outcomes, however, it was found that AS eye drops provided lesser post-intervention OSDI score after 12-weeks of therapy ($p = 0.184$) which was statistically insignificant, yet, the percentage reduction in the OSDI score from baseline levels was significantly higher with AS drops rather than AT drops ($p = 0.025$). In comparison to this, a comparative study was conducted with similar aim in which it was found that at the end of three months of therapy, OSDI score was significantly less among DES patients who were treated with AS eye drops rather than AT ($p < 0.001$).[18] In another study where a comparison of effectiveness of AS and AT eye drops was made, it was found that the mean OSDI score at the end of three months of therapy in AS eye drops treatment group was 43.9 ± 24.3 while in AT eye drops treatment group, it was 66.6 ± 19.8, ($p < 0.0001$).[19] In one study, similar comparison revealed that AS was significantly more effective in reducing the OSDI score as compared to AT eye drops in dry eye disease patients with a mean difference of OSDI score between the two study groups of –20.9 ($p < 0.0001$).[20]

In addition to this strong evidence in favour of higher effectiveness of AS eye drops therapy in comparison to AT eye drops therapy in DES, there are even single group studies that have exhibited high degree of effectiveness of this useful therapy in managing DES patients with high degree of safety.[21,22] Despite such strong evidence in favour of preferential use of AS eye drops over AT therapy, still no consensus guidelines support use of this therapy in management of DES as a primary mode of intervention. Even in Pakistan, its use as a primary modality of treating DES has neither been authorised by the drug regulators, nor is it used by the ophthalmologist as the primary intervention. This study adds to the current strong evidence regarding the effectiveness of AS in managing DES and its superiority over AT and has the potential to serve as a stepping stone towards modification of standard practice and procedures towards using this modality of treatment as primary treatment choice in DES cases at local level.

One major limitation of present study was that an official document regarding the deniability of AS eye drops use as primary intervention in DES cases could not be accessed. Another limitation was inability to find any studies that exhibited either a non-significant difference between the two intervention or better effectiveness of AT eye drops. In addition, safety assessment and sustained effectiveness in the long term could not be assessed in this study due to time constraints. To address these, further studies that can gauge these factors are recommended to be conducted.

CONCLUSION

In conclusion, autologous serum is an effective and comparable therapeutic intervention in management of dry eyes syndrome as compared to artificial tears in terms of post-intervention OSDI score and post-

intervention OSDI severity, however, median % reduction in OSDI score was better with autologous serum rather than artificial tears.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
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2	**Tehreem Tahir:** Drafted, Methodology.
3	**Muhammad Mumtaz Chaudhry:** Supervision.
4	**Rabia Akhtar:** Critically revised.
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