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Mohamed Khedr Mohamed
- Department of Ophthalmology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Mostafa Elsayed Elewa
Department of Ophthalmology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt

Mohamed Hussein Mohamed Alashmawi
Department of Ophthalmology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt., m.ashmawy2014@gmail.com

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ORIGINAL ARTICLE

Tear Film Changes After Autologous Serum in Managment of Dry Eye Using Ocular Surface Analyser

Mohamed Khedr Mohamed, Mostafa Elsayed Eliwa, Mohamed Hussein Al ashmawi*

Department of Ophthalmology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Abstract

Background: **The aetiology of dry eye disease (DED) includes abnormalities in the neurosensory system, ocular surface inflammation, tear film instability, as well as hyperosmolarity (DED), a multifactorial ocular surface condition with absent tear film homeostasis and uncomfortable eyes.**

Aim and objectives: **To detect changes in the tear film in patients of sever DED after Autologous serum (AS) using ocular surface analyzer (OSA).**

Patients and methods: **In this interventional trial, AS eye drops were administered to 10 patient eyes who presented to the AL-Azhar University's Department of Ophthalmology with a moderate to severe DED, tear. The case went on for 6−12 months.**

Result: **Measurements of the Ocular Surface Disease Index (OSDI) were made both before and during the injection of AS. When using AS, the OSDI ranged from 18 to 44 with mean SD = 27.7 8.21, having a difference between the two groups that is very statistically significant ($P = 0.001$). OSDI before AS measurements ranged from 42 to 87 with mean SD = 69.4 12.88.**

Conclusion: **According to an advancement in OSDI, for the safe and efficient treatment of severe DED, eye drops containing AS are used. Schirmer's First, LLD, TMH, Noninvasive break up time (NIBUT), Tear Film Break-Up Time.**

Keywords: Autologous serum, Dry eye, Ocular surface analyser, Tear film

1. Introduction

Dry eye disease (DED), a multifactorial illness, has three main causes: tear film instability, neurosensory problems, ocular surface inflammation, and hyperosmolarity, as well as ocular pain and a tear film imbalance, the likelihood of DED, which ranges from 5 to 50%, is influenced by age.[1] (see Fig. 1)

Most DED patients had moderate-to-severe DED, and initial treatments including changing one's lifestyle and using artificial tears did not help them.[2]

People with moderate-to-severe DED have had good success using biological tear substitutes made from blood products to lessen their symptoms of dry eyes and ocular surface stains.[3]

The biochemistry of autologous serum (AS) eye drops is comparable to that of human tears. They are particularly rich in minerals, proteins, and growth factors that support tissue repair and regeneration, includes transforming growth factors, epidermal growth factors, and growth factors generated from platelets. The tear film is composed of an aqueous layer and a lipid layer. The tear film integrity in this structure is influenced by the lipid layer, aqueous fluid, secretory mucins (particularly MUC5AC10), and membrane-associated mucins. (particularly the longest MUC11, MUC16). The lipid layer stabilises the tear film's surface after blinking because the aqueous tear fluid needs to be disseminated and redistributed to prevent it from evaporating. This preserves the tear film. The new

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* Corresponding author at: Department of Ophthalmology, Faculty of Medicine for Boys, Al-Azhar University, Resident of Ophthalmology at National eye Centre, Cairo, 11765, Egypt.
E-mail address: m.ashmawy2014@gmail.com (M.H. Al ashmawi).

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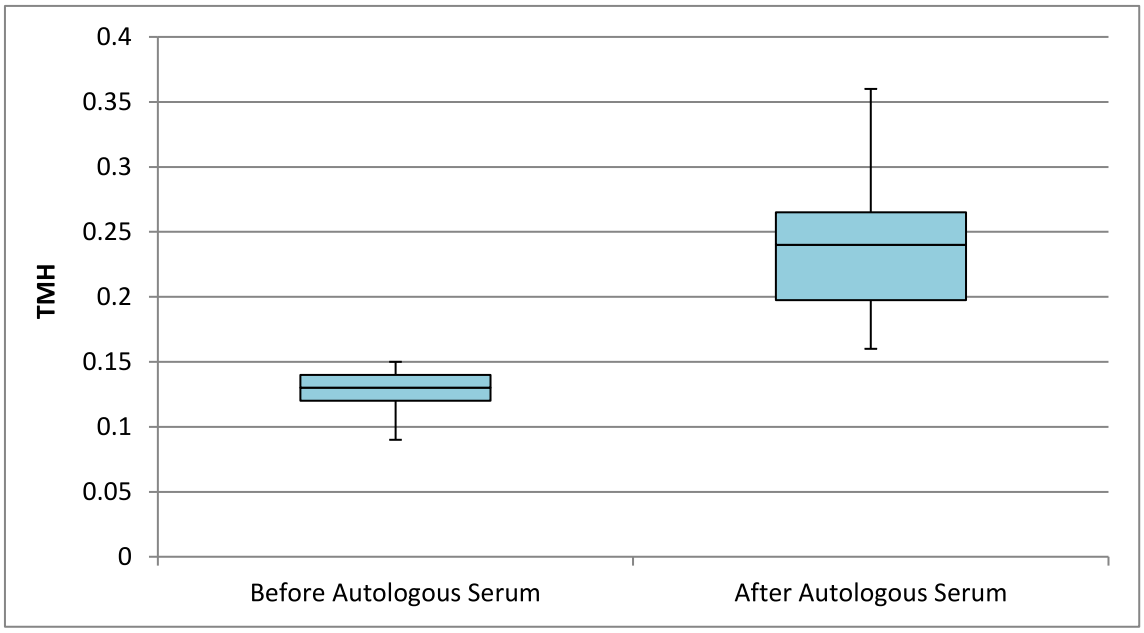

Fig. 1. Box-plot displaying TMH differences across research groups Measurements of tear meniscus height (TMH) before and after AS.

individual tear film analysis tool, known as ocular surface analyzer (OSA), enables rapid structural research on the tear film's lipid, aqueous, and mucin layers as well as research on their composition. In regard to the kind of insufficiency, OSA also assists in determining which layers can be treated with a particular treatment.[4]

The goal of this study was to detect changes in the tear film in patients of sever DED after AS using OSA.

2. Patients and methods

The Ophthalmology Department at AL-Azhar University treated 10 patients with AS eye drops for mild to severe DED. Tear film will be assessed by ocular surface analyzer device.

2.1. Inclusion criteria

Age group between 20 and 60 years old of both sexes.

2.2. Exclusion criteria

Anemia or Heart failure and active infection or advanced cancer.

2.3. Instruments used for assessment of tear film

Patients was subjected to OSA device (IDRA, Sistemi, Italy) examination to assess: Noninvasive break up time (NIBUT) test, tear meniscus height, and lipid layer thickness.

2.4. Methods

All candidates will be subjected to full ophthalmological examination in the form of: Full ophthalmic history, slit lamp examination, Schirmer tear test, Ocular Surface Disease Index (OSDI) examination of tear film condition before and after AS, and visual acuity uncorrected (UCVA) and best corrected (BCVA). The OSA device measures the thickness of the lipid layer and the height of the damaged meniscus (TMH), harmful fluroscine break breakdown time test.

Follow-up intervals: Before treatment and after 2 months of treatment.

2.5. Statistical analysis

Using SPSS 26.0 for Windows, all data were gathered, tabulated, and statistically examined (SPSS Inc., Chicago, IL, USA). The qualitative data was expressed in terms of numbers and percentages. Quantitative data were described using the range (minimum and maximum), mean, standard deviation, and median. Significant levels of *P* value were utilised to indicate significance in all two-tailed statistical comparisons, extremely significant, and non-significant differences, respectively.

3. Results

Table 1 showed Demographic characteristics among the study population. Number of male patients in the study population was 7 (70%). Number

Table 1. Demographic characteristics among the study population.

	Study population ($n = 10$) n (%)
Sex	
Male n (%)	7 (70%)
Female n (%)	3 (30%)
Age (years)	
Mean ± SD.	40.6 ± 10.76
Median (IQR)	41 (32.25–50)
Range (Min-Max)	31 (24–55)

Table 2. Measurements of visual acuity before and after autologous serum.

	Before autologous serum ($n = 10$)	After autologous serum ($n = 10$)	Test of significance.	P
Visual acuity				
Mean ± SD.	0.65 ± 0.16	0.75 ± 0.14	t = −1.447	0.165
Median (IQR)	0.65 (0.52–0.7)	0.75 (0.7–0.8)		
Range (Min-Max)	0.5 (0.4–0.9)	0.5 (0.5–1)		

of female patients in the study population was 3 (30%). Age in the study population ranged from 24 to 55 with mean ± SD = 40.6 ± 10.76.

Table 2 showed Measurements of visual acuity before and after AS. Visual acuity in Before AS measurements ranged from 0.4 to 0.9 with mean ± SD = 0.65 ± 0.16 while in After AS measurements the visual acuity ranged from 0.5 to 1 with mean ± SD = 0.75 ± 0.14 with no statistical significant difference ($P = 0.165$) between the two groups.

Table 3 showed Measurements of Schirmer tear test before and after AS. Schirmer tear test in Before AS measurements ranged from 1 to 4 with mean ± SD = 2.2 ± 0.92 while in After AS measurements the schirmer ranged from 6 to 13 with mean ± SD = 9.2 ± 2.25 with highly statistical significant difference ($P =< 0.001$) between the two groups.

Table 4 showed Measurements of break up time test (BUT) after and before using AS. The BUT varied from 1 to 6 with mean SD = 3.3 1.7 in measures taken before AS, but the BUT ranged from 8 to 18 with mean SD = 12.3 3.65 after AS, with a very statistically significant difference ($P = 0.001$) between the two groups.

Table 3. Measurements of schirmer tear test before and after autologous serum.

	Before autologous serum ($n = 10$)	After autologous serum ($n = 10$)	Test of significance.	P
Schirmer tear test				
Mean ± SD.	2.2 ± 0.92	9.2 ± 2.25	t = −9.105	<0.001
Median (IQR)	2 (2–2.75)	8.5 (8–10.75)		
Range (Min-Max)	3 (1–4)	7 (6–13)		

Table 4. Measurements of break time test (BUT) before and after autologous serum.

	Before autologous serum ($n = 10$)	After autologous serum ($n = 10$)	Test of significance	P
BUT				
Mean ± SD.	3.3 ± 1.7	12.3 ± 3.65	t = −7.061	<0.001
Median (IQR)	3 (2.25–4.75)	11.5 (9.5–15.25)		
Range (Min-Max)	5 (1–6)	10 (8–18)		

Table 5. Measurements of lipid layer thickness (LLT) before and after autologous serum.

	Before Autologous Serum ($n = 10$)	After Autologous Serum ($n = 10$)	Test of Significance	P
LLT				
Mean ± SD.	36.6 ± 6.36	77.6 ± 7.32	t = −13.366	<0.001
Median (IQR)	38 (31.5–41)	77.5 (71–82.75)		
Range (Min-Max)	20 (25–45)	21 (68–89)		

Table 5 measured the thickness of the lipid layer (LLT) before and after the injection of autologous serum. LLT in Before AS varied from 25 to 45 with mean SD = 36.6 6.36 while LLT in After AS ranged from 68 to 89 with mean SD = 77.6 7.32. The difference between the two groups was highly statistically significant ($P = 0.001$).

Table 6 shown NIBUT (non-invasive break up time) measurements taken before and after the injection of AS. The NIBUT varied from 1 to 5 with a mean and SD of 2.93 1.32 before AS, whereas the NIBUT ranged from 7 to 12 with a mean and SD of 9

	Before autologous serum ($n = 10$)	After autologous serum ($n = 10$)	Test of significance	P
NIBUT				
Mean ± SD.	2.93 ± 1.32	9 ± 1.76	t = − 8.717	<0.001
Median (IQR)	3 (2.25–3.75)	9 (7.25–10)		
Range (Min-Max)	4 (1–5)	5 (7–12)		

t: and after Autologous Serum.

1.76 after AS, with a very statistically significant difference ($P = 0.001$) between the two groups.

4. Discussion

This interventional study was conducted on 10 eyes of patients attending the Ophthalmology Department at AL-Azhar University presenting AS eye drops were used to treat patients with mild to severe dry eye condition tear. The trial lasted between 6 and 12 months. As regard demographic characteristics among the study population. Seven patients, or 70% of the study group, were men. There were 3 (or 30%) female patients in the study population. Age in the study population ranged from 24 to 55 with mean ± SD = 40.6 ± 10.76. However, in the study of Celebi and colleagues,[5] 20 individuals with severe DED (40 eyes), with a mean age of 56.05 8.07 years (18 females and 2 males) were included in the study. Whereas in the study of Mohammed Zakaria and colleagues,[6] they included 30 patients. They all were between 53 and 72 years old. The mean age was 63.01 years ± 5.09 SD. Sex of patients was 18 (60%) females and 12 (40%) males.

Regarding assessments of visual acuity before and after AS, the investigation underwent today made that clear. There was no statistically different that was identified ($P = 0.165$) in the two teams' visual acuity measures before and after the administration of AS, which ranged from 0.4 to 0.9 with mean SD = 0.65 0.16 and 0.5 to 1 with mean SD = 0.75 0.14, respectively. Our results supported those of the Jirsova and colleagues investigation,[7] who discovered ? The BCVA was found to be unaffected by AS eye drop therapy before or after ($P = 0.29$); four eyes deteriorated, albeit only by one line on the conventional Snellen chart, while eight eyes improved. The OSDI measurements performed before and after the administration of AS served as the foundation for the trial's findings, using the AS procedures, the OSDI varied from 18 to 44, with a mean SD of 27.7 8.21 and a very statistically significant difference ($P = 0.001$) between the two groups. The OSDI in Before AS measurements ranged from 42 to 87 with mean SD = 69.4 12.88. 63 patients' 123 eyes were evaluated in Hussain and colleagues[16] analysis, which mirrored our findings, with an average 12-month follow-up (range, 3–48 months). At the 3- to 6- and 6- to 12-month follow-ups, the mean OSDI scores increased ($P = 0.029$ and 0.003, respectively; range: 49.5 8.2 and 39.3 21.4) from a mean baseline of 54.1 22.3. According to Beylerian and colleagues,[8] the OSDI score decreased between P0 and P1 by 19.32 points and between P0 and P4 by 23.06 points and P0, respectively. Before initiating AST treatment, Fluorescein staining was used during the clinical evaluation of patients at P0, P1, P2, P3, P3, (9–15 months), P4, (15–24 months), and P5, (>24 months).

In addition, 12 individuals with severe DED were included, according to Urzua and colleagues In comparison to conventional treatment, AS treatment significantly ($P = 0.002$) increased the OSDI drop to 50%.In the study in our hands, as regard as regard measurements of Schirmer tear test before and after AS. Schirmer tear test in Before AS measurements ranged from 1 to 4 with mean ± SD = 2.2 ± 0.92 while in After AS measurements the schirmer ranged from 6 to 13 with mean ± SD = 9.2 ± 2.25 with highly statistically significant difference ($P =< 0.001$) between the two groups.

Our results were in line with study of Mohammed Zakaria and colleagues,[6] According to what they stated, using autologous serum before and after the Schirmer test.

With a P value of 0.001, the improvement following AS is statistically significant. Jirsova and colleagues[7] also showed that the Schirmer test improved statistically significantly following the administration of AS. Additionally, Schirmer scores increased at the 12- to 24-month follow-up (mean baseline, 6.6 6.5 mm) (mean = 10.7 11.4, $P = 0.03$). according to Hussain and colleagues. Additionally, Valencia Castillo and colleagues,[9] found a significant change between pre and posttreatment in the mean millimetres in Schirmer's test and the mean time in the BUT test 16.7% ($n = 4$) of the patients had grade 4 metaplasia at the start of their treatment, 25% ($n = 6$) had grade 3, 41.7% ($n = 10$) had grade 2, and 16.7% ($n = 4$) had grade 1 metaplasia.

Additionally, Schirmer test results with AST demonstrated a substantial reduction in dry eye symptoms over time at P1 (P = 0.05), according to Beylerian and colleagues, Wang and colleagues' meta-analysis contained 16 7 RCTs with 267 individuals, in contrast to Wang and colleagues meta-analysis. The average age of research participants was 50, and treatments typically lasted eight weeks. Following therapy, Schirmer I test results comparing the two groups showed no differences, the MD was 1.68 mm (95% CI, −0.65; 4.00). Measurements of the BUT test before and after using AS provided evidence of this in the current experiment. The BUT varied from 1 to 6 in measures done prior receiving AS, with a mean and standard deviation of 3.3 and 1.7, with a very statistically significant difference ($P = 0.001$) between the two groups. While the BUT in measures after AS had a mean and standard deviation of 12.3 3.65 and ranged from 8 to 18. Our results supported Mohammed Zakaria and colleagues[6] study, which showed that the tear break-up

time test (TBUT) was conducted both before and after the delivery of AS. With a *P* value of 0.001, the improvement following AS is statistically significant. Additionally, Beylerian and colleagues[8] state that at P1, with AST, the BUT also demonstrated a progressive improvement in dry eye problems (P0.05). Franchini and colleagues completes study of the TBUT[10] contained data from extra follow-up intervals (2–12 months); nonetheless, there were no overt changes between the groups, and the quality of the evidence was evaluated as poor to extremely low. Our findings were corroborated by Pan and colleagues[11] study, which showed that 20% AS might be helpful in lowering patient-reported symptoms over the short term (2 weeks), despite extended follow-up periods not revealing any advantage over longer periods. Additionally, Francesco and colleagues[12] showed that treating patients with DED from various etiologies with AS eye drops improved both the clinical signs and symptoms.

In addition, Takashi Kojima and colleagues,[13] discovered that people who utilised AS eye drops significantly improved their scores for ocular surface vital staining, pain symptoms, and tear stability without any unfavourable side effects.

Moreover, in other study, Geerling and colleagues,[14] demonstrate that serum promotes ocular surface epithelial cells' survival, proliferation, and migration superior than replacements for unpreserved pharmaceutical tears.

And Kojima and colleagues,[15] showed that after 2 weeks of treatment, when compared with those who used artificial tears without preservatives, those who were randomly assigned to AS eye drops significantly improved in terms of mean tear film breakup time, fluorescein score, Rose Bengal score, and subjective symptom scores.

4.1. Conclusion

This study demonstrates the safe and effectively treating severe DED with AS eye drops Test Schirmer's 1, the OSDI, the TBUT, the LLD, the TMH, and the NIBUT all showed improvements.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

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Conflicts of Interest

The authors declared that there were NO conflicts of Interest.

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