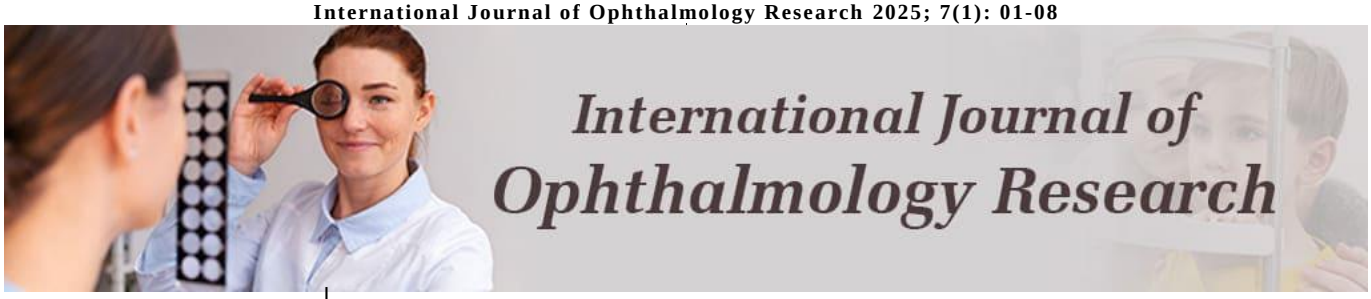


**ISSN Print:** 2618-1495
**ISSN Online:** 2618-1509
IJOR 2025; 7(1): 01-08
www.ophthalmologyjournal.in
Received: 15-03-2025
Accepted: 16-04-2025

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# Artificial tears vs. autologous serum eye drops: Which is more effective for severe dry eye?

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**DOI:** https://www.doi.org/10.33545/26181495.2025.v7.i1a.26

**Abstract**
**Background**: The severe dry eye disease (DED) represents a widespread condition which combines persistent eye discomfort with impaired tear film functionality. The management of DED can be achieved through artificial tears and autologous serum eye drops as potential treatment solutions. The exact effectiveness between these two treatments has not been established.
**Aims** This study compared Artificial Tears (Group A) with Autologous Serum Eye Drops (Group B) for treating severe DED during twelve weeks.
**Methods**: The research study included 300 patients with severe DED who received participation at Tikrit Teaching Hospital in Iraq. The research study divided 150 patients into the Artificial Tears group and 150 patients into the Autologous Serum Eye Drops group. Patients received their assigned treatment three times daily for twelve weeks during the study period. The research study evaluated treatment effectiveness by using OSDI and VAS scores for symptom assessment and tear film stability tests including TBUT and Schirmer test and ocular surface integrity evaluation through fluorescein staining and adverse effect assessment.
**Results** Group B achieved superior symptom relief than Group A based on OSDI and VAS scores which showed lower values ($p<0.01$). The objective tests of TBUT and Schirmer test showed better results in Group B than in Group A ($p<0.05$). Group B showed superior ocular surface healing based on fluorescein staining scores ($p<0.01$). Patients tolerated the treatments well because they experienced minimal adverse effects.
**Conclusion**: Autologous serum eye drops proved superior to artificial tears because they delivered superior symptom relief and improved tear film stability and ocular surface healing for patients with severe DED. The treatment of refractory DED should include autologous serum eye drops as a viable option.

**Keywords:** Dry eye disease, artificial tears, autologous serum, ocular surface, treatment efficacy

## Introduction
Dry eye disease (DED) represents a complex disorder which causes ongoing eye discomfort together with visual problems and damage to the eye surface. The condition exists as a common health issue which affects numerous people across the globe because of changing lifestyles and environmental factors and an aging population. The condition develops when tear production and tear composition fail to balance properly thus damaging both ocular surface health and tear film stability (Messmer, 2015) [17]. The two primary subtypes of dry eye exist as aqueous-deficient dry eye which shows reduced tear production and evaporative dry eye which results from excessive tear drying. Symptoms of this condition span from minor irritation through to severe discomfort and vision problems (Stern *et al.*, 2013) [18].
The disease process of DED results from a combination of lacrimal gland dysfunction and ocular surface inflammation and immune system activation. The development of DED depends heavily on chronic ocular surface inflammation which damages both corneal and conjunctival epithelium (Wei & Asbell, 2014) [15]. The inflammatory response leads to increased production of cytokines and proteases which intensifies the condition through continuous worsening. Treatment plans focus on symptom relief as well as inflammation reduction and ocular surface health recovery (Pflugfelder & Stern, 2009) [7].

The standard DED treatment consists of artificial tears which provide temporary relief by lubricating the eyes. Artificial tears containing sodium hyaluronate and glycerin and carboxymethylcellulose agents serve to moisten the ocular surface and enhance tear film stability according to Semp *et al.* (2023) [10]. The treatments fail to stop inflammatory processes and they do not bring enough relief to patients who have moderate to severe DED. Patients with severe DED cases usually require extra treatment options (Hynnekleiv *et al.*, 2022) [5].

Autologous serum eye drops (ASEDs) present a promising treatment solution for severe DED patients who do not respond to standard therapies. The patient's blood source allows the creation of autologous serum which contains multiple growth factors and cytokines and bioactive proteins that help heal epithelial tissues while reducing inflammation (Zheng & Zhu, 2023) [16]. Autologous serum functions as an ophthalmological product because it provides natural tear components which stabilize tear films and promote better ocular surface health. Studies indicate that ASEDs lead to major symptom and health improvements for patients with severe dry eye while demonstrating superior biological relevance compared to artificial tears (He *et al.*, 2024) [4].

Current evidence from well-controlled large studies does not establish how effective ASEDs are compared to artificial tears. The studies have shown positive results with ASEDs but the evidence does not show that these products are better than standard artificial tear solutions (Tsubota *et al.*, 1999) [13]. The ASED manufacturing process requires blood collection and laboratory work and strict adherence to sterile protocols which may limit their availability for particular patients. The lack of information about artificial tears versus autologous serum eye drops for treating severe DED necessitates additional research (Seghatchian & Krailadsiri, 1997) [9]. This research evaluates the performance of Artificial Tears and Autologous Serum Eye Drops for treating severe dry eye disease (DED) during a 12-week period.

## Materials and Methods

The research was conducted to compare the effectiveness of Artificial Tears and Autologous Serum Eye Drops in the management of severe dry eye disease (DED). The study was conducted from October 2024 to January 2025. Three hundred participants were enrolled in the study for the research based on the inclusion criteria of having severe dry eye disease as diagnosed by Tear Film Break-up Time (TBUT) and Schirmer test and ocular surface staining results. The clinical and laboratory procedures were conducted at Tikrit Teaching Hospital in Iraq that used modern diagnostic tools for dry eye assessment through non-invasive TBUT measurement and ocular surface staining and Schirmer testing. The ophthalmology department of the hospital made follow-up appointments and patients were given contact information for the study coordinator to ask questions about their treatment or to report adverse effects.

### Patient Recruitment and Inclusion Criteria

A detailed screening procedure was followed to select the most suitable participants. The study included participants between 18 and 70 years old who had experienced severe dry eye symptoms for at least six months before the study began. The study was also excluded participants with systemic diseases like autoimmune disorders or diabetes and those with ocular infections as well as people who received recent eye surgery or experimental dry eye treatments. Pregnant and breastfeeding women were also excluded from the study to guarantee both safety and result applicability.

### Study Design

The research divided participants into two separate treatment groups through a randomized controlled trial (RCT) design. Group A participants underwent treatment with artificial tears that contained sodium hyaluronate. The drops were administered three times a day. The treatment for Group B consisted of autologous serum eye drops which started with blood serum extraction from patients followed by processing and filtration before using the solution as eye drops three times daily.

### Preparation of Autologous Serum

The autologous serum eye drops were made in accordance with the standard procedures of the hospital. Blood collection from each participant was done in sterile conditions and then centrifuged to separate the serum. The serum solution was made into a 20% concentration by diluting it with saline and then placed in sterile vials. The participants received the drops through sealed and sterile containers to ensure that the formulation was uniform.

### Treatment Administration

The treatment duration for both interventions was 12 weeks. The participants were given eye drop treatment three times per day with 4 hours between each administration. The study team followed up with the participants once a week to monitor the treatment process and to look for any adverse effects or complications.

### Outcome Measures

**The main outcome measures included the following**

1. Symptom Relief: The participants completed the Ocular Surface Disease Index (OSDI) and Visual Analog Scale (VAS) questionnaires at the start of the study and during weekly check-ups to assess dry eye symptom severity. The researchers measured the changes in these scores to determine symptom improvement.
2. The functional status of tear film was evaluated through objective measures which included Tear Film Break-up Time (TBUT) and Schirmer test. The research team conducted these tests when the study began followed by additional assessments every 4 weeks until the study ended.
3. The ocular surface damage received evaluation through Fluorescein staining which produced results that researchers documented at regular intervals.
4. The research team documented all adverse effects which resulted from the treatments administered to participants. The study participants needed to inform the research team about any discomfort or irritation and other side effects they experienced throughout the study duration.

### Statistical Analysis

The data collection underwent analysis through SPSS software version 23. The demographic and baseline characteristics of participants received presentation through descriptive statistical methods. The analysis used paired t-tests to evaluate changes between pre-treatment and post-treatment symptom scores and TBUT measurements and Schirmer test results and fluorescein staining outcomes. The

independent t-test served to analyze the differences in these parameters between study groups. Results reached statistical significance when p values were less than 0.05.

### Ethical Considerations

The research adhered to all principles of the Declaration of Helsinki for ethical studies with human participants. The Ethics Committee of Tikrit Teaching Hospital provided approval for the research to begin. The researchers described all crucial study elements including research goals and methods together with risks and advantages to each research participant. The researchers obtained informed consent from each participant who received full details about the study's goals and procedures together with its possible risks and advantages before study enrollment. The study participants retained the freedom to withdraw from the research at any point without experiencing adverse outcomes.

**Results:** The results of this study compared the effectiveness of Artificial Tears (Group A) with Autologous Serum Eye Drops (Group B) for the treatment of severe Dry Eye Disease (DED) for twelve weeks.

### Demographic Characteristics of Participants

The research included 300 participants who received Group A (Artificial Tears) with 150 participants and Group B (Autologous Serum Eye Drops) with 150 participants. The groups had no initial differences in age, gender distribution or symptom duration which resulted in equivalent starting conditions for both groups as shown in Table 1.

**Table 1:** Demographic Characteristics of Participants

| Characteristic | Group A (Artificial Tears) | Group B (Autologous Serum) |
|---|---|---|
| Age (Mean ±SD) | 45.2±12.1 years | 44.8±11.4 years |
| Gender (M:F ratio) | 70:80 | 72:78 |
| Mean Duration of Symptoms (Months ±SD) | 18.5±5.4 months | 17.9±5.2 months |
| Comorbidities (n, %) (Diabetes, Autoimmune) | 0 (0%) | 0 (0%) |

### Symptom Relief (OSDI and VAS Scores)

Symptom relief was evaluated through the Ocular Surface Disease Index (OSDI) and Visual Analog Scale (VAS). Participants completed symptom severity assessments at the beginning of the study and then once per week throughout the treatment duration. Symptom scores decreased substantially in both study groups but Group B demonstrated the larger improvement. Group B demonstrated a substantial greater improvement in OSDI scores than Group A throughout the 12-week study period ($p<0.01$). The results showed the largest improvement at Week 12 when Group B maintained significantly lower mean OSDI scores than Group A according to Table 2 and Figure 1.

**Table 2:** OSDI Score in studied groups

| Time Point (Weeks) | Group A (Mean OSDI Score ±SD) | Group B (Mean OSDI Score ±SD) |
|---|---|---|
| Baseline | 73.2±12.4 | 74.1±11.9 |
| Week 4 | 60.4±13.5 | 47.3±10.6 |
| Week 8 | 52.1±15.3 | 35.9±9.8 |
| Week 12 | 45.6±14.2 | 27.2±8.3 |

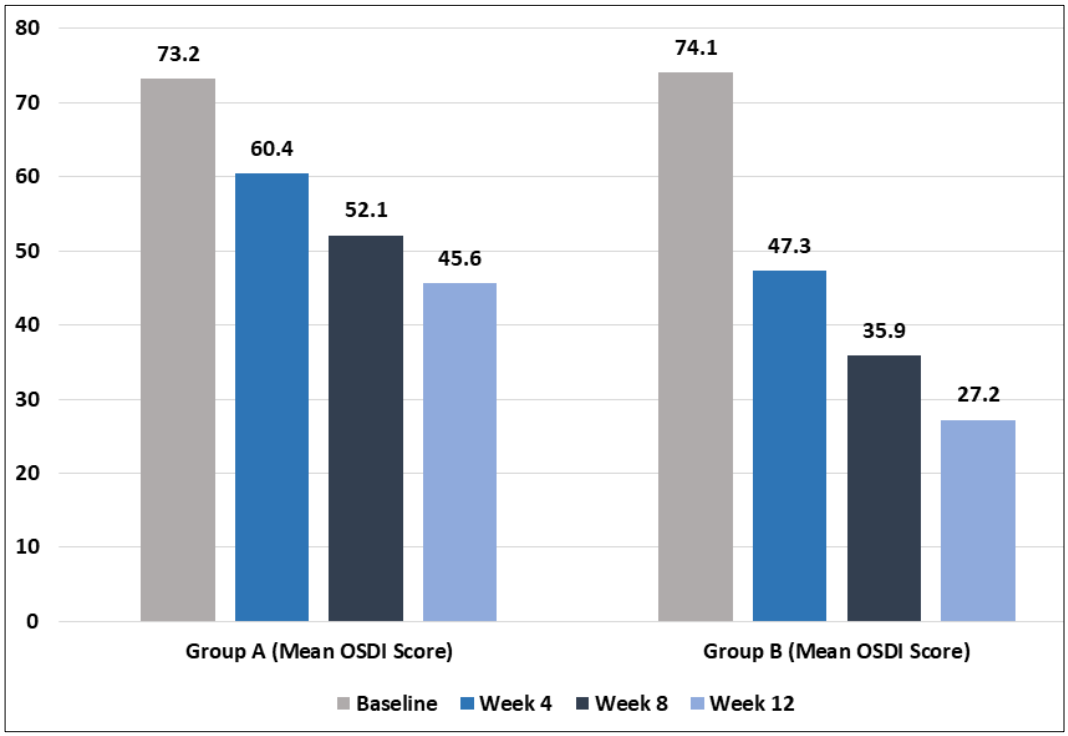


**Fig 1:** OSDI scores over time

VAS scores demonstrated better improvement in Group B than Group A with a statistically significant lower score at Week 12 ($p<0.01$). The results confirm that autologous serum eye drops gave better symptom relief than the other treatment (Table3 and Figure 2).

**Table 3:** VAS scores in studied groups

| Time Point (Weeks) | Group A (Mean VAS Score ±SD) | Group B (Mean VAS Score ±SD) |
|---|---|---|
| Baseline | 7.8±1.3 | 8.0±1.1 |
| Week 4 | 6.2±1.5 | 4.9±1.2 |
| Week 8 | 5.4±1.6 | 3.3±1.0 |
| Week 12 | 4.5±1.4 | 2.1±0.8 |

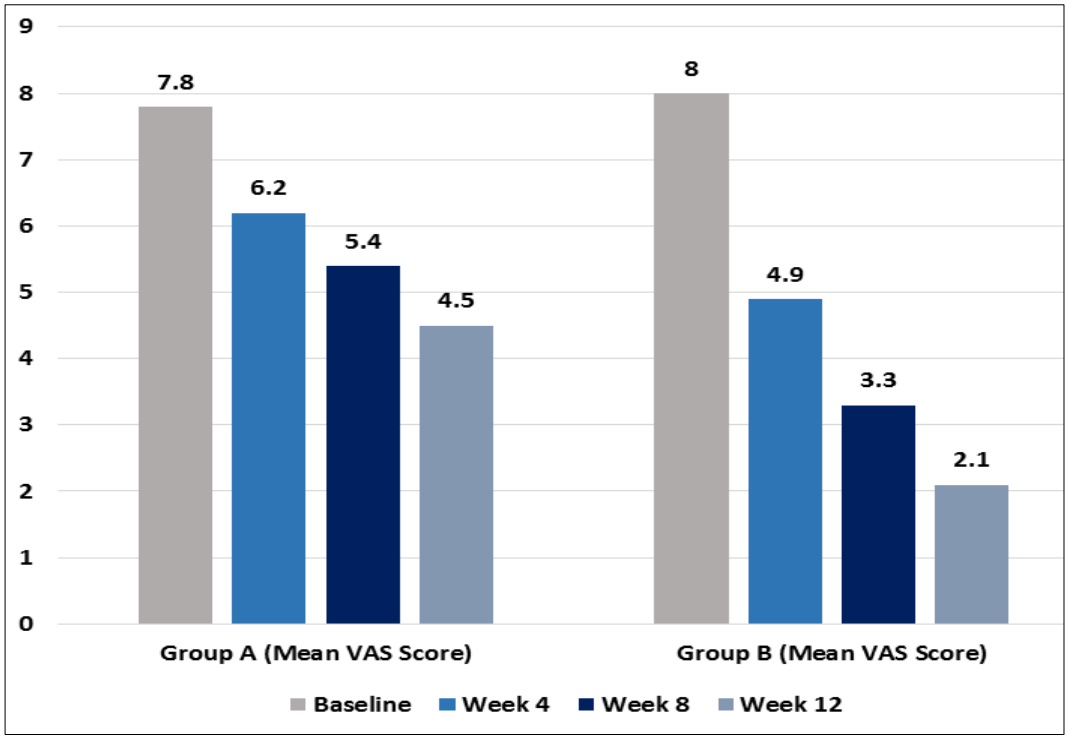


**Fig 2:** VAS scores over time

**Objective Assessment (TBUT and Schirmer Test)**

The Schirmer test together with Tear Film Break-up Time (TBUT) served as objective tests to evaluate tear film stability and ocular dryness. Group B demonstrated better results than Group A through both tests. The TBUT values from Group B exceeded those of Group A at all follow-up time points ($p<0.05$) which demonstrated superior tear film stability with autologous serum eye drops (Table 4 and Figure 3).

**Table 4:** TBUT in studied groups

| Time Point (Weeks) | Group A (Mean TBUT ±SD) | Group B (Mean TBUT ±SD) |
|---|---|---|
| Baseline | 4.1±1.2 sec | 4.0±1.1 sec |
| Week 4 | 5.5±1.4 sec | 7.2±1.5 sec |
| Week 8 | 6.1±1.6 sec | 9.1±1.6 sec |
| Week 12 | 6.7±1.5 sec | 11.3±2.2 sec |

The Schirmer test values increased substantially in both groups with Group B demonstrating the largest rise ($p<0.01$). The results indicate that autologous serum eye drops enhanced tear production better than artificial tears (Table 5 and Figure 3).

**Table 5:** Schirmer Test in studied groups

| Time Point (Weeks) | Group A (Mean Schirmer Test ±SD) | Group B (Mean Schirmer Test ±SD) |
|---|---|---|
| Baseline | 2.5±1.1 mm | 2.4±1.2 mm |
| Week 4 | 4.1±1.3 mm | 6.8±1.6 mm |
| Week 8 | 5.0±1.5 mm | 8.5±2.1 mm |
| Week 12 | 5.5±1.7 mm | 10.4±2.4 mm |

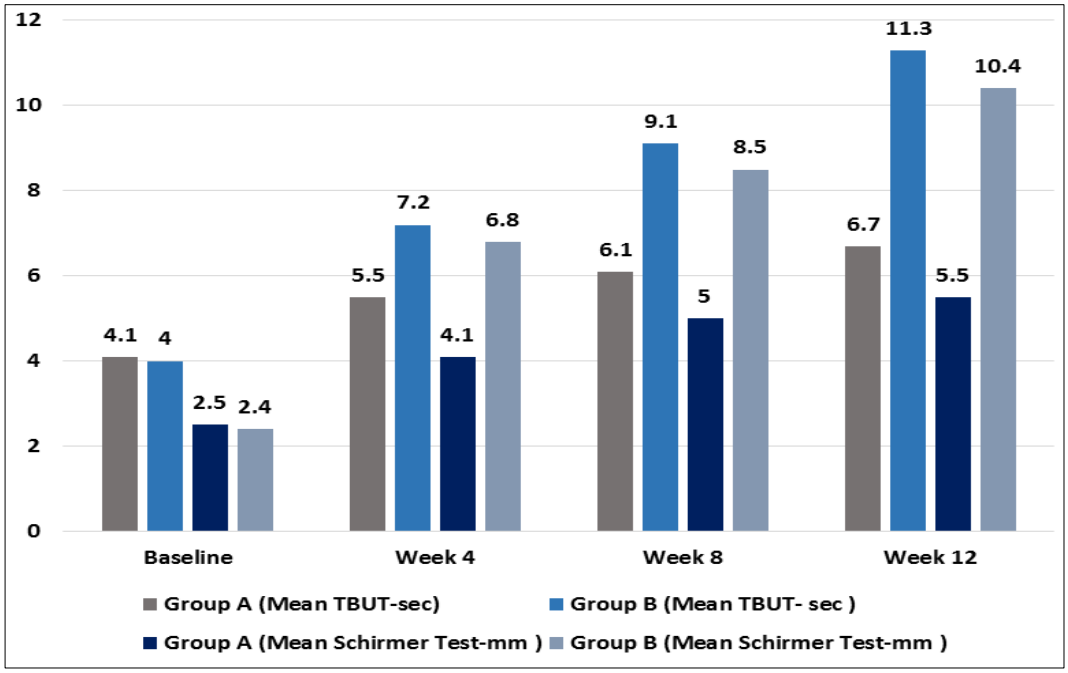


**Fig 3:** TBUT and Schirmer test scores over time

**Ocular Surface Integrity (Fluorescein Staining)**

The assessment of ocular surface integrity with fluorescein staining showed that corneal and conjunctival health improved in both treatment groups over time Figure 4. However, Group B showed better healing of the ocular surface. Fluorescein staining scores were significantly lower in Group B than in Group A at all-time points ($p<0.01$), indicating better ocular surface healing with autologous serum eye drops (Table 6 and Figure 5).

**Table 6:** Fluorescein Staining Score in studied groups

| Time Point (Weeks) | Group A (Fluorescein Staining Score ±SD) | Group B (Fluorescein Staining Score ±SD) |
|---|---|---|
| Baseline | 6.3±1.7 | 6.5±1.8 |
| Week 4 | 5.2±1.4 | 3.6±1.3 |
| Week 8 | 4.4±1.3 | 2.3±1.0 |
| Week 12 | 3.6±1.1 | 1.1±0.7 |

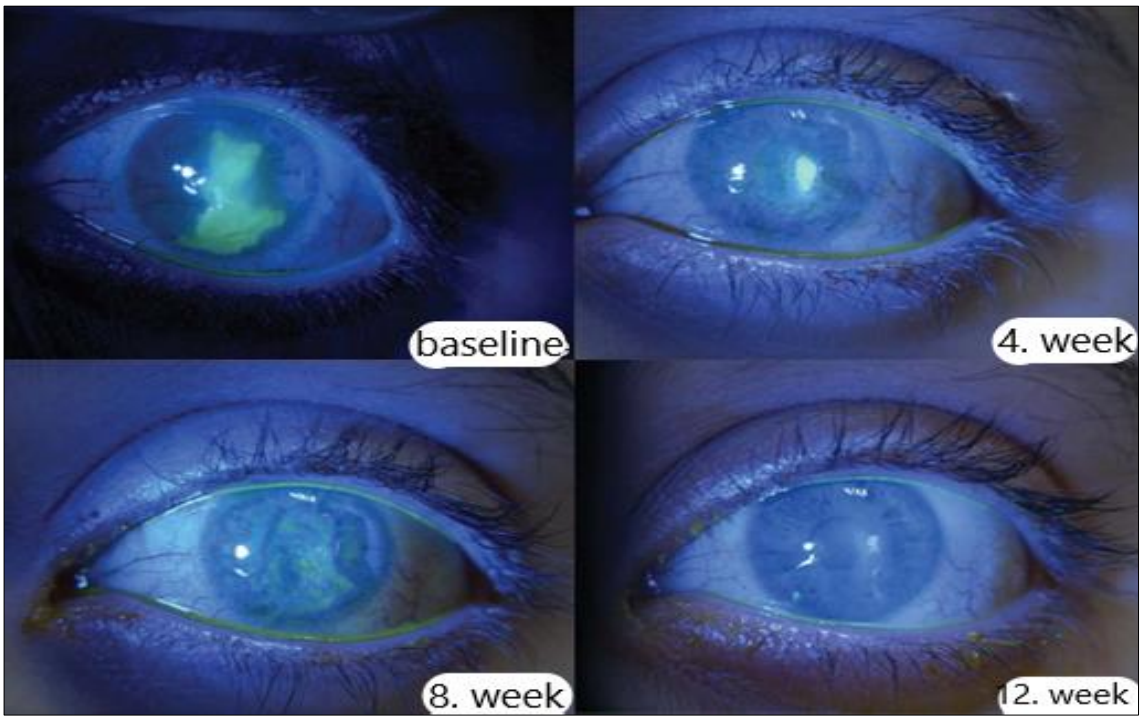


**Fig 4:** Corneal and conjunctival health in both treatment groups over time

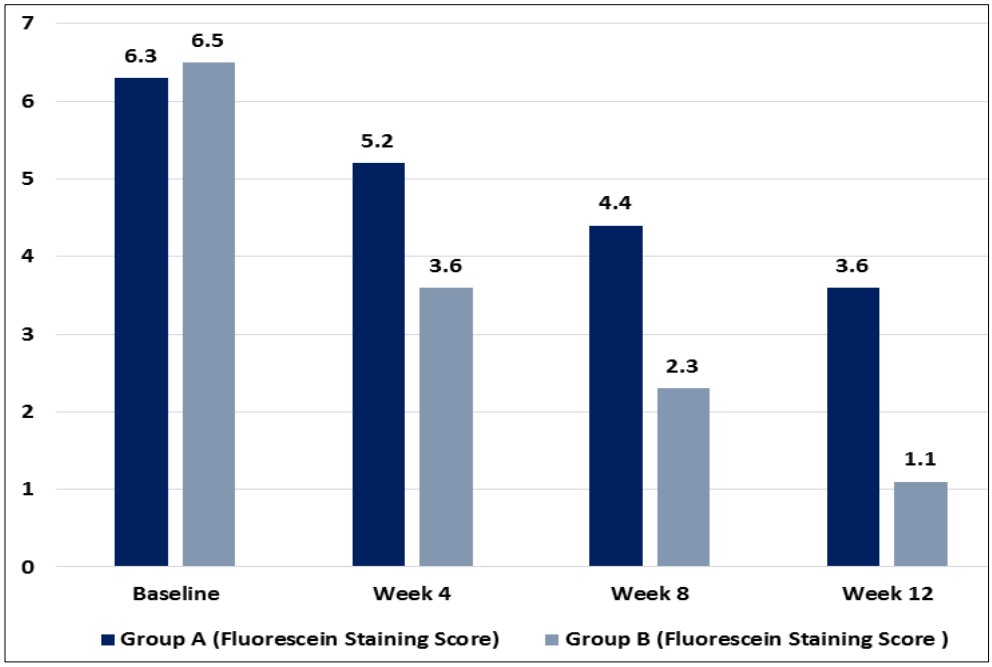


**Fig 5:** Fluorescein Staining Score over time

**Adverse Effects**

The treatments were well tolerated with minimal side effects reported. Five participants in Group A and three participants in Group B reported mild ocular irritation which resolved without further intervention. No serious adverse effects were observed.

**Discussion**

The research shows autologous serum eye drops produce better results than artificial tears for symptom relief and tear film stability and ocular surface integrity. The research findings match the expanding scientific evidence which demonstrates autologous serum as a treatment for severe dry eye disease.

The study results demonstrated that autologous serum eye drops provided superior benefits than artificial tears because patients reported better symptom relief through Ocular Surface Disease Index (OSDI) and Visual Analog Scale (VAS) evaluations. The study findings aligned with existing systematic reviews and meta-analyses which confirmed autologous serum performs better than artificial tears for treating dry eye symptoms. Wang *et al.* (2020) [14] analyzed randomized controlled trials through a meta-analysis to demonstrate that autologous serum eye drops provided superior symptom relief for dry eye patients because they contained healing tissue factors and anti-inflammatory cytokines (Wang *et al.*, 2020) [14].

Franchini *et al.* (2019) [3] state that serum eye drops enhance the quality of life of patients with ocular surface diseases by providing a natural tear substitute that offers better lubrication and reduces inflammation (Franchini *et al.*, 2019) [3]. The treatment is useful for patients with severe dry eye disease because their tear film stability and ocular surface integrity deteriorates in such conditions.

The autologous serum group showed the greatest improvement in TBUT and Schirmer test results among both treatment groups. The objective measures show that autologous serum provides better tear film stability because it contains multiple growth factors including epidermal growth factor (EGF) which promotes tear production and heals the ocular surface (Soni & Jeng, 2016) [12]. Our research supports the findings of Celebi *et al.* (2014) [2] who documented that autologous serum eye drops elevated TBUT values in patients who had severe dry eye syndrome thus supporting the beneficial effects of serum eye drops on ocular surface health (Celebi *et al.*, 2014) [2].

The Schirmer test results showed better improvement in tear production among patients who received autologous serum eye drops. The research of Soni and Jeng (2016) [12] supports this finding because they demonstrated that serum eye drops enhance tear production through their delivery of vital growth factors and nutrients to the ocular surface (Soni & Jeng, 2016) [12]. The results of our research indicate that autologous serum improves tear film stability and promotes tear production recovery in patients suffering from DED.

The standard ocular surface assessment tool fluorescein staining showed better healing of ocular surface integrity in patients who received autologous serum eye drops compared to the other treatment group. The research conducted by Shahraki *et al.* (2024) [11] demonstrated that autologous serum contains regenerative elements which restore epithelial tissue integrity and accelerate wound healing and minimize inflammation (Shahraki *et al.*, 2024) [11]. The healing properties of autologous serum stem from its abundant growth factors and cytokines and vitamins which fix damaged ocular surfaces in patients with chronic dry eye disease.

Bron *et al.* (2014) [1] also pointed out the anti-inflammatory effect of autologous serum in the treatment of dry eye disease. Autologous serum eye drops improve epithelial health and thus decrease the severity of ocular surface damage as indicated by the decrease in fluorescein staining scores in our study (Bron *et al.*, 2014) [1].

The two treatment groups showed no important differences in safety and adverse effects were infrequent. The most common side effect was mild ocular irritation that did not need any additional actions. Kim *et al.* (2021) [6] found that both autologous serum eye drops and artificial tears were well tolerated by patients and few serious adverse events were reported (Kim *et al.*, 2021) [6]. Autologous serum eye drops

represent a natural and biologically relevant treatment option for patients with severe dry eye disease because they have minimal side effects even though their preparation time is longer due to blood collection and serum processing.

Autologous serum eye drops emerge as a medical solution which effectively treats patients who have severe dry eye disease that artificial tears and conventional therapies cannot effectively manage. According to Rolando and Merayo-Lloves (2022) [8] autologous serum treatment has become increasingly vital for evaporative dry eye disease especially when inflammation and epithelial damage play major roles (Rolando & Merayo-Lloves, 2022) [8]. Franchini *et al.* (2019) [3] conducted research which demonstrated that serum eye drops show promise as an additional treatment for severe ocular surface diseases that do not react to standard therapies (Franchini *et al.*, 2019) [3]. The research results support that individualized treatment methods should be employed to treat dry eye disease. Patients with severe refractory dry eye may experience better outcomes from autologous serum eye drops than artificial tears because the eye drops address the root causes of the disease.

## Limitations and Future Research

The research provides vital information about artificial tears versus autologous serum eye drops but has certain limitations. The duration of the research was short so more studies are required to determine the effects of autologous serum eye drops on dry eye disease over long term. Future research should compare autologous serum treatment with other therapeutic approaches such as anti-inflammatory medications and punctual plugs to enhance their effectiveness.

The research confirms autologous serum eye drops as better than artificial tears for the treatment of severe dry eye disease because they give better symptom relief and better tear film stability and healing of the ocular surface. Further studies are required to determine which patients will benefit most from this treatment and how this treatment will affect patients over time.

## Conclusion

Autologous serum eye drops demonstrate better effectiveness than artificial tears for treating severe dry eye disease according to this research. The autologous serum group demonstrated superior outcomes in symptom relief and tear film stability and ocular surface integrity which shows serum-based therapies hold promise for treating refractory dry eye conditions. The autologous serum eye drops treatment was well tolerated by patients as it used a biologically relevant solution to address dry eye disease mechanisms through inflammation and epithelial damage. The study supports autologous serum eye drops as a viable treatment option for patients with severe dry eye disease who do not respond to standard therapies. Additional research involving bigger participant groups and extended observation periods should be conducted to assess both the extended advantages and proper implementation of autologous serum in dry eye treatment.

## Acknowledgments

We are grateful to all the participants in this study and the medical and administrative staff of Tikrit Teaching Hospital in Iraq for their contribution to this research. We also thank our colleagues in the field of ophthalmology for their continuous support which was very helpful in the completion of this work.

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