

IMPACT OF LUBRICANT AND PLATELET-RICH PLASMA EYE DROPS IN THE TREATMENT OF DRY EYE DISEASE

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Abstract

Background: Dry Eye Disease (DED) is a disease that gives symptoms of discomfort and instability of tear film. Although traditional forms of lubricants are temporary, platelet rich plasma (PRP) is a less common supplement that has growth factors that can potentially help regenerate lubricants.

Goal: To test the effectiveness of lubricants and PRP eye drops in DED patients in order to assess Tear Film parameters and the symptoms in these patients.

Methods: A total of 30 eyes of 15 patients were given standard lubricant and then they would be given the PRP drops for a period of 7 days. The Ocular Surface Disease Index (OSDI), Tear Break-up Time (TBUT), Schirmer test I and Tear Prism Height (TPH) were used to determine pre and post-treatment values.

Results: PRP therapy significantly improved outcomes: OSDI decreased from 42.13 ± 6.40 to 11.81 ± 4.13 , TBUT increased from 4.93 ± 1.28 s to 12.73 ± 2.01 s, Schirmer I from 5.30 ± 1.08 mm to 16.66 ± 3.66 mm, and TPH from 0.25 ± 0.06 mm to 0.71 ± 0.16 mm ($p < 0.001$).

Conclusion: PRP eye drops have been shown to be an effective treatment to reduce symptoms and improve tear film parameters in DED, and is a promising treatment for regeneration when tear substitutes do not provide enough benefits.

INTRODUCTION

The most common, multi-factorial diseases of the tear film and ocular surface are dry eye disease (DED), tear film instability, hyperosmolarity of tear film, inflammation, and neuro-sensory abnormalities (1). It is also a frequent eye problem in clinical practice and a major and increasing public health problem all over the world. Dry eye disease prevalence is around 5–50% in different

parts of the world according to different diagnostic criteria, geographic regions and population characteristics (2). It occurs more often in females and in people with systemic autoimmune diseases, affecting almost 8% of people (3). Dry eye disease is a burdensome condition, with about 1 in 4 patients visiting an ophthalmologists' clinic complaining of dry eyes (4).

The tear film has a pivotal role in the maintenance of the ocular surface integrity, in its role as a lubricant, an optical surface and as protection against environmental and microbial challenge. It consists of three layers: Inner mucin layer, middle aqueous layer and outer lipid layer. Disruption of each of these layers leads to instability in the tear film, more evaporation and damage to the ocular surface (5). Dry eye disease can be broadly classified into aqueous deficient dry eye (ADDE) and evaporative dry eye (EDE); both have similar clinical symptoms including irritability, burning sensation, foreign body sensation, visual disturbances and photophobia (6).

Many factors can increase the risk for developing and/or exacerbating dry eye disease. Widespread digital devices usage, low humidity and air pollution play a significant role in tear film stability. Some other systemic diseases have also significant association with dry eye disease, such as diabetes mellitus (6), thyroid disorders (12), arthritis (4), and autoimmune diseases (10) (7). Another significant factor is aging which causes lower tear production and more tear evaporation because of a dysfunction of the meibomian glands (8). Also, a small number of medications, like antihistamines, anti-depressants and anti-hypertensive, can cause increased- or-reduced tear production and, therefore, worsen the symptoms of dry eye (7).

Maintenance treatment for mild, dry eye disease has traditionally been one of treating symptoms. Lubricating eye drops are often used for first-line treatment and have no beneficial biological factors like growth factors and cytokines that would be present in natural tears (9). In moderate to severe cases, anti-inflammatory drugs are used to suppress inflammation of the surface of the eye, such as cyclosporine and corticosteroids. Other treatments include diet changes (including omega-3 fatty acid supplements) (9), lifestyle changes and punctal occlusion (9). With all these efforts, many patients still suffer with the symptoms and better regeneration therapies must be developed.

Platelet-rich plasma (PRP) is an autologous blood product which contains a high concentration of platelets and growth factors such as epidermal

growth factors (EGF), platelet-derived growth factors (PDGF) and transforming growth factor (TGF- β). These are important in the regeneration of the epitopes, in wound healing and modulate inflammation on the ocular surface (10). These characteristics make PRP a potential therapy for the treatment of DES.

There are several clinical studies that have shown that PRP can alleviate the subjective symptoms and clinical parameters. Alio et al. showed that moderate to severe dry eye cases demonstrated improvements with PRP therapy of tear film stability, corneal staining and patient reported symptoms (11). In a similar manner, tear breakup times/ocular surface inflammation improved following PRP (12). In addition, Avila et al. showed that PRP treatment also improved tear secretion and Ocular Surface Disease Index (OSDI) scores in their patients (13).

The efficacy of PRP is also confirmed by comparative studies, which uphold its effectiveness when compared to other treatments. Garcia-Conca et al. found that PRP produced more significant results in evaluating the tear film parameters and in relieving symptoms than did artificial tears (14). Similarly, Muhammad et al. showed that PRP eye drops had a significant improvement in the Tear Break Up Time, a Schirmer test and Corneal Staining than did the therapy with autologous serum (15). Another improvement that Ribeiro et al. saw was in tear film stability and symptoms for patients who were treated with PRP (16). Further, Sanchez-Avila et al. reported very promising results in patients that had undergone LASIK surgery before treatment with growth factor derived from PRP for dry eye symptoms (17).

Although there are promising results, inter-individual differences do exist in how treatments are applied and the length of time treatments have to be conducted, and there is limited local information about the short-term efficacy of platelet-rich plasma eye drops, especially among younger age groups. With the above in mind, the present study was carried out to assess the efficacy of lubricants along with PRP eye drops on a

subjective and objective clinical consideration of dry eye disease (DED) (18).

MATERIALS AND METHODS

Ethical letter was taken from the ethical review committee at University of Faisalabad and ethical standards of the International Research on the study were followed and informed verbal and written consent was secured from all the participants. The present quasi-experimental study aimed to assess the efficacy of platelet-rich plasma (PRP) eye drops in patients with dry eye disease (DED) for 4-month period (September to December 2023) in Madinah Teaching hospital. The sampling method employed was purposive (non-probabilistic) because it allowed collecting the total sample of 30 eyes from 15 patients who would meet the clinical criteria for dry eye which would CROSS with the study objectives. Because the tear film parameters were in the normal range, all patients were age 18 to 35 years old and their complete blood counts were normal, those with any other ocular/systemic condition/factors which might have masked the effect of treatment were excluded to ensure that the parameters assessed were in normal range.

Baseline was obtained by two methods, a subjective and an objective assessment, and fully evaluated the severity of dry eye. The OSDI questionnaire was used for symptom measurement and other selected tests were standard clinical metrics of tear film stability (TaurUS), secretion (ST I) and volume (TPH) due to their global validation and reliability. For detailed examination of the eye, slit lamp biomicroscopy was used, while standardized and accurate data collection was ensured by measuring tear production, using Schirmer strips, and measuring tear prism height by using a calibrated slit lamp scale, TBUT was measured with fluorescein strips and a stopwatch. As PRP contains PRGF medicinal substances which are necessary for healing of the ocular surface, 10 ml of autologous blood was drawn and then

centrifuged to obtain the PRP in sterile conditions.

Patients were first treated with lubricating eye drops and then with PRP eye drops six times a day for one week to compare the difference between these two treatments and “regular” treatment. Follow-up assessments were made at 3, 7 and 14-days after the intervention to gauge the sustainability of immediate and short-term results. All the data were collected by a structured proforma and data was analyzed by SPSS version 20 where descriptive statistics were used to summarise the demographic variables and repeated ANOVA or independent t-tests were used to test changes over time and treatment stability. This method was chosen to promote reliability, reduce the bias and for the feasibility of a well-rounded evaluation of the efficacy of PRP for dry eye disease.

RESULTS

A Quasi Experimental study was conducted at Madinah Teaching Hospital, Faisalabad 30 eyes of 15 patients age between 18-35 year old were included in this study. The nonprobabilistic purposive sampling technique were used in gathering of the data. In selected subjects, indices of Ocular Surface Disease (OSDI), Tear Breakup Time (TBUT), Schirmer test 1 and Tear Prism height (TPH) was measured. Subsequent, plateletrich plasma (PRP) eye drops were installed and variation in Ocular surface disease index (OSDI), Tear breakup time (TBUT), Schirmer test 1 and Tear prism height (TPH) were measured after 3 days, 7 days and 14 days post treatment.

Age Distribution of Study Participants

Total fifteen patients (30 eyes) were diagnosed with dry eye disease in this quasi experimental study. The mean age was 23.53 ± 2.61 years, with ages ranging from 20 to 29 years. Among the participants, 10 (66.7%) were females and 5 (33.3%) were males.

Table: Age of Dry Eye Patients

Variables	Minimum	Maximum	Mean $\pm$ SD
Age (years)	20	29	23.53 $\pm$ 2.615

Gender Distribution of Study Participants

For 15 subjects, descriptive statistic was used to investigate the gender distribution. According to

their gender distribution 10 (66.6%) females and 5 (33.3%) males were selected.

Table: Gender Distribution

Gender	Frequency(n)	Percentage%
Female	10	66.6
Male	5	33.3
Total	15	100

Comparison of Baseline and Follow-up of Ocular surface disease index (OSDI) at Baseline and Follow-U

As per the analysis of the results it is summarized that the variation of Ocular surface disease index (OSDI) the mean value and standard deviation of OSDI before using platelet-rich eye drops in dry eye patients was 42.13 $\pm$ 6.40 and the mean value and standard deviation of OSDI after 3 days of follow-up was 26.05 $\pm$ 6.91. The mean value and

standard deviation of OSDI after 7 days of follow-up was 11.81 $\pm$ 4.13. The difference in the level of ocular surface disease index (OSDI) before and after treating with PRP eye drops is significant with $P < 0.05$ ($P < 0.001$). The results of the repeated measure ANOVA showed a significant decrease in OSDI score. Thus, there is significant evidence to reject null hypothesis. Based on this, it can be concluded that PRP eye drops leads to a reduction in the OSDI score.

Time Point	Mean $\pm$ SD	p- value
Baseline	42.13 $\pm$ 6.40	
Day 3	26.05 $\pm$ 6.91	
Day 7	11.81 $\pm$ 4.31	<0.001

Comparison of Tear Breakup Time (TBUT) at Baseline and Follow-Up

As per the analysis of the results it is summarized that the variation of Tear Breakup Time (TBUT) the mean value and standard deviation of TBUT before using platelet-rich eye drops and in dry eye patients was 4.93 $\pm$ 1.28 and the mean value and standard deviation of TBUT after 3 days of follow-up was 7.93 $\pm$ 1.46. The mean value and standard deviation of TBUT after 7 days of follow-up was

12.73 $\pm$ 2.01. In comparison with the pre application value, the platelet-rich eye drops significantly improve the Tear break up time $P < 0.05$ ($P < 0.001$). Repeated measure ANOVA result reveals there was a significant decrease in Tear breakup time. Thus, there is significant evidence to reject null hypothesis. Therefore, it is believed that PRP eye drops reduces the tear breakup time.

Time Point	Mean ± SD (seconds)	p-value
Baseline	4.93 ± 1.28	
Day 3	7.93 ± 1.46	
Day 7	12.73 ± 2.01	<0.001

Comparison of Tear Prism Height (TPH) at Baseline and Follow-Up

Variation of Tear prism height (TPH) the mean value of Tear prism height before using platelet rich eye drops and in dry eye patients is 0.25 ± 0.06 and mean value of tear prism height after 3 days of follow up is 0.48 ± 0.13 respectively. After 7 days of follow up, the mean of the tear prism height was

0.71 ± 0.16 . The differences show a great value in tear prism height before and after the application of platelet-rich eye drops, $P < 0.05$ ($P < 0.001$). Repeated measure ANOVA result showed that Tear Prism height significantly decreased. Thus, there is significant evidence to reject null hypothesis. Based on this, it is concluded that PRP eye drop leads to a decrease in tear prism height.

Table: Comparison of Baseline and Follow-up of Tear Prism Height

Time Point	Mean ± SD (mm)	Std. Deviation	P Value
Baseline	0.25 ± 0.06		
Day 3	0.48 ± 0.13		
Day 7	0.71 ± 0.16		<0.001

Comparison of Schirmer test I at Baseline and Follow-Up

There was a significant difference between the mean of the schirmer test before the platelet rich plasma eye drops were applied in the patient with dry eye and the mean value after 3 days of follow-up, where before patient application the mean of schirmer test was 5.30 ± 1.08 and the Mean of the schirmer test after 3 days of follow up was 8.70 ± 2.19 respectively according to the analysis of the results. The mean value and standard

deviation of schirmer test after 7 days of follow up was found to be 16.66 ± 3.66 . Before and after platelet rich eye drops, there exists a significant difference in Schirmer test I $P < 0.05$ ($P < 0.001$). The result of repeated measure ANOVA showed that there was a significant decrease in Schirmer test. So, there is a strong degree of belief that null hypothesis should be dismissed. Therefore, it can be concluded that PRP eye drops leads to a decrease in the schirmer test value.

Time Point	Mean ± SD (mm)	P Value
Baseline	5.30 ± 1.08	
Day 3	8.70 ± 2.19	
Day 7	16.66 ± 3.66	<0.001

Comparison of OSDI Score at 7 Days and 14 Days Follow-Up

An independent (one-way) t test was used to examine OSDI after platelet rich plasma eye drop therapy compared to the 14 day time point, which received no treatment. There was no significant

difference $P=1.00$ between the score. Mean value of OSDI at 7 days was 11.81 ± 4.13 and at 14 days was 11.81 ± 4.13 . The independent t-test results showed OSDI score was not different in any of the 7 days follow-up and 14 days follow up group which was not intervened.

Table: Comparison of Ocular Surface Index at 7 Days and 14 Days Follow-Up Independent t test

Follow-Up Time	Mean $\pm$ SD	p-value
Day 7	11.18 ± 4.13	
Day 14	11.18 ± 4.13	1.00

Comparison of Tear Breakup Time at 7 Days and 14 Days Follow-Up

An independent t test was done to see if the tear break up time at 7 days after the PRP eye drop treatment was different from tear break up time at 14 days without treatment. Note that there was no significant difference in the score $P=0.04$. Mean

value of tear breakup time at 7 days was 13.46 ± 1.88 and at 14 days was 12.00 ± 1.92 . Independent t-test shows minimal difference in tear breakup time results between the 0 day, 7-day and 14-day follow-ups for both groups with no intervention.

Table: Comparison of Tear Breakup Time at 7 Days and 14 Days Follow-Up Independent t test

Follow-Up Time	Mean $\pm$ SD (seconds)	p-value
Day 7	13.46 ± 1.88	
Day 14	12.00 ± 1.92	0.04

Comparison of Tear Prism Height at 7 Days and 14 Days Follow-Up

The t test was used for comparing tear prism height, 7 days after platelet-rich plasma (PRP) eye drops and 14 days without any treatment. There was no significant difference between the scores

$P=0.35$. Mean value of tear prism height at 7 days was 0.77 ± 0.13 and at 14 days was 0.64 ± 0.17 . The Independent t-test test showed significant drop in tear prism at 7 days follow-up, further minor decrease in tear prism at 14 days follow-up without any intervention yet.

Table: Comparison of Tear Prism Height at 7 Days and 14 Days Follow-Up Independent t test

Follow-Up Time	Mean $\pm$ SD (mm)	p-value
Day 7	0.77 ± 0.13	
Day 14	0.64 ± 0.17	0.35

Comparison of Schirmer test I at 7 Days and 14 Days Follow-Up

For comparisons, an independent t test was performed between the schirmer test when treated with platelet rich plasma eye drops at 7 days and 14 days without any treatment. If not, there were

no significant differences between the score, $P=0.13$. Mean value of schirmer test at 7 days was 17.66 ± 3.17 and at 14 days was 15.66 ± 3.94 . Independent t-test result shows that there is a slight increase in the schirmer value at 7 days follow up and 14 days follow up following no intervention.

Table: Comparison of Schirmer test at 7 Days and 14 Days Follow-Up

Follow-Up Time	Mean $\pm$ SD (mm)	p-value
Day 7	17.66 $\pm$ 3.17	
Day 14	15.66 $\pm$ 3.94	0.13

DISCUSSION

In the present quasi-experimental study, eye drops containing platelet-rich plasma (PRP) seemed to be effective in improving subjective and objective parameters in patients with dry eye disease. In our study, the mean Ocular Surface Disease Index (OSDI) declined from 42.13 ± 6.40 (baseline) to 11.81 ± 4.13 (Day 7) that reflects significant symptomatic relief. These findings are comparable with Alio et al. (2017), who reported a reduction in OSDI from 42.9 ± 26.7 to 18.1 ± 17.0 ($p < 0.05$) after six weeks of PRP therapy. Despite the high level of improvement in both studies, the improvement was faster and more extensive using our treatment, which may have been more concentrated (shorter but more intense) and in a younger population.

In our study, the values of the Schirmer Test I showed a significant rise from 5.30 ± 1.08 mm to 16.66 ± 3.66 mm (P Value < 0.001) demonstrating an increase in tear secretion. In comparison, Avila et al. (2019) observed an increase from 5.6 ± 0.7 mm to 9.0 ± 1.1 mm after 90 days of treatment. Both studies showed an improvement, but the increase seems greater in our study as we applied PRP topically and applied it more frequently, which implies that the response to the application of PRP would be more immediate therapeutic in our study.

Similarly, Tear Break-Up Time (TBUT) improved from 4.93 ± 1.28 seconds to 12.73 ± 2.01 seconds ($p < 0.001$) in our study. This health result of TBUT was higher compared to Jung et al. (2019) recorded an increase from 3.45 ± 1.89 s to 6.25 ± 1.97 s after six months. This improvement may be caused by the difference in the duration of treatment, the preparation of PRP and among patients.

Tear Prism Height (TPH) also showed a significant increase from 0.25 ± 0.06 mm to 0.71 ± 0.16 mm ($p < 0.001$). In contrast, Murtaza et al. (2022)

reported a smaller increase from 0.26 ± 0.19 mm to 0.34 ± 0.18 mm after four weeks. The higher score of improvement in our study may show that there is an improvement of both tear volume and ocular surface hydration, even if both studies were effective.

On follow-up, there was no difference between day 7 and day 14 OSDI scores ($p = 1.00$) suggesting continued symptomatic relief. After discontinuation of therapy however, slight decreases in TBUT and Schirmer test and TPH were seen ($p = 0.04, 0.13$ and 0.35 respectively). It indicates that there are indications of continuous use are necessary to obtain an objective improvement while long term use of PRP can endure a certain useful symptom.

In general, our results corroborate those of previous studies demonstrating marked improvements in the various parameters of dry eye after PRP treatment. But the degree of improvement in our study, as well as the swift improvement that occurred, were slightly higher, perhaps because of the differences in study design, treatment protocol and patient demographics. The outcomes of this study confirms the effectiveness and quickness of PRP as a therapeutic method that can be used in the treatment of Dry Eye disease.

STRENGTHS OF THE STUDY

The present study has several strengths:

- Both subjective and objective parameters were measured such as Ocular Surface Disease Index (OSDI), Tear Breakup Time (TBUT), Schirmer Test I and Tear Prism Height.
- It was a short-term effectiveness study to look at the efficacy of PRP eye drops in dry eye, giving early clinical proof of their therapeutic promise in the condition.

- Standardised diagnostic tests were used and follow up assessments were carried out to enhance the measured outcomes of this study.

LIMITATION

The present study has several limitations:

- The findings may not be generalizable, as there were only 15 participants in the study (30 eyes).
- The short duration of treatment, of follow-up and the difficulty to assess long-term efficacy of platelet-rich plasma therapy.
- No control group, limiting the ability to compare outcome of PRP treatment against traditional treatments for dry eye disease.
- Limited age range of participants (18-35 year) which could limit generalizability of information to older age groups, who are more likely to have wet eyes.

Further research with a larger sample size, longer follow-up period and randomized controlled design is recommended as a method of further establishing the therapeutic potential of PRP in treating DES.

RECOMMENDATION

- Can be recommended for patients with moderate to severe DED.
- Awareness program should be designed to introduce platelet rich plasma (PRP) eye drops which are beneficial in dry eye disease.
- Further research is suggested to determine the advantages and disadvantages of lubricant versus platelet-rich plasma (PRP) eye drops.

The impact of healthy and young person, researchers merely ended their research and suggested that more studies on elderly person be carried out to assess the effect of platelet-rich plasma.

Author's Contribution

The whole conception and design of the study was carried out by the author. The author's clinical examination and participation in the assessment is used to collect data. The author was also involved in data organization, interpretation of result and writing of the manuscript. Regular literature review, finding analysis and compilation of the final thesis was conducted by author in the presence of guidance and supervision from a research supervisor.

CONCLUSION

In this quasi-experimental study, the authors conclude platelet-rich plasma (PRP) eye drops are very effective in both improving the subjective symptoms and improving tear film parameters in the treatment of dry eye disease. After 7 days of treatment there was a statistically significant reduction in OSDI scores ($p < 0.001$) and significant improvement measure was seen in TBUT, Schirmer test and tear prism height values. The observed outstanding improvement in tear film stability and tear release rate indicates a PRP has a regenerative as well as an anti-inflammatory action on the ocular surface. Objective parameters were slightly decreased following therapy, but there was no decrease in the objective parameters after therapy cessation suggesting long-term therapeutic effects.

These results corroborate the use of PRP eye drops as the safe, effective and biologically active treatments choice in young patient who has moderate dry eyes. Future large-scale, randomized controlled trials lasting longer are suggested to further confirm the efficacy in the long term and to define treatment guidelines.

Conflict of Interest

The authors state that there is no conflict of interest with regards the publication of the aforementioned.

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