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# Clinical effectiveness of polyvinyl alcohol in post-cataract dry eye and their effects on ccl1, IL-13 and IL-10 tear levels

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**Abstract**: This research evaluated the clinical effectiveness of PVA eye drops in the treatment of post-cataract dry eye and their effects on tear levels of CCL1, IL-13 and IL-10. From January 2021 to January 2023, 100 patients with post-cataract dry eye were randomly assigned into control (conventional treatment) and study groups (conventional + PVA), 50 in each group. Outcome measures included symptom relief, stability of the tear film, Ocular Surface Disease Index (OSDI), cytokine levels (CCL1, IL-13, IL-10) and safety. The study group had a higher effective rate (96.0%) than controls (88.0%, $P<0.05$). Both groups had lower CCL1 and IL-13 and higher IL-10 after treatment, with greater responses in the PVA group ($P<0.05$). Tear breakup time, Schirmer's test, fluorescein staining and OSDI were similarly improved more in the PVA group. No side effects, such as burning, foreign body sensation, or congestion, were noted. These results confirm the application of PVA eye drops as tolerable and efficacious therapy for post-cataract surgery dry eye by improving tear film stability and modulating inflammatory cytokines.

**Keywords**: Polyvinyl alcohol; cataract surgery; dry eye; tear cytokines; clinical outcomes

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## INTRODUCTION

Cataract remains a primary cause of visual impairment globally, particularly in individuals older than 60 years, with incidence in individuals above the age of 75 years being up to 80-95% (Hashemi *et al.,* 2020; Chen *et al.,* 2020). Though cataract surgery, especially phacoemulsification, restores vision successfully, it can also compromise ocular surface by injuring corneal nerves, reducing the density of goblet cells and altering tear film dynamics. These changes have a tendency to result in postoperative dry eye symptoms such as photophobia, burning sensation, blurred vision and foreign body sensation (Park *et al.,* 2021; Son *et al.,* 2020).

Dry eye disease (DED) is a multifactorial disorder that involves instability of the tear film, inflammation of the ocular surface and neurosensory dysfunction (Kato *et al.,* 2022). It is particularly pertinent after cataract surgery, with approximately 9.8% of patients developing post-cataract DED, frequently within a week (Vaccaro *et al.,* 2020). Such symptoms may compromise quality of life, slow down recovery and result in dissatisfaction with surgical results despite technically uneventful operations.

Treatment of postoperative DED is generally artificial tears, anti-inflammatory drugs and ocular surface lubricants. Of the artificial tear preparations, polyvinyl alcohol (PVA) is a synthetic polymer commonly employed as it is viscoelastic, keep surface-wet and is biocompatible (Phan *et al.,* 2019). PVA stabilizes the tear film by the formation of a hydrophilic layer on the ocular surface that captures moisture and reduces evaporation (Supplementary table 1). However, while its lubricating effect has been well documented, there is not strong clinical evidence supporting its molecular impact on ocular inflammation or regulation of tear cytokine in post-cataract DED (Jensen *et al.,* 2020; Fydanaki *et al.,* 2022).

This study bridges the gap as it explores the effect of PVA eye drops not only on subjective symptoms and tear film parameters but also on main tear cytokines: CCL1, IL-13 and IL-10. These markers have been selected due to their critical roles in ocular surface inflammation. IL-13 and CCL1 are pro-inflammatory cytokines involved in epithelial injury and immune cell recruitment, while IL-10 is an anti-inflammatory cytokine that plays a role in tissue repair and immunoregulation (Jung *et al.,* 2022; Nakamura *et al.,* 2021). Measuring these cytokines gives insight into the inflammation status of the ocular surface and the therapeutic effect of PVA (Jiang *et al.,* 2016).

All the patients in this random trial were given standard postoperative care with topical PVA eye drops, which is a standard in clinical practice to manage inflammation. The patients belonging to the study group were also given PVA eye drops to assess any extra benefit. This approach is patient-safe but pragmatically simulates modern ophthalmic treatment. In addition to the clinical symptom score and tear film testing, cytokine shifts were also investigated in the study to identify the biological action of PVA on ocular surface healing and tear microenvironment.

Therefore, the goal of this study was to evaluate the clinical efficacy and safety of PVA eye drops in the treatment of dry eye syndrome following cataract surgery and to find out how they act on tear biomarkers during inflammation and repair. The findings may contribute to the optimization of postoperative therapy in cataract patients with a tendency to develop dry eye syndrome.

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## MATERIALS AND METHODS

### *Study design and participants*

The randomized controlled trial enrolled 100 patients with dry eye following cataract surgery at Jiaozhou Center Hospital of Qingdao from January 2021 to January 2023. The patients were assigned randomly in a 1:1 ratio using a computer-generated randomization list by an independent researcher. Blinding concealment of the allocation was secured by opaque sealed envelopes. Outcome assessors were blinded. The study was approved by the Department of Ophthalmology, Jiaozhou Center Hospital of Qingdao, Ethics Committee (Approval No. JCHQ-2023-01). Written informed consent was obtained from all the participants prior to their recruitment.

### *Inclusion and exclusion criteria*

Patients could also be enrolled if they met the Chinese Ophthalmological Society's diagnostic criteria for cataract and postoperative dry eye. The other inclusion criteria were between 25 and 85 years of age, having undergone uncomplicated cataract surgery with the onset of subsequent dry eye symptoms, not having used medications for dry eye during the past two weeks and not having cognitive or psychiatric disorders and providing voluntary informed consent.

Exclusion factors were as follows: history of any serious systemic diseases such as cardiovascular, hepatic, renal, or neurological disease; autoimmune conditions such as rheumatoid arthritis or systemic lupus erythematosus; metabolic disorders such as diabetes mellitus or uncontrolled hypertension; ocular comorbidities such as traumatic cataract, corneal edema, trachoma, or a history of corneal transplantation; and hypersensitivity or known allergies to the drugs utilized in this trial.

### *Interventions*

The control group (n = 50) was treated with standard postoperative care for dry eye, including eyelid hygiene, warm compresses and instillation of tobramycin-dexamethasone eye drops (ALCON, China Pharmacopoeia H20150119). Treatment commenced on the second postoperative day with 1-2 drops every 2 hours for 48 hours, followed by 1-2 drops every 4-6 hours for the next week and then tapered weekly. The study group (n = 50) also received the same treatment regimen including the use of polyvinyl alcohol (PVA) eye drops (Hubei Yuanda Tiantianming Pharmaceutical Co., Ltd., H20046681), at a dose of 1-2 drops three times daily for two months. Both groups completed the full 2-month regimen (Table 1).

### *Outcome measures*

Clinical effectiveness was the principal outcome and was graded into four degrees: Cured-complete recovery of dry eye symptoms, normal slit-lamp findings, tear film break-up time (BUT) >10 seconds, negative fluorescein staining (FL) and Schirmer I test (SIT) >10 mm/5 min; Markedly effective-apparent symptom improvement with minimal slit-lamp pathologies, normalization of two of three indices (BUT, FL, SIT) and a score <2; Effective-moderate symptom improvement with normalization of one index and a 2-6 score; and Ineffective-lack of symptom improvement or worsening with a score >6. The total effective rate was calculated as: (Cured + Markedly effective + Effective cases) / Total cases × 100%.

Tear cytokines were evaluated as secondary biochemical markers. For each subject, 15 µL of tear fluid was collected using micropipettes following instillation of 10 µL of sterile saline to facilitate sampling. Samples were stored at -80°C and subsequently analyzed by enzyme-linked immunosorbent assay (ELISA) kits for CCL1, IL-13 and IL-10 (Beijing Biolabs and Shanghai Crystal Resistance Bioengineering). Saline dilution would reduce absolute cytokine levels but identical collection and processing protocols in both groups made comparative interpretation feasible.

Recovery indices included BUT, SIT, FL and the Ocular Surface Disease Index (OSDI). BUT was measured by slit-lamp biomicroscopy using fluorescein dye to assess tear film stability. SIT was performed by placing standard Schirmer strips in the inferior conjunctival sac for 5 minutes to assess tear secretion. FL scoring was graded between 0 and 3 and represents the grade of increasing corneal epithelial disruption. OSDI, a 12-item questionnaire with established validity, quantified symptom severity and vision-related discomfort and higher scores occurred with more dry eye symptoms.

Systematic monitoring of adverse events was conducted to assess safety. Participants were evaluated weekly in clinic and also accessible through structured phone interviews for foreign body sensation, ocular burning, conjunctival hyperemia, or allergic reaction symptom reporting. All events reported were recorded and compared between the two study groups.

## STATISTICAL ANALYSIS

Data were analyzed with SPSS v24.0. Continuous variables were presented as mean ± SD and compared with independent t-tests. Categorical variables were contrasted with chi-square ($\chi^2$) tests. A p-value of <0.05 was utilized to determine statistical significance

## RESULTS

### *Comparison of baseline characteristics*

As shown by table 2, there were no differences in gender, age, BMI, disease duration, dry eye type and severity (P > 0.05) between the study and control groups, with good baseline comparability.

**Table 1**: Comparative Summary of Interventions in Control and Study Groups

| Component | Control Group (n = 50) | Study Group (n = 50) |
|---|---|---|
| Routine Care | ✓ Eyelid hygiene<br>✓ Warm compresses<br>✓ Periocular cleaning | ✓ Same as control group |
| Anti-inflammatory Treatment | Tobramycin-dexamethasone eye drops:<br>• 1-2 drops every 2 h (Day 2-3)<br>• Then every 4-6 h (Week 1)<br>• Weekly tapering in Week 2 | Same tobramycin-dexamethasone regimen as control group |
| Additional Treatment | None | Polyvinyl alcohol (PVA) eye drops:<br>• 1-2 drops, three times daily |
| Duration of Treatment | 2 months | 2 months |

**Table 2**: Baseline characteristics of participants (n = 50 per group)

| Characteristic | Control Group | Study Group | P-value |
|---|---|---|---|
| Gender (Male/Female) | 27 (54%) / 23 (46%) | 28 (56%) / 22 (44%) | 0.832 |
| Age (years, mean ± SD) | 67.45 ± 9.48 | 67.51 ± 9.50 | 0.946 |
| BMI (kg/m²) | 23.94 ± 1.53 | 23.89 ± 1.57 | 0.798 |
| Disease duration (years) | 1.92 ± 0.36 | 1.94 ± 0.31 | 0.741 |
| Dry Eye Type (Hydro/Evap/Mixed) | 10 / 14 / 26 | 11 / 14 / 25 | 0.873 |
| Dry Eye Severity (Mild/Mod) | 21 / 29 | 23 / 27 | 0.685 |

**Table 3**: Comparison of clinical efficacy (% only)

| Outcome | Control Group (%) | Study Group (%) |
|---|---|---|
| Cured | 26 | 52 |
| Markedly effective | 12 | 10 |
| Effective | 40 | 34 |
| Ineffective | 22 | 4 |
| Total Effective | 88 | 96 |

**Table 4**: Pre-treatment and post-treatment tear cytokine levels (mean ± SD)

| Biomarker | Time | Control Group | Study Group |
|---|---|---|---|
| CCL1 (ng/L) | Before | 287.34 ± 54.29 | 289.51 ± 54.63 |
| | After | 231.95 ± 44.83* | 193.24 ± 30.76*# |
| IL-13 (pg/mL) | Before | 21.39 ± 5.01 | 21.41 ± 5.03 |
| | After | 15.86 ± 3.74* | 10.02 ± 2.39*# |
| IL-10 (pg/mL) | Before | 2.18 ± 0.52 | 2.17 ± 0.54 |
| | After | 2.97 ± 0.78* | 3.52 ± 0.86*# |

Note: *P < 0.05 vs. before treatment; #P < 0.05 vs. control group after treatment

**Table 5**: Comparison of rehabilitation parameters (mean ± SD)

| Index | Time | Control Group | Study Group |
|---|---|---|---|
| BUT (s) | Before | 5.42 ± 1.36 | 5.43 ± 1.34 |
| | After | 7.15 ± 1.48* | 10.27 ± 1.59*# |
| FL (score) | Before | 4.81 ± 2.78 | 4.83 ± 2.75 |
| | After | 1.75 ± 1.79* | 0.76 ± 0.46*# |
| SIT (mm) | Before | 7.29 ± 1.78 | 7.30 ± 1.79 |
| | After | 9.37 ± 2.26* | 12.49 ± 2.91*# |
| OSDI (score) | Before | 36.53 ± 2.21 | 36.56 ± 2.24 |
| | After | 30.28 ± 1.46* | 20.68 ± 1.05*# |

Note: *P < 0.05 vs. before treatment; #P < 0.05 vs. control group after treatment

***Clinical efficacy***

Global clinical efficacy was also much higher in the study group (96%) compared to the control group (88%) ($\chi^2$ = 4.89, P = 0.027), as shown in table 3.

***Tear biomarkers (CCL1, IL-13, IL-10)***

There were no differences in the baseline reading of both the groups for CCL1, IL-13, or IL-10. Both groups exhibited improved tear profiles following treatment, but the study group demonstrated significantly greater changes based on table 4 (P < 0.05).

***Recovery parameters***

There was a remarkable improvement in BUT, SIT, FL and OSDI in both groups after treatment (P < 0.05), though greater benefits were noted for all the parameters in the study group (Table 5).

***Adverse events***

Side effects were monitored with both phone interviews and clinic follow-ups. No severe adverse events occurred in either group. Discomfort such as foreign body sensation or minimal irritation was noted in 2 (4%) patients of the control group and 1 (2%) patient of the study group, which was not significant (P > 0.05).

## DISCUSSION

Dry eye disease (DED) is a multidimensional condition that is diagnosed based on tear film instability, hyperosmolarity, inflammation on the ocular surface and neurosensory impairment. It is particularly prevalent following cataract surgery due to mechanical disturbance of the ocular surface, damage to the cornea's nerve and topical postoperative treatment using preservative-containing medications (Uchino *et al*., 2018; Sheppard *et al*., 2023). Research indicates that between 36% of patients who undergo cataract surgery experience postoperative dry eye symptoms, with maximum severity at one month after surgery (Vaccaro *et al*., 2020).

Cataract surgery initiates a cascade of structural and inflammatory modification in the corneal microenvironment. Corneal nerves are severed, which causes diminished reflex tear production and abnormally altered blinking patterns and inflammation and goblet cell loss compromise mucin production and destabilize the tear film (Gore *et al*., 2015; Park *et al*., 2021). Under such conditions, adjunctive therapies to stabilize the tear film and repair the ocular surface are crucial.

This study demonstrated that therapy with polyvinyl alcohol (PVA) eye drops, in addition to standard postoperative care, significantly improved both clinical and biochemical indices of dry eye. All objective indices of significance-tear film break-up time (BUT), Schirmer I test (SIT), fluorescein staining (FL) and the Ocular Surface Disease Index (OSDI)-were improved. Such measures are considerably established within clinical and research settings to assess the quality of tear film and ocular surface integrity (Craig *et al*., 2017). The magnitude of change in the PVA group makes it preferable to use as a useful adjunct to DED management after cataract surgery.

PVA is a synthetic polymer that functions by mimicking mucin, promoting ocular lubrication and forming a protective film on the corneal epithelium. Its physicochemical properties-hydrophilicity, intermediate viscosity and surface adhesion-permit prolonged contact on the ocular surface, thereby increasing comfort and evaporation inhibition (Bedos *et al*., 2023; Phan *et al*., 2019). Compared with carbomer- or lipid-containing agents, PVA is less likely to cause blurring and is well tolerated for repeated use.

The cytokine profile of the tear also further elucidates PVA's potential immunomodulatory role. CCL1, which is a chemokine responsible for leukocyte recruitment and IL-13, a Th2 cytokine responsible for mucin dysfunction and epithelial inflammation, were suppressed significantly in the PVA group. Conversely, IL-10, an anti-inflammatory cytokine which is known to inhibit macrophage and dendritic cell activation, increased more predominately in the PVA group. These findings are consistent with experimentally modeled data showing that artificial tears are able to influence local cytokine production and promote corneal epithelial healing (Gómez-Aguado *et al*., 2021; Liu *et al*., 2022).

It is worth mentioning that all patients received tobramycin-dexamethasone eye drops as background treatment. Corticosteroids are known to inhibit inflammatory mediators and may individually contribute to improvement in symptoms and regulation of biomarkers. Therefore, while group difference is statistically and clinically significant, the role of background therapy should be considered on interpreting this result.

To facilitate accurate cytokine measurement, tear samples were diluted in a standard fashion with saline. This is a standard practice employed in ophthalmic biomarker research to provide sufficient volume and to prevent protein degradation. While dilution can be expected to underestimate the absolute concentrations, the uniform protocol applied to groups ensured valid relative comparisons.

There were no adverse effects reported over the course of 2 months' treatment, although caution is warranted in the interpretation of this. Adverse effect reporting was dependent on patient self-report and follow-up assessment, which may underestimate infrequent or delayed reactions. Future studies should consider inclusion of formal pharmacovigilance methods and extended follow-up to enhance safety monitoring.

There are several limitations to this research. The sample size was small and although powered for detection of the primary outcomes statistically, the absence of an exact power calculation may limit generalizability. The subjects were not stratified by DED subtype despite the presence of pathophysiologic heterogeneity between aqueous-deficient and evaporative subtypes. Further, while three cytokines were examined, a more extensive panel that involves MMP-9, IL-6, or TNF-α would provide more mechanistic insight.

Despite such limitations, these findings provide clinically significant evidence that PVA is effective to improve tear film stability, reduce ocular surface inflammation and improve postoperative comfort when used adjunctively following cataract surgery. Its enhanced safety profile, biocompatibility and ease of use further support its inclusion in treatment of the ocular surface postoperatively.

## CONCLUSION

In conclusion, polyvinyl alcohol eye drops are a safe and convenient treatment for cataract surgery-induced dry eye syndrome. They were capable of improving tear stability, reducing inflammatory mediators (CCL1 and IL-13), enhancing anti-inflammatory responses (IL-10) and healing the cornea and ocular surface. With outstanding therapeutic efficacy and outstanding safety profile, PVA eye drops warrant broader clinical applications and more studies to elucidate their molecular mechanisms.

***Conflict of interest***

The authors declare that there are no conflicts of interest regarding the publication of this paper.

***Author Contribution Statement***

Yubo Wu contributed to the study conception, patient recruitment, data collection, and statistical analysis. Yanjie Hao supervised the project, contributed to the study design, data interpretation, and critically revised the manuscript for important intellectual content. Both authors contributed to drafting the manuscript, reviewed the final version, and approved it for submission.

***Supplementary data***

https://www.pjps.pk/uploads/2025/09/SUP1757752971.pdf

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