Clinical and Experimental Vision and Eye Research (2023), 6, 10–16

ORIGINAL ARTICLE

Comparison of the effectiveness of perioperative versus post-operative use of advanced hydration therapy in ocular surface health in post-cataract surgery patients

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Keywords:

Advanced hydration therapy,
Cataract surgery,
Dry eye disease,
Ocular surface health

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Received: 10-10-2023;
Accepted: 12-11-2023
doi: 10.15713/ins.clever.103

Abstract

Purpose: The purpose is to evaluate the efficacy of advanced hydration therapy on the ocular surface and dry eye disease when used perioperatively versus only postoperatively in patients undergoing cataract surgery.

Methods: In the present randomized prospective interventional cross-sectional study, patients over 45 with simple cataracts who underwent monofocal intraocular lens (IOL) implantation and routine phacoemulsification were included in the study. While Group 2 had hydroxypropyl guar/hyaluronic acid (HPG/HA) for 4 weeks post-operatively, Group 1 received HPG/HA for 2 weeks pre-operatively and 4 weeks after surgery. The two groups were given the standard post-operative medications. Both pre-operative and post-operative examinations comprised ocular examinations and biometry, as well as dry eye workup and symptom evaluation using the standard patient evaluation of eye dryness (SPEED) questionnaire.

Results: In Group 1, the median pre-test Schirmer's score was 16.5, which significantly increased to 25.0 postoperatively ($P < 0.001$). In Group 2, the median pre-test Schirmer's score was 18.5, which increased to 21 post-operatively, and it was statistically significant ($P < 0.001$).The median pre-operative tear breakup time score was 10.0, which significantly increased to 12.0 ($P = 0.001$) and 13.0 ($P < 0.001$) in Groups 1 and 2, respectively. Group 1 revealed significant improvements in total SPEED scores, with scores decreasing from the pre-operative period to the day of surgery and further decreasing at the 4-week follow-up, while in Group 2, the speed score increased on the day of surgery.

Conclusion: Compared to post-operative use alone, the use of HPG/HA both pre-operatively and post-operatively may improve ocular surface health and reduce the symptoms of dry eye illness.

Introduction

Keratoconjunctivitis sicca, commonly known as "dry eye syndrome (DES)," is caused by multiple factors.[1] DES can cause ocular symptoms and discomfort due to pain, irritation, and impaired vision. Severe dry eye can negatively impact a patient's ocular surface and overall health, well-being, and quality of life.[1] The primary goal of cataract surgeons is to perform high-quality surgeries and achieve optimal post-operative visual acuity. However, patients may place greater emphasis on intraoperative and post-operative ocular comfort, as well as a strong desire to achieve 6/6 visual acuity. After undergoing cataract surgery, which is one of the most frequently performed procedures in ophthalmic units, a significant number of patients have reported experiencing dry eye-related symptoms of irritation.[2] In previously published studies, it has been documented that dry eye symptoms and signs can worsen following procedures such as laser in-situ keratomileusis and photorefractive keratectomy.[3,4] These procedures are known to be associated with a high incidence of dry eye disease (DED)

as a post-operative complication. However, even in advanced procedures such as phacoemulsification, a lesser percentage of DED has been reported.[2,3] Some studies have reported that dry eye symptoms and signs may worsen after cataract surgery.[5,6]

The primary reason for dry eye is the reduction in corneal sensation, which leads to a lack of feedback from the lacrimal gland and a decrease in tear production.[3] Other factors that can contribute to dry eye include medication toxicity, inflammation, and increased evaporation.[3] Although dry eye can sometimes lead to issues with corneal healing and visual acuity, these effects are temporary and typically last for a few weeks to a year.[2]

The appropriate treatment for post-operative dry eye disease should be based on the severity of the symptoms and the primary underlying cause. Prior to surgery, patients with a high risk for dry eye should undergo an evaluation to determine if they already have dry eye disease or are susceptible to developing it after the procedure.[7]

Artificial tears comprising polymers such as hydroxypropyl guar (HPG) and hyaluronic acid (HA) are used to treat dry eyes. By reducing surface resistance and mimicking the rheological characteristics of natural tears, HPG serves as a gellable agent. HA plays a significant role in cell proliferation, anti-inflammation, and wound healing.[8] The therapeutic value of HPG and HA in lowering the signs and symptoms of dry eyes has been established.

The combination of HPG and HA in a single artificial-tear formulation holds potential benefits for dry-eye patients by synergistically combining the properties of individual polymers and enhancing the ocular bioavailability of active ingredients, thereby potentially improving the overall well-being of the ocular surface.[8]

Systane Hydration®'s composition, which includes HPG and/or HA, stabilizes the tear film and offers long-lasting relief from dry eye symptoms. After cataract surgery, Systane Hydration® improves ocular surface health, reduces the need for repeated application, and enhances patient quality of life. It accomplishes this by providing sustained hydration and lubrication to the ocular surface. Systane Hydration® may therefore be a viable alternative to manage the dryness of the eyes following cataract surgery. In support of this, Systane Hydration® has been shown to improve ocular surface health and reduce the symptoms of dry eye disease.[9]

The efficacy of this advanced hydration therapy (AHT) in the post-operative management of cataract surgery patients has not been well studied.

Therefore, this study aimed to compare the efficacy of peri-operative versus post-operative use of AHT (HPG/HA) on ocular surface health in post-cataract surgery patients. We hypothesized that the use of AHT (HPG/HA) both pre-operatively and post-operatively will lead to improved ocular surface health and a reduction in the symptoms of dry eye disease compared to only post-operative use in cataract surgery patients.

Materials and Methods

After obtaining approval from the Institutional Ethics Committee (EC Ref No. C/2021/09/03), the present prospective interventional cross-sectional study was conducted. The study design involved the randomization of patients into two groups using a random table of numbers. The patients included in the study were over 45 years of age and had uncomplicated cataracts. These patients underwent an uncomplicated standard phacoemulsification procedure with foldable, in-the-bag monofocal intraocular lens (IOL) implantation. Patients who were previously diagnosed with dry eye disease, those on long-term ocular or topical steroids, patients with a history of previous intra- or extra-ocular surgery, or any other ocular comorbidities were excluded from the study. Written informed consent was obtained from all the participants prior to their inclusion in the study.

The sample size for the present study was calculated using the below formula.,

$$n = \frac{2\left(Z_{\alpha/2} + Z_{\beta}\right)^2}{d^2}$$

$$\text{where, } d = \left(\frac{|\mu_1 - \mu_2|}{\sigma}\right)$$

Where μ_1 is the mean of the first group, μ_2 is the mean of the second group, σ^2 is the common error variance, the $Z_{(\alpha/2)}$ value is 1.96 for a 95% confidence level, and the Z^{β} value is 0.8416 for 80% power. Considering the effect size of tear breakup time (TBUT) between the groups to be large (0.8), at 5% level of significance and 80% power, a sample size of 26 subjects was obtained for each group. The total required sample size was 26 × 2 = 52 subjects. Considering a 10% loss to follow-up, a sample size of 29 subjects for each group was estimated. The total sample size required was calculated as 29 × 2 = 58 subjects. The sample size was calculated using G*Power software by considering the TBUT variable using the unpaired t-test.

The final sample size for the study was estimated at 64 eyes, with 32 patients each in Group A and Group B.

Pre-operatively, a detailed ophthalmic examination was performed, including uncorrected visual acuity assessment using the Snellen chart, slit lamp examination, dry eye workup comprising Schirmer's 1 test,[10] TBUT,[11] standard patient evaluation of eye dryness (SPEED) questionnaire,[12] biometry and IOL power calculation using Lenstar 900 and IOL Master 700, fundus examination, and optical coherence tomography macula/B-scan ultrasound (using equipment from Argos (Alcon) and Heidelberg Engineering, respectively) by a single experienced observer. All procedures were performed by a single experienced surgeon.

Group 1 patients received AHT/Systane Hydration (HPG/HA) for 2 weeks pre-operatively and 4 weeks post-operatively, in addition to a routine topical post-operative antibiotic and anti-inflammatory treatment (Moxifloxacin 0.5% QDS for 2 weeks, Prednisolone Acetate 1% in tapering doses for 4 weeks, and Nepafenac 0.1% for 6 weeks). Group 2 patients received AHT/Systane Hydration (HPG/HA) for 4 weeks post-operatively, in addition to the same routine topical post-operative medication regimen.

Post-operatively, patients were evaluated at 1-month follow-up. Best-corrected visual acuity (BCVA), slit lamp examination, and dry eye workup (Schirmer's 1, TBUT, and SPEED Questionnaire) were performed at the follow-up visit. The same equipment and medications used pre-operatively were used during the post-operative period.

The non-operated eyes of the same patients were also evaluated at 1-month follow-up. BCVA, slit lamp examination, and dry eye workup (Schirmer's 1, TBUT, SPEED Questionnaire), and the observations were compared with the operated eyes at the respective visits.

Statistical analysis

The data were analyzed using SPSS software version 20.0. Dry eye parameters, including Schirmer's and TBUT, were described in terms of median and interquartile range (IQR), as the data were not normally distributed. The normality of the data was assessed using the Kolmogorov-Smirnov test. The variables of grittiness, soreness, irritation, burning, and eye fatigue were described in terms of percentages for both groups. The median dry eye Schirmer's and TBUT between the two groups were compared using the Mann-Whitney U test, while the intragroup comparison was performed using the Wilcoxon signed-rank test. The frequency of dryness, grittiness, soreness, irritation, burning, and eye fatigue between the two groups was compared using the chi-square test. A $P < 0.05$ was considered statistically significant.

Results

The mean age (±SD) of the patients in Groups 1 and 2 was 63.3 ± 6.2 and 63.8 ± 7.7 years, respectively, with a male population of 51.56%. Table 1 presents a comparison of Dry Eye Schirmer's test results and TBUT measurements between baseline and final (post-operative 1-month) assessments, including the comparisons between Group 1 and Group 2 among operated eyes. For Group 1, the Schirmer's test showed a significant increase in median values from 16.5 (IQR: 12.0–29.5) at pre-assessment to 25.0 (IQR: 18.0–35.0) at the final assessment ($P < 0.001$). The TBUT also improved, with the pre-assessment median of 10.0 (IQR: 10.0–11.8) increasing to 12.0 (IQR: 10.0–13.0) at the final assessment ($P = 0.001$).

In Group 2, Schirmer's test revealed a significant increase in median values from 18.5 (IQR: 15.0–24.0) at pre-assessment to 21.0 (IQR: 18.0–27.3) at the final assessment ($P < 0.001$). Similarly, the TBUT improved, with the pre-assessment median of 10.0 (IQR: 10.0–12.0) increasing to 13.5 (IQR: 11.3–14.0) at the final assessment ($P < 0.001$).

Table 2 compares Schirmer's test results and TBUT between baseline and final measurements in both groups (Group 1 and Group 2) among non-operated eyes. No statistically significant difference was observed in Schirmer's test values between baseline and final measurements in both groups ($P > 0.05$). Similarly, no significant changes in TBUT values were found within Group 1, while a slight, non-significant increase was noted in Group 2 ($P > 0.05$).

The comparison of the total SPEED scores of Group 1 and Group 2 at different stages is shown in Table 3. The comparisons between the groups at each stage were not statistically significant ($P > 0.05$). However, significant differences were observed within each group over time ($P < 0.001$ for Group 1, $P = 0.050$ for Group 2). The SPEED score in Group 2 increased on the day of surgery, whereas in Group 1, there was a consistent decrease from the pre-operative period up to 4 weeks post-surgery. Additionally, a significant difference was noted between the day of surgery and the 4-week mark within Group 1 ($P = 0.001$) and Group 2 ($P = 0.017$).

Table 4 presents a comparative analysis of symptom prevalence in Group 1 and Group 2 at different stages. The key findings reveal significant differences in symptom manifestation. On the day of surgery, the majority of the participants did not experience any symptoms in Group 1, while participants in Group 2 exhibited significantly higher prevalences of dry grittiness (53.1% vs. 6.2%), sore irritation (50.0% vs. 6.2%), burning or watering (50.0% vs. 9.4%), and eye fatigue (62.5% vs. 15.6%) compared to Group 1 ($P < 0.001$). However, by the 4th week, dry grittiness, sore irritation, and eye fatigue ($P = 0.001$) resolved in all the participants in Group 2. Notably, 28.1% of Group 2 participants still reported burning or watering symptoms in the 4th week ($P = 0.001$).

Table 5 presents the comparison of the frequency of symptoms between Group 1 and Group 2 at different stages, along with the corresponding *P*-values. The analysis indicates no significant difference in symptom frequency between the groups at the pre-operative stage and on the day of surgery. However, by the 4th week, Group 1 exhibited higher patients reporting no dry grittiness (81.2% vs. 62.5%, $P = 0.095$), no soreness or irritation (90.6% vs. 62.5%, $P = 0.008$), no burning or watering (84.4% vs. 65.6%, $P = 0.083$), and no eye fatigue (93.8% vs. 68.8%, $P = 0.010$) compared to Group 2. These findings suggest that Group 1 had a higher proportion of participants reporting a reduced frequency of symptoms by the 4th week.

Table 1: Comparison of pre-andpost-operativeSchirmer's 1 test, TBUT measurements between group 1 and group 2 among operated eyes

Groups	Schirmers				TBUT			
	Pre Median (IQR)	Final Median (IQR)	Difference	*P*-value	Pre Median (IQR)	Final Median (IQR)	Difference	*P*-value
Group-1	16.5 (12.0–29.5)	25.0 (18.0–35.0)	5.0 (1.0–7.5)	<0.001*	10.0 (10.0–11.8)	12.0 (10.0–13.0)	1.5 (0.0–2.8)	0.001*
Group-2	18.5 (15.0–24.0)	21.0 (18.0–27.3)	3.5 (0.3–5.0)	<0.001*	10.0 (10.0–12.0)	13.5 (11.3–14.0)	2.0 (0.0–3.0)	<0.001*
P-value	0.603	0.330	0.205		0.247	0.050	0.461	

*indicates significant *P*-value

Table 2: Comparison of pre-and post-operative Schirmer's 1 test, TBUT measurements between group 1 and group 2 among non-operated eyes

Groups	Schirmers				TBUT			
	Pre Median (IQR)	Final Median (IQR)	Difference	*P*-value	Pre Median (IQR)	Final Median (IQR)	Difference	*P*-value
Group-1	12.3 (18.0–25.0)	18.0 (14.0–29.5)	0.0 (0.0–2.0)	0.215	10.0 (10.0–12.0)	10.0 (10.0–12.0)	0.0 (0.0–0.8)	0.352
Group-2	18.0 (15.0–24.8)	18.0 (15.0–24.8)	0.0 (0.0–1.0)	0.327	10.0 (10.0–12.0)	11.0 (10.0–12.0)	0.0 (0.0–1.0)	0.439
P-value	0.636	0.866	0.379		0.380	0.287	0.586	

Table 3: Comparison of total SPEED scores between the groups and within the groups

Total SPEED score	Group 1	Group 2	*P*-value
Pre-op	0.23 (0.07–0.39)	0.07 (0.00–0.37)	0.176
On the day of surgery	0.12 (0.00–0.21)	0.21 (0.00–0.53)	0.129
4 weeks	0.00 (0.00–0.06)	0.00 (0.00–0.29)	0.097
P-value	<0.001*	0.050*	
Pre-op versus On the day of surgery	0.015*	0.369	
Pre-op versus 4 weeks	< 0.001*	0.109	
On the day of surgery Vs 4 weeks	0.001*	0.017*	

*indicates significant *P*-value* indicates significant *P*-value

Discussion

Cataract can lead to visual impairment and blindness, and it accounts for a significant portion of visual disabilities worldwide.[13] Phacoemulsification is the most common surgical procedure for cataract removal but can have adverse effects and complications, such as dry eye, in spite of advancements in technology.[13,14]

Dry eye after cataract surgery can result from various mechanisms, including the use of topical anesthesia and eye drops containing preservatives, exposure to the light of an operating microscope, and changes in corneal innervation during the surgical procedures.[15] Artificial tears are a common treatment for dry eyes, and polymers like HPG and HA play an important role in their formulation.[8,16]

Artificial tears containing both HPG and HA may offer better benefits for the dry eye than those containing only one polymer. A dual formulation combining HPG and HA polymers in artificial tears has demonstrated superior effectiveness compared to a single polymer alone. This combination synergizes the properties of HPG and HA, leading to enhanced ocular surface hydration, lubrication, and wound healing. The dual formulation improves the ocular bioavailability of the active ingredients, resulting in prolonged retention on the ocular surface and a reduced frequency of application. By addressing multiple aspects of dry eye pathology, the HPG-HA dual formulation provides greater relief and improved management of dry eye symptoms compared to single polymer-based formulations.[8,16] In vitro and animal studies have shown promising results for this formulation, indicating its potential as a treatment option for dry eye in patients undergoing cataract surgery.[17]

The present study was carried out to address a knowledge gap and evaluate the effects of AHT on dry eyes in patients who underwent phacoemulsification surgery. The frequent occurrence of dry eye problems following cataract surgery, which can greatly affect patients' quality of life and patient dissatisfaction with surgery, is the driving force behind the necessity for this study. Although lubricants are frequently used following surgery, comprehensive information on the efficiency of AHT in this group of patients is lacking. The study found that HPG-HA significantly improved Schirmer's score in Group 1 and TBUT in both groups, but the difference was more significant in Group 1. This observation was similar to the findings of Favuzza *et al.*, who reported that patients using HPG/HA solution 3 times a day for a week before surgery and for 2 months after the surgery had higher scores of tear break-up time compared to the group who only used HPG/HA for 2 months after the surgery.[9]

In the present study, patients in both groups treated with HPG-HA experienced a reduction in dry eye disease symptoms. However, Group 1 patients who received HPG-HA both pre-operatively and post-operatively showed a statistically significant reduction in the symptoms of dry eye disease compared to Group 2 patients who received HPG-HA only post-operatively. Additionally, in Group 1, the total SPEED scores showed significant improvements, and the scores decreased significantly from the pre-operative stage to the day of surgery and further decreased at the 4-week follow-up visit. Whereas the speed score increased during the day of surgery in group 2, indicating a worsening of symptoms on the day of surgery.

Favuzza *et al.* noted that patients who used HPG/HA solution 3 times a day for a week before surgery and continued for 2 months after the surgery had lower scores on the SPEED questionnaire administered to evaluate the severity of dry eye symptoms.[9]

Recent studies have shown that eye drops containing HPG, a component of Systane Hydration®, can improve the symptoms of dry eye disease.[18] A randomized controlled trial by Craig *et al.* demonstrated sustained reduction of dry eye symptoms in participants using HPG containing ATs Systane Complete and Systane Ultra.[19] Previous clinical trials have also shown similar findings for the treatment of dry eye symptoms using HPG.[20]

Similarly, HA, which is another component of Systane Hydration®, was found to be effective in improving both signs and symptoms of DED in the strengths of 0.1–0.4% because of its lubricating, anti-inflammatory, antioxidant, and anti-toric effects.[21]

The present study findings support the hypothesis that both pre-operative and post-operative use of AHT would

Table 4: Comparison of symptoms between the two groups at different stages

Symptom	Stage	Group 1 (*n*=32)		Group 2 (*n*=32)		*P*-value
		Yes *n* (%)	No *n* (%)	Yes *n* (%)	No *n* (%)	
Dry Grittiness	Pre-op	13 (40.6)	19 (59.4)	12 (37.5)	20 (62.5)	0.794
	Day of surgery	2 (6.2)	30 (93.8)	17 (53.1)	15 (46.9)	<0.001*
	4th Week	0 (0.0)	32 (100.0)	10 (31.2)	22 (68.8)	0.001*
	P-value	<0.001*		0.186		
Sore irritation	Pre-op	13 (40.6)	19 (59.4)	12 (37.5)	20 (62.5)	0.798
	Day of surgery	2 (6.2)	30 (93.8)	16 (50.0)	16 (50.0)	<0.001*
	4th Week	0 (0.0)	32 (100.0)	10 (31.2)	22 (68.8)	0.001*
	P-value	<0.001*		0.295		
Burning/Watering	Pre-op	13 (40.6)	19 (59.4)	12 (37.5)	20 (62.5)	0.798
	Day of surgery	3 (9.4)	29 (90.6)	16 (50.0)	16 (50.0)	<0.001*
	4th Week	0 (0.0)	32 (100.0)	9 (28.1)	23 (71.9)	0.001*
	P-value	<0.001*		0.196		
Eye Fatigue	Pre-op	14 (43.8)	18 (56.2)	11 (34.4)	21 (65.6)	0.442
	Day of surgery	5 (15.6)	27 (84.4)	20 (62.5)	12 (37.5)	<0.001*
	4th Week	0 (0.0)	32 (100.0)	10 (31.2)	22 (68.8)	0.001*
	P-value	<0.001*		0.021*		

*indicates significant *P*-value

Table 5: Comparison of frequency of symptoms between the two groups at different stages

Symptom	Stage	Group 1 (*n*=32)		Group 2 (*n*=32)		*P*-value
		Nil *n* (%)	≥1 *n* (%)	Nil *n* (%)	≥1 *n* (%)	
Dry Grittiness (0–3)	Pre-op	14 (43.8)	18 (56.2)	17 (53.1)	15 (46.9)	0.453
	Day of surgery	18 (56.2)	14 (43.8)	15 (46.9)	17 (53.1)	0.453
	4th Week	26 (81.2)	6 (18.8)	20 (62.5)	12 (37.5)	0.095
	P-value	0.008*		0.451		
Sore irritation (0–3)	Pre - op	13 (40.6)	19 (59.4)	17 (53.1)	15 (46.9)	0.316
	Day of surgery	19 (59.4)	13 (40.6)	16 (50.0)	16 (50.0)	0.451
	4th Week	29 (90.6)	3 (9.4)	20 (62.5)	12 (37.5)	0.008*
	P-value	<0.001*		0.578		
Burning/Watering (0–3)	Pre - op	15 (46.9)	17 (53.1)	17 (53.1)	15 (46.9)	0.617
	Day of surgery	19 (59.4)	13 (40.6)	16 (50.0)	16 (50.0)	0.451
	4th Week	27 (84.4)	5 (15.6)	21 (65.6)	11 (34.4)	0.083
	P-value	0.006*		0.411		
Eye Fatigue (0–3)	Pre - op	15 (46.9)	17 (53.1)	16 (50.0)	16 (50.0)	0.802
	Day of surgery	21 (65.6)	11 (34.4)	12 (37.5)	20 (62.5)	0.204
	4th Week	30 (93.8)	2 (6.2)	22 (68.8)	10 (31.2)	0.010*
	P-value	<0.001*		0.042*		

*indicates significant *P* value

lead to improved ocular surface health and reduced dry eye symptoms compared to post-operative use alone. The significant improvements observed in dry eye parameters, including Schirmer's test and TBUT, indicate the effectiveness of this therapeutic approach. Furthermore, the comparison between Group 1 and Group 2 suggests that pre-operative use of AHT might provide additional benefits in terms of ocular surface health and dry eye symptom management.

The present study provides valuable insights regarding the efficacy of HPG-HA therapy in improving ocular surface health

post-cataract surgery. This study also highlights the importance of proper pre-operative evaluation and the use of appropriate treatment to ensure the best outcomes for post-operative patients.

This study design involved randomizing participants into two groups, which allowed for a nun-biased comparison. The participants were divided into perioperative and post-operative groups in order to identify the unique effects of each regimen at various points in the surgical procedure. This study's methodology offers insightful information about the relative efficacy of the treatment in various settings, which can help guide clinical decision-making.

The presented study's strength is in its randomized design, which lessens bias and improves the reliability of the results. The robustness of our investigation is also improved by using standardized outcome measures and a control group. Additionally, the sample size was carefully chosen to ensure sufficient statistical power, further enhancing the validity of the study.

The observations of this study can be beneficial in guiding treatment decisions for patients with dry eyes after cataract surgery. The peri-operative regimen highlights the need for ocular homeostasis in patients preparing for cataract surgery. The stabilization of ocular surfaces significantly impacts surgical outcomes, reducing biometric errors and visual disturbances.

Despite the fact that this study offers insightful information about the advantages of perioperative Systane Hydration®, it's crucial to remember that no single study can definitively prove the necessity of a particular course of action. However, while deciding whether to provide perioperative or post-operative care, clinical decision-making should take into account the unique patient variables, preferences, and professional skills.

Conclusion

The present study evaluated the efficacy of AHT with HPG/HA in peri-operative cataract surgery patients. Perioperative use of AHT can be effective in patients undergoing cataract surgery by reducing dry eye symptoms and improving comfort compared to only post-operative use. The study findings suggest that AHT with HPG/HA may be a useful adjunctive therapy for improving tear film stability in post-cataract surgery patients. Further studies with a larger sample size and longer follow-up periods are warranted to confirm these findings.

Grant Support

This study was supported by an IIT research grant from Alcon Vision LLC.

Acknowledgment

We would like to thank Healthminds Consulting Pvt. Ltd. for the data analysis and medical writing support.

Conflicts of Interest

None.

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How to cite this article: Shetty N, Tejal SJ, Ranade RR. Comparison of the effectiveness of perioperative versus post-operative use of advanced hydration therapy in ocular surface health in post-cataract surgery patients. Cli Exp Vis Eye Res J 2023;6(2):10-16.