

The treatment effect of cyclosporine 0.05% and artificial tears for the lid wiper epitheliopathy of dry eye disease after phacoemulsification surgery

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Abstract

We evaluate the effectiveness of cyclosporine 0.05% and artificial tears for the lid wiper epitheliopathy of dry eye disease after phacoemulsification surgery. In the cyclosporine group, a total of 58 eyes of 42 patients newly diagnosed with dry eye disease at 1 week after phacoemulsification surgery received a twice-daily treatment of cyclosporine 0.05% eye drop for 2 months, plus antibiotic eye drops every 3 Hours (Q3H) for one week and steroid eye drops Q3H for one week. In the artificial tear group, 39 eyes of 30 newly diagnosed patients with dry eye disease 1 week after phacoemulsification surgery received a treatment of aqueous-based artificial tears four times a day for 2 months, plus antibiotic eye drops every 3 Hours (Q3H) for one week and steroid eye drops Q3H for one week. In the control group, 14 eyes of 11 newly diagnosed patients with dry eye disease 1 week after phacoemulsification surgery only received a treatment of antibiotic eye drops Q3H for one week and steroid eye drops Q3H for one week, and did not receive any treatment of cyclosporine or artificial tears. Compared to the control group, grading of lid wiper epitheliopathy of upper eyelid in the cyclosporine group and artificial tear group both showed a significant decrease at 1 month ($p=0.04$) and 2 months ($p=0.02$), and showed a trend of decrease without significance and at 1 week; Grading of lid wiper epitheliopathy of lower eyelid in the cyclosporine group and artificial tear group both showed a significant decrease at 2 months ($p=0.047$), and showed a trend of decrease without significance and at 1 week and 1 month. Our findings suggest that

cyclosporine 0.05% or aqueous-based artificial tears eye drop can be an effective treatment for the lid wiper epitheliopathy of dry eye disease after phacoemulsification surgery.

Introduction

Dry eye disease is now recognized as a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles[1]. Cataract surgery is one of the most successfully performed eye surgeries, which usually obtain good postoperative visual acuity, and now the mainstream is phacoemulsification[2]. However, postoperative complaints of dry eye disease may occur after phacoemulsification surgery[3, 4]. The prevalence of dry eye disease may be high as 80% in patients after phacoemulsification surgery[5]. There were many parameters for evaluation of the degree of dry eye disease, such as Ocular Surface Disease Index (OSDI) questionnaire, Tear film height, tear film break-up time (TBUT), noninvasive tear film break-up time (NITBUT), conjunctival redness, Oxford grading of superficial punctate keratitis, and Oxford grading of conjunctival staining[4]. There have been many studies describing the changing pattern of these parameters in the patients with dry eye disease after phacoemulsification surgery[3, 4, 6, 7]. Lid wiper epitheliopathy, an alteration of that portion of the marginal conjunctival epithelium of the eyelid that wipes the ocular surface during blinking, also correlate with symptoms indicative of dry eye conditions[8]. There were little reports about the disease course or the treatment of lid wiper epitheliopathy after phacoemulsification surgery. In this report, we evaluate the effectiveness of cyclosporine

0.05% eye drop and aqueous-based artificial tears for the treatment of lid wiper epitheliopathy of dry eye disease after phacoemulsification surgery.

Materials and methods

This was a retrospective study of 111 eyes of 83 patients received phacoemulsification surgery at Tri-Service General Hospital, National Defense Medical Center, Taipei City, Taiwan, from January 2012 to December 2020. We enrolled patients with cataract without dry eye disease within 3 months before cataract surgery, but was newly diagnosed with dry eye disease 1 week after cataract surgery. Dry eye disease was defined TBUT <10 sec and OSDI score > 12 points. Therefore, if patients had TBUT <10 sec and OSDI score > 12 points 1 week after cataract surgery, they were included. All patients underwent cataract extraction by phacoemulsification and intraocular lens implantation at Tri-Service General Hospital. Other exclusion criteria were previous use of eye drops within 3 months before cataract surgery, a history of previous ocular surgery or trauma, and presence of ocular comorbidities such as uveitis or glaucoma. These patients were classified into cyclosporine, artificial tear, and control group. In the cyclosporine group, a total of 58 eyes of 42 patients newly diagnosed with dry eye disease at 1 week after phacoemulsification surgery received a twice-daily treatment of cyclosporine 0.05% eye drop (RESTASIS®, Allergan Inc., Texas, U.S.A) for 2 months, plus antibiotic eye drops (Cravit® ophthalmic solution, Santen Pharmaceutical Co.,

Osaka, Japan) every 3 Hours (Q3H) for one week and steroid eye drops (ECONOPRED® Plus suspension, Alcon Laboratories, Inc., Texas, U.S.A.) Q3H for one week. In the artificial tear group, 39 eyes of 30 patients newly diagnosed with dry eye disease at 1 week after phacoemulsification surgery received a treatment of aqueous-based artificial tears (SYSTANE® ULTRA Lubricant Eye Drops, Alcon Laboratories Inc., Singapore) four times a day for 2 months, plus antibiotic eye drops (Cravit®) every 3 Hours (Q3H) for one week and steroid eye drops (ECONOPRED®) Q3H for one week. In the control group, 14 eyes of 11 patients newly diagnosed with dry eye disease 1 week after phacoemulsification surgery only received a treatment of antibiotic eye drops (Cravit®) Q3H for one week and steroid eye drops (ECONOPRED®) Q3H for one week, and did not receive any treatment of artificial tears or immunosuppressant. Dry eye disease severity was measured at one week, 1 month, 2 months after the surgery by the following dry eye related parameters.

Dry eye related parameters

1. Ocular Surface Disease Index (OSDI) questionnaire

A structured symptom-based survey was conducted to identify patients with symptoms suggestive of dry eyes. According to the score of OSDI, which is based upon the response to a questionnaire of 12 questions, subjective symptoms were graded as normal (0-12 points), mild (13-22 points), moderate (23-32 points) and severe (33-100 points) based on the

guidelines of Dry Eye Workshop (DEWS) report[9]. The OSDI score > 12 points was suggestive of dry eye.

2. Tear meniscus height

Tear meniscus height was measured by Oculus Keratograph 5M (K5M; Oculus Optikgeräte GmbH, Wetzlar, Germany). The tear meniscus height can be used to estimate tear volume. A tear meniscus height less than 0.25 mm is suggestive of dry eye[10].

3. Tear film break-up time (TBUT)

For TBUT, a fluorescein strip was placed in the inferior fornix after sufficient anesthesia with proparacaine hydrochloride ophthalmic solution (Alcaine® 0.5%, Alcon Laboratories, Fort Worth, TX, USA) and the patient was asked to blink several times and with slit lamp biomicroscopy by using cobalt blue filter, the interval between last blink and first appearance of a dry spot or tear film break-up was recorded, and this was repeated three times and the average was determined. Values shorter than 10s indicate dry eye disease[7].

4. Conjunctival redness scores

Conjunctival redness scores were measured with the Oculus Keratograph 5M (K5M; Oculus Optikgeräte GmbH, Wetzlar, Germany). It can automatically and objectively document the blood vessels in the conjunctiva and evaluates the degree of redness. Scores are calculated by

the device's software as the area percentage ratio between the vessels and the rest of the analyzed area. For example, if the ratio is 10%, then the score is 1.0. The maximum ratio is 40% and thus the score ranges from 0.0 to 4.0[11]. The score is positive correlated with the degree of the dry eye disease[12].

5. Oxford grading of superficial punctate keratitis

For Oxford grading of superficial punctate keratitis, the fluorescein was instilled on the patients, and with slit lamp biomicroscopy by using cobalt blue filter, the pattern of superficial punctate keratitis on the cornea was observed and the grade was recorded by using the Oxford Scheme. The grade ranges from 0 to 5, and is positive correlated with the degree of the dry eye disease[13].

6. Oxford grading of conjunctival staining

For Oxford grading of conjunctival staining, the lissamine green was instilled on the patients, and with slit lamp biomicroscopy, the pattern of conjunctival staining was observed and the grade was recorded by using the Oxford Scheme. The grade ranges from 0 to 5, and is positive correlated with the degree of the dry eye disease[13].

7. Grading of lid wiper epitheliopathy of upper eyelid and lower eyelid.

For grading of lid wiper epitheliopathy of upper eyelid and lower eyelid, the lissamine green was instilled on the patients, and with slit lamp biomicroscopy, the pattern of lid wiper epitheliopathy was observed at the marginal conjunctiva and the grade was recorded by using the grading system developed by Korb et al. The grade ranges from 0 to 3, and is positive correlated with the degree of the lid wiper epitheliopathy[8].

Statistical Analysis

Statistical analysis was performed using IBM-SPSS for Windows software, version 22 (SPSS Inc., Chicago, IL, USA). Analysis of Variance(ANOVA) was used to compare the parameter of dry eye disease severity between the cyclosporine group, artificial tear, and control group. A p-value smaller than 0.05 was considered to be statistically significant. A post hoc test is used when we find a statistically significant result and need to determine where our differences between the groups came from.

Results

1. cyclosporine group v.s. control group

For the dry eye disease severity measured after surgery, compared to the control group, the grading of lid wiper epitheliopathy of upper eyelid showed a significant decrease at 1 month (cyclosporine group vs. control group: mean = 0.09 vs. 0.42, $p=0.04$) and 2 months

(cyclosporine group vs. control group: mean = 0.07 vs. 0.50, $p=0.02$), and showed a trend of decrease without significance at 1 week (cyclosporine group vs. control group: mean = 0.16 vs. 0.38, $p=0.285$) (Table 1 & 2 & Figure 1); the grading of lid wiper epitheliopathy of lower eyelid in the cyclosporine group showed a significant decrease at 2 months (cyclosporine group vs. control group: mean = 0.27 vs. 0.83, $p=0.047$), and showed a trend of decrease without significance and at 1 week (cyclosporine group vs. control group: mean = 0.36 vs. 0.62, $p=0.229$) and 1 month (cyclosporine group vs. control group: mean = 0.20 vs. 0.42, $p=0.377$) (Table 3 & Figure 2). Besides, there is no significant difference in the OSDI questionnaire, tear film height, TBUT, NITBUT, conjunctival redness, Oxford grading of superficial punctate keratitis, and Oxford grading of conjunctival staining between the 2 groups during the 2 months follow up (Table 1).

Table 1. Dry eye disease severity measured at one week, 1 month, 2 months after the surgery

OSDI	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)		P value	post hoc analysis
	Mean	SE	Mean	SE	Mean	SE		
Post-op one week	12.24	1.74	15.63	2.01	14.42	2.78	0.428	
Post-op 1 month	12.61	1.52	17.77	2.62	15.34	2.44	0.168	
Post-op 2 month	13.04	1.98	12.50	2.93	14.58	5.51	0.947	

Tear film height(mm)								
	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis
Post-op one week	0.23	0.02	0.23	0.02	0.18	0.02	0.473	
Post-op 1 month	0.26	0.03	0.23	0.03	0.19	0.02	0.477	
Post-op 2 month	0.25	0.03	0.18	0.02	0.20	0.04	0.444	

Conjunctival redness (score)								
	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis
Post-op one week	1.47	0.07	1.36	0.07	1.21	0.11	0.172	
Post-op 1 month	1.51	0.07	1.43	0.09	1.43	0.20	0.737	
Post-op 2 month	1.44	0.06	1.32	0.12	1.10	0.18	0.156	

TBUT (sec)								
	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis
Post-op one week	2.60	0.20	2.35	0.28	2.77	0.47	0.656	
Post-op 1 month	2.82	0.19	2.97	0.40	3.00	0.78	0.920	

Post-op 2 month	3.13	0.34	3.31	0.61	1.50	0.62	0.222	
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Oxford SPK (grade)								
	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis
Post-op one week	1.76	0.14	1.58	0.16	1.69	0.35	0.730	
Post-op 1 month	1.45	0.14	0.84	0.14	1.08	0.19	0.014	A>B
Post-op 2 month	1.24	0.14	0.38	0.14	0.67	0.21	0.007	A>B
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Conjunctival stain (grade)								
	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis
Post-op one week	0.77	0.11	0.45	0.14	0.62	0.24	0.210	
Post-op 1 month	0.29	0.07	0.53	0.16	0.75	0.28	0.084	
Post-op 2 month	0.22	0.07	0.46	0.22	0.17	0.17	0.323	

Table 2. Upper eyelid: Grading of lid wiper epitheliopathy measured at one week, 1 month, 2 months after the surgery

	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)			
	Mean	SE	Mean	SE	Mean	SE	P value	post hoc analysis

Post-op one week	0.16	0.06	0.16	0.06	0.38	0.21	0.285	
Post-op 1 month	0.09	0.05	0.13	0.06	0.42	0.19	0.040	C>A; C>B
Post-op 2 month	0.07	0.05	0.00	0.00	0.50	0.34	0.020	C>A; C>B

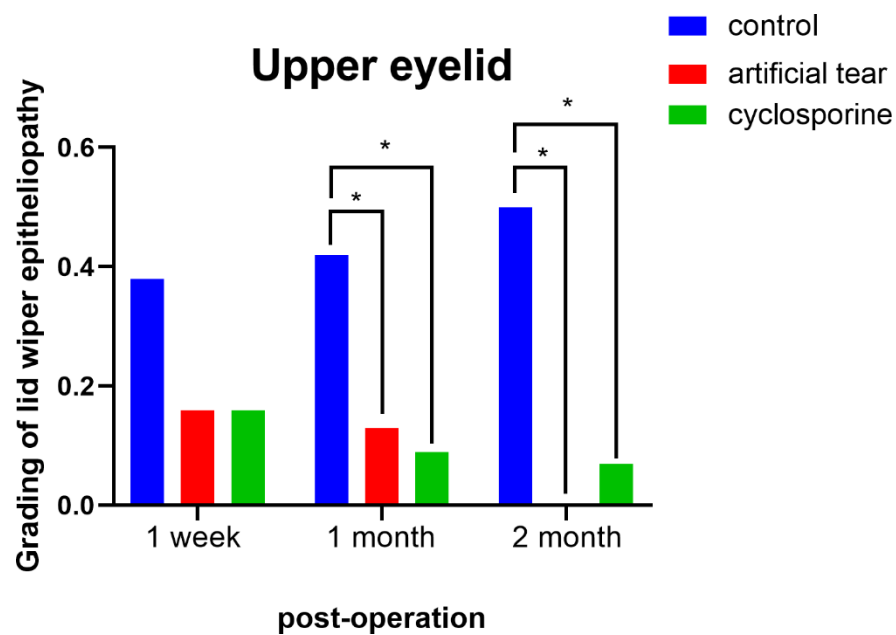


Fig 1. Grading of lid wiper epitheliopathy of upper eyelid after phacoemulsification surgery.

*: P value <0.05

Table 3. Lower eyelid: Grading of lid wiper epitheliopathy

	Cyclosporine 0.05%(A)		Artificial tear (B)		Control (C)		P value	post hoc analysis
	Mean	SE	Mean	SE	Mean	SE		
Post-op one week	0.36	0.09	0.24	0.10	0.62	0.29	0.229	
Post-op 1 month	0.20	0.07	0.31	0.10	0.42	0.15	0.377	

Post-op 2 month	0.27	0.09	0.15	0.10	0.83	0.31	0.047	C>A; C>B
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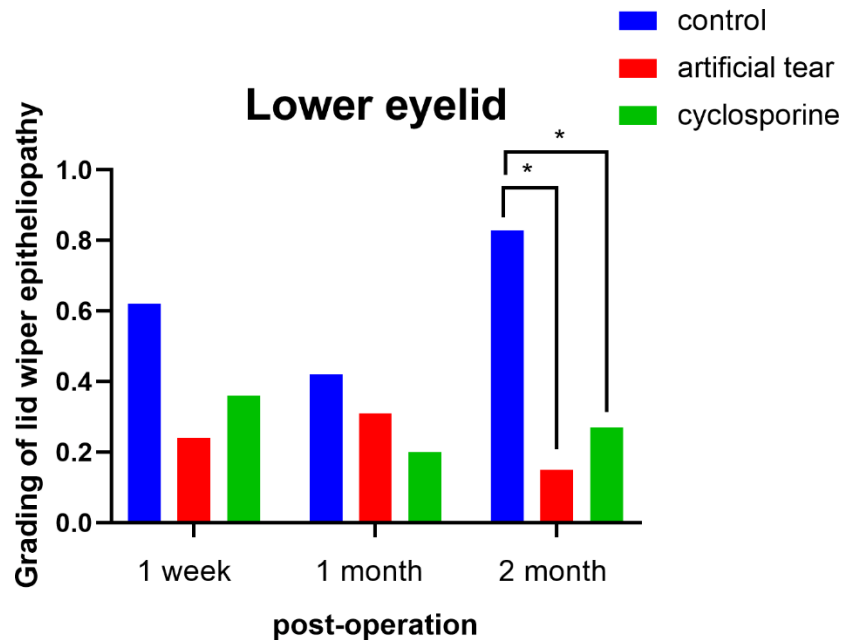


Fig 2. Grading of lid wiper epitheliopathy of lower eyelid after phacoemulsification surgery.

*: P value <0.05

2. artificial tear group v.s. control group

For the dry eye disease severity measured after surgery, compared to the control group, the grading of lid wiper epitheliopathy of upper eyelid showed a significant decrease at 1 month (artificial tear group vs. control group: mean = 0.13 vs. 0.42, $p=0.04$) and 2 months (artificial tear group vs. control group: mean = 0.00 vs. 0.50, $p=0.02$), and showed a trend of decrease without significance at 1 week (artificial tear group vs. control group: mean = 0.16 vs. 0.38, $p=0.285$) (Table 1 & 2 & Figure 1); the grading of lid wiper epitheliopathy of lower eyelid in

the artificial tear group showed a significant decrease at 2 months (artificial tear group vs. control group: mean = 0.15 vs. 0.83, $p=0.047$), and showed a trend of decrease without significance and at 1 week (artificial tear group vs. control group: mean = 0.24 vs. 0.62, $p=0.229$) and 1 month (artificial tear group vs. control group: mean = 0.31 vs. 0.42, $p=0.377$). Besides, there is no significant difference in the OSDI questionnaire, tear film height, TBUT, NITBUT, conjunctival redness, Oxford grading of superficial punctate keratitis, and Oxford grading of conjunctival staining between the 2 groups during the 2 months follow up (Table 1). The figure 3 showed an example of a 60-year-old female had dry eye disease after phacoemulsification surgery: Under the treatment of artificial tears, grading of lid wiper epitheliopathy of lower eyelid improved from post-operation one month to post-operation two months.

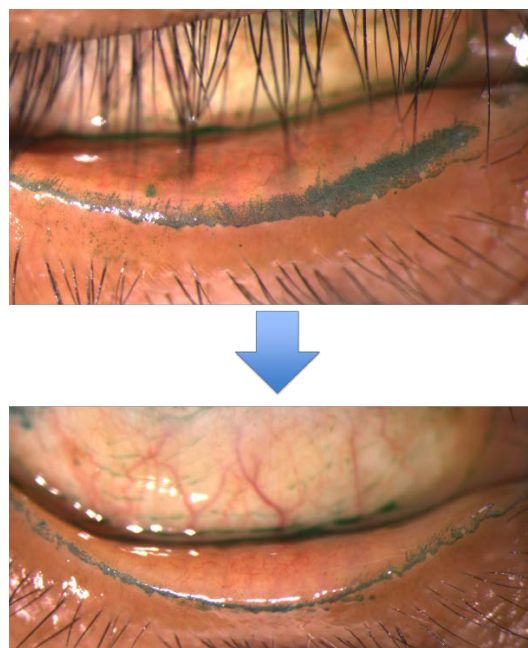


Fig 3. A 60-year-old female had dry eye disease after phacoemulsification surgery. Under the treatment of artificial tears, grading of lid wiper epitheliopathy of lower eyelid, which was detected by staining of lissamine green, showed decrease from post-operation 1 month (upper figure) to post-operation 2 month (lower figure).

3. cyclosporine group v.s. artificial tear group

For the dry eye disease severity measured after surgery, compared to the cyclosporine group, Oxford grading of superficial punctate keratitis in the artificial tear group showed a significant decrease at 1 month (mean = 0.84 vs. 1.45, $p=0.014$) and 2 months (mean = 0.38 vs. 1.24, $p=0.007$) (Table 1). For the grading of lid wiper epitheliopathy of upper eyelid or lower eyelid, there is no significant difference between the two groups (Table 2 & 3). Besides, there is no significant difference in the OSDI questionnaire, Tear film height, TBUT, NITBUT, conjunctival redness, and Oxford grading of conjunctival staining between the 2 groups during the 2 months follow up (Table 1).

Discussion

In this study within follow up period of 2 months, for the patients developed with new eye disease after receiving cataract extraction by phacoemulsification and intraocular lens

implantation, we revealed that treatment of cyclosporine 0.05% eye drop can significantly lower the grading of lid wiper epitheliopathy both in the upper eyelid and lower eyelid. Treatment of aqueous-based artificial tears also can significantly lower the grading of lid wiper epitheliopathy both in the upper eyelid and lower eyelid. Comparing the cyclosporine 0.05% eye drop and artificial tears, there was no difference in the treatment effect for the lid wiper epitheliopathy both in the upper eyelid and lower eyelid.

Dry eye disease is caused by ocular surface injury, ocular surface inflammation or abnormal tear quantity or hydrodynamics, which lead to loss of homeostasis of the tear film, resulting in a series of symptoms such as dryness, irritation and itching of the eyes. Surgeries on the eye can cause ocular surface injury. Therefore, traumatic surgeries such as cataract extraction by phacoemulsification and intraocular lens implantation may lead to dry eye. These kinds of dry eye often occurred after the surgery, and without such symptoms before the surgery. Based on many previous studies[4, 6, 14], the main reasons may be as follows: First, the anesthetic eye drops used before the surgery stimulate the surface of cornea and conjunctiva. The mucin layer of lacrimal film was therefore damaged to varying degrees. Second, the injury of corneal nerve fibers caused by surgical incision can reduce the corneal sensitivity, which made the tear reflex reduced, and make the tear film on the ocular surface unevenly distributed and further reduce its stability. Third, the ocular surface epithelial cells were

directly damaged by mechanical operation and ultrasonic energy during the surgery.

As a sign of dry eye disease, lid wiper epitheliopathy is a clinical condition characterized by alteration of the epithelium of the portion of the marginal conjunctiva of the eyelid that wipes the ocular surface, which can be diagnosed by staining with lissamine green dyes[8, 15]. It was found in dry eye patients or soft contact lens wearers[16]. The primary cause of lid wiper epitheliopathy is thought to be increased friction between the lid wiper and ocular surface or anterior contact lens surface due to inadequate lubrication, which could be caused by dry eye disease and may be exacerbated by factors such as abnormal blinking patterns, poor contact lens surface lubricity in contact lens wearers and adverse environmental influences, which resulting in inflammation of the ocular surface[17]. Therefore, if we can give adequate lubrication, lid wiper epitheliopathy can be treated[18-20]. Decreasing the inflammation of the ocular surface may also treat lid wiper epitheliopathy[21].

Artificial tears can treat the lid wiper epitheliopathy maybe due to its effect of adequate lubrication, which reduce the friction between the lid wiper and ocular surface. El-Rayess et al showed that an oil-in-water emulsion lubricant were effective for the treatment of lid wiper epitheliopathy[19]. Guthrie et al also show that lipid-based lubricant can reduce the sign of lid wiper epitheliopathy in symptomatic contact lens wearers[18]. Jennifer et al showed that both

lipid and non-lipid-based artificial tear supplements can decrease lid wiper epitheliopathy grades in the superior eyelid[20]. In Jennifer's study, they used SYSTANE® ULTRA Lubricant Eye Drops as aqueous-based and non-lipid-based artificial tear supplements, which was the same artificial tears as we used in our study. The SYSTANE® ULTRA contains aminomethylpropanol, boric acid, hydroxypropyl guar, POLYQUAD (polyquaternium-1) 0.001% preservative, polyethylene glycol 400, potassium chloride, propylene glycol, purified water, sodium chloride, and sorbitol. The combined effect of these gradients can provide good effect of adequate lubrication[22, 23]. Compared to the Jennifer's study which only showed aqueous-based artificial tear decrease lid wiper epitheliopathy grades in the upper eyelid, our study further showed that aqueous-based artificial tear can treat lid wiper epitheliopathy in the both upper and lower eyelids.

Cyclosporine 0.05% eye drop can treat the lid wiper epitheliopathy maybe due to its effect of anti-inflammatory effects, which reduces the inflammation of the ocular surface. To our knowledge, before our study, there is no study directly showing the treatment effect of lid wiper epitheliopathy by using cyclosporine 0.05% eye drop. However, there were some studies proved that the similar anti-inflammatory eye drop could have the treatment effect of lid wiper epitheliopathy, such as corticosteroid eyedrop or topical rebamipide. El-Rayess et al showed that corticosteroid eyedrop can have equal effectiveness in treatment of lid wiper

epitheliopathy compared with oil-in-water emulsion eye drop[19]. Itakura et al showed that topical rebamipide was effective for corneal and conjunctival disorders, including lid wiper epitheliopathy[21]. Our study not only showed that cyclosporine 0.05% eye drop was effective in treating the lid wiper epitheliopathy, but also showed that the treatment effect was equal to aqueous-based artificial tear supplements.

For the general dry eye disease related parameter, besides Oxford grading of superficial punctate keratitis in the artificial tear group showed a significant decrease at 1 month and 2 months compared to the cyclosporine group, there is no significant difference in the OSDI questionnaire, Tear film height, TBUT, NITBUT, conjunctival redness, Oxford grading of superficial punctate keratitis, and Oxford grading of conjunctival staining between the 3 groups during the 2 months follow up. However, for the dry eye disease, cyclosporine group and artificial tear group should have more treatment effect compared with control group. But the general dry eye disease related parameter in our study did not show this result. The following two reasons may cause this situation. First, antibiotic eye drops and steroid eye drops in the control group may have some lubricant effects which could treat the dry eye disease. Second, it may be due to the sample size in our study was too small. However, the lid wiper epitheliopathy may be a more sensitive parameter of dry eye disease, which still can show the significant different treatment effect between the groups even when the sample size

was small. Larger scale prospective study in the future is needed for further investigation.

There is some limitation in our studies. First, the follow up time was short, and the sample size was small. More researches with larger sample size and longer follow up period were needed for further investigation. Second, these included patients were newly diagnosed with dry eye disease 1 week after phacoemulsification surgery, but some of them maybe had dry eye disease before the surgery. However, they did not tell the ophthalmologist about the dry eye symptoms before the surgery, so the dry eye diseases were misdiagnosed. Third, on this retrospective study, we did not have the measurement data of dry eye related parameters before the surgery, which made us could not find out the dry eye disease and lid wiper epitheliopathy which was underdiagnosed before the surgery.

Conclusion

Our findings suggest that cyclosporine 0.05% eye drop or aqueous-based artificial tears both can be an effective treatment for the lid wiper epitheliopathy of dry eye disease after phacoemulsification surgery. Considering the limited time and the small sample size in our study, more researches with longer follow up time and larger sample size are warranted for further investigation.

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