

# Effect of Temporary Punctal Plugs Implanted at the End of Biaxial Phacoemulsification in Preventing Dry Eye Disease

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## Research Article

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# Abstract

**Objective:** to evaluate the effectiveness of temporary punctal plugs implanted at the end of biaxial phacoemulsification in preventing dry eye disease. Setting: Department of Ophthalmology, Faculty of Medicine, Damascus University; Syrian Private University; Al Andalus University for medical sciences.

**Materials and method:** Prospective randomized controlled study, comprised 30 eyes of 30 patients with age related cataract, divided into two groups, in the first-study group( 17eyes) temporary punctal plugs were implanted through the upper punctum after biaxial phaco, while in the second- control group(13 eyes) biaxial phaco was performed without punctal plugs. Results were studied one day, one week and one month after surgery, outcome measures were uncorrected visual acuity UCVA, meniscus height, tear film break up time (FTBUT), and patient's satisfaction. All surgeries were performed using direct chop technique.

**Results:** the difference in UCVA between the two groups was statistically evident at all follow up intervals (P= 0.002, 0.014, 0.006 respectively). Meniscus height was better in the first group compared to the second, the difference was statistically evident one day and one week after surgery( P= 0.02, 0.03 respectively), while the difference was not evident one month after surgery. FTBUT values were better in the first group, but the difference was not statistically evident one day and one week after surgery (P=0.60- 0.21 respectively), while it became statistically evident one month after surgery (P= 0.02). No statistically evident difference was found between the two groups regarding patient's satisfaction.

**Conclusion:** Temporary punctal plugs implanted at the end of biaxial phacoemulsification were effective in preventing dry eye disease.

## Introduction

Dry eye disease after phacoemulsification is an important complication, it does not only bother patients and affect surgery's visual outcome, but may lead to serious complications as conjunctivitis, blepharitis, recurrent corneal erosions, ulcers, and a disappointed patient despite improved visual acuity and excellent surgery. Dry eye disease is one of the most misdiagnosed complications after cataract surgery. Doctors relate early patient's complaints to surgical trauma, while it is often caused by dry eye disease, reducing chances for treatment. Many studies have shown that dry eye disease appeared after phacoemulsification and remained till the end of the third month [1],[2], when tear indices came back to near preoperative values. While the study of Iglesias E. et al. [3] showed an increased risk of any and severe DE-like symptoms 6 months after cataract surgery (odds ratio (OR) 4.4, 95% confidence interval). Researchers related this to many factors including damaged corneal sensory nerve endings, as it is supposed that they play a role not only in lacrimal glands secretion, but in Meibomian glands secretion, blinking reflex and corneal epithelium metabolism as well. It is believed that all these factors have a role in dry eye disease, because induced dryness increases tear film osmolarity, resulting in chronic dry eye disease and great difficulties in treatment due to combined blepharitis and eye surface inflammation [4].

Accordingly, measures undertaken to prevent the incidence of dry eye disease after phacoemulsification are of major importance. We chose to benefit from temporary punctal plugs, because they melt 60-180 days after implantation, which is about the same period needed for the corneal nerve endings to regenerate and tear film function indices (FTBUT, SHIRMER T) to return to normal or near normal preoperative values [1], [2], [3]. To our knowledge, we were the first to propose the use of temporary punctal plugs during phaco surgery to prevent dry eye disease, and was presented by us in the ESCRS congress, Vienna 2011 ;( Sameh Issa, L. Nehmeh, L. Youssef, R. Moustafa, M.Wahba, Punctal plugs applied at the end of phaco surgery for preventing dry eye syndrome). Our work was reported in Ocular Surgery News-2012 (Ocular Surgery News Europe Edition Feb 1, 2012 | Sameh Issa. Punctal plugs, cooling minimize dry eye, thermal trauma after phacoemulsification). Punctal plugs use was limited to treatment of dry eye disease before surgery in patients diagnosed with dry eye disease [1], or after surgery as a treatment of dry eye disease or a drug delivery system. Studies about prevention of dry eye disease after phacoemulsification were confined to the use of artificial tears[4],[5], or risk factors predisposing to dry eye disease after phacoemulsification [6], [7],[8] or treating the disease after it has already started using Cyclosporine 0.05% [9], or the irreversible destructive cauterization of the punctum. Artificial tears cannot be compared with patient's own tear film preserved by temporary punctal plugs. We have not found any publication about temporary punctal plugs implantation as an intraoperative measure for the prevention of dry eye disease during phacoemulsification. The principle that says, "Prevention is better than treatment" is true especially in this, difficult to treat, disease.

## Materials And Methods

This was a prospective randomized controlled study, conducted between 2011 and 2021. Included were 30 eyes of 30 patients with age related cataract, prepared for phacoemulsification. Patients were divided into two groups; in the first-study group, (17eyes) temporary punctal plugs were implanted through the upper punctum after biaxial phaco. In the second (control) group, (13 eyes) biaxial phacoemulsification was performed without punctal plugs. Patients with age related cataract prepared for phacoemulsification were included. Exclusion criteria were patients with dry eye disease, any lacrimal system or other ocular pathologies. Patients with previous trauma, previous ocular surgery or complicated phaco surgery were excluded. Patients under local or systemic treatment with drugs affecting lacrimal system or using artificial tears or contact lenses were excluded. Patients with respiratory or systemic infections were also excluded.

Same surgical technique was used in both groups. Tropicamide-phenylephrine hydrochloride 0.5%/0.5% was used three times over half an hour to dilate the pupil before the surgery. Oxybuprocaine HCL 0.4% was used as surface anesthesia. Instilled three times 15 minutes prior to surgery.

Biaxial phaco was performed through two 1.6 mm. clear corneal incisions, 90 degrees apart. Direct chop phacoemulsification was performed through temporal incision, which was enlarged to 3.2 mm. before implanting hydrophilic IOL through the temporal incision into the capsular bag. Temporary Punctal plug was implanted through the upper punctum at the end of surgery (Fig. 1). The same surgeon (Dr. Sameh

Issa) performed all surgeries. Postoperatively, patients received topical prednisolone acetate 1% 6x/day for duration of 1 month. In addition, topical levofloxacin 1.5% 6x/day for duration of 3 weeks.

Temporary punctal plugs Eaglevision-Duraplugs are made of E-Caprolactone-L- Lactide (copolymer PCL), 0.3-mm. diameter, 1.6-mm. length. They were chosen because they melt after 60- 80 days, which is approximately the same period needed for corneal nerve fibers to regenerate. It is known that punctal plugs may induce irritation or foreign body sensation in some cases, so that our study included estimation of patient's satisfaction by grading feeling of irritation into four grades determined by the patient, in addition to measuring best corrected visual acuity UCVA. Meniscus height was measured at the slit lamp with a narrow straight vertical beam set at 0.2 or 1 mm. The tear meniscus height was measured from the lid margin to the top of the meniscus along the globe surface. The 1 mm beam was used first. In cases where the tear meniscus was less than half of the height of the 1 mm beam, the 0.2 mm beam was used. Fluorescein tear break-up time (FTBUT) was determined using a fluorescein impregnated paper strip. The fluorescein strip was moistened with one drop of normal saline and applied onto the inferior fornix, avoiding contact with the ocular surface. The patient was instructed to close eyes, without squeezing for 10 seconds, and then the patient was asked to blink twice before staring ahead without blinking. The interval in seconds between the last blink and the appearance of the first fluorescein progressive discontinuity at the center of the cornea was observed through a slit lamp with diffuse illumination and 10-x magnification using cobalt blue light. Time was measured using a digital timer. Three consecutive FTBUTs were measured and the average was used for analysis of data.

Results were followed up one day, one week and one month after surgery. Statistical analysis performed using SPSS 25; T-test results were regarded statistically significant when P value was equal or less than 0.05. We calculated effect size and power using G power hoc. Statistical metanalysis. Informed consent was obtained from all patients after they received detailed explanation. The Institutional Ethics Committee approved the study (DAMASCUS UNIVERSITY BIO-ETHICS COMMITTEE 471,2021/5/12-2021/9/19-1).

## Results

Patients distribution according to age was similar in both first and second groups ( $67.4 \pm 3$ ,  $71.7 \pm 10.9$ ) respectively (tab.1), there was no statistically evident difference between the two groups ( $P=0.22$ ). The difference was not significant regarding UCVA between the two groups one day before surgery ( $P=0.42$ ). The difference became significant one day, one week and one month after surgery regarding UCVA ( $P=0.01$ ,  $0.01$ ,  $0.01$  respectively) (tab.2). Meniscus height study results showed higher values in in the first group compared to second (tab. 3), the difference was evident on the first day and first week after surgery, while it became insignificant one month after surgery ( $P=0.02$ ,  $0.03$ ,  $0.37$  respectively). Tear film break up time FTBUT showed statistically evident difference between the two groups one month after surgery ( $P=0.02$ ), where FTBUT value was 18.4 sec. in the first group compared to 10.0 sec. in the second (tab. 4). We calculated effect size and power using G power hoc. statistical metanalysis. Effect size was 0.98, power was 0.73, but the difference was not evident one day and one week after surgery, where P value

was 0.21, 0.53 respectively. Patient's satisfaction was not different between the two groups in all follow up periods (P=0.42, 0.57, 0.84 respectively) (tab.5).

## Discussion

Clear corneal incisions used in phacoemulsification sever ophthalmic nerve endings, which are responsible for sensory innervation of the cornea. This trauma leads to decreased stimulation necessary for tear production, eventually resulting in dry eye disease. Other, not less important factors include topical anesthesia, preservatives in eye drops used during and after surgery, microscope light toxicity, frequent irrigation, older age group, prolonged phaco time and many other factors [1]. Dry eye disease is difficult to treat, with time becomes chronic and complicated, while measures undertaken to prevent its incidence may result in far better results. We chose to benefit from temporary punctal plugs as they resolve within 60-80 days after implantation, which is the time needed for corneal nerve fibers to regenerate [1], [2]. The upper punctum is responsible for 30 % of tear film drainage, after being occluded the inferior punctum compensates, resulting in 20% retention of tear film, which is about the same amount of average decrease in FTBUT one week after surgery (22.60%) according to control group in our study (tab. 4).

Implanting temporary punctal plugs DURAPLUGS – EAGELVISION resulted in an important increase in visual acuity in the first (study) group, compared to second (control) group in all follow up periods ( one day, one week, one month ) after surgery ( tab.2). These results might be explained by the role of punctal plugs in tear film function improvement and prevention of dry eye disease. Meniscus height improvement in the first group compared to second was evident one day and one week after surgery, while the difference was not evident one month after surgery (tab. 3). Similar results were obtained regarding FTBUT(tab. 4), which became better in the first group compared to the second one week and one month after surgery, but the difference was statistically evident only one month after surgery. Meniscus height results might be due to reflex tearing during the first week caused by surgical trauma, which augmented tear retention effect of the punctal plugs, thus increasing meniscus height difference between the two groups, while FTBUT difference between the two groups became evident only one month post- surgery after recession of reflex tearing. Occluding only one punctum (upper), led to a favorable moderate balanced increase in tear film retention, seen one month after surgery in eyes implanted with temporary punctal plugs. We presume that punctal plugs compensated decreased lacrimal film function seen in eyes without implants.

Patients treated with temporary punctal plugs might experience foreign body sensation or irritation, so we investigated patient's satisfaction, as to whether they had foreign body sensation or irritation. Results showed that the difference was not evident between the two groups, which might be related to surgical trauma that super imposed the suspected probable irritating effect of punctal plugs. We have not encountered any case of canaliculitis or retention of lacrimal plugs or any other complications in the lacrimal system even in patients seen during 10 years after surgery. This might be due to exclusion of

patients with any eye or lacrimal system infections or pathologies, in addition to implanting punctal plugs in the sterile operating room environment.

Post-phaco dry eye disease is a chronic, difficult to treat complication, often leads up to disappointing results [1]. We suggest a new approach for dealing with it, using preventive measures, as prevention is better than treatment.

## Conclusion

Temporary punctal plugs implanted at the end of biaxial phacoemulsification were effective in preventing dry eye disease, better visual and lacrimal function results were achieved with them. Further studies are needed to investigate effectiveness and safety of temporary punctal plugs in phacoemulsification and other ophthalmic surgeries.

## Declarations

**Funding:** No funding sources

**Conflicts of interest/Competing interests:** On behalf of all authors, the corresponding author states that there is no conflict of interest.

**Ethics approval:** The study was approved by DAMASCUS UNIVERSITY BIO-ETHICS COMMITTEE 471,2021/5/12- 2021/9/19-1.

**Consent to participate:** Available

**Consent for publication:** Available

**Availability of data and material (data transparency):** Available

**Code availability (software application or custom code):** Not applicable.

**Authors' contributions:** The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Tables

Table 1  
Patient's distribution according to age in the first  
and second groups

<b>Distribution according to age</b>		
	Average age	Std. deviation
First group	67.4	9.256658
Second group	71.7	10.81749
P value	0.22	

Table 2  
patient's distribution according to UCVA in the first and second groups

<b>UCVA</b>				
	Before surgery	One day after surgery	One week after surgery	One month after surgery
First group	0.16	0.34	0.45	0.49
Second group	0.27	0.27	0.34	0.39
P value	0.42	0.01	0.01	0.01

Table 3  
patient's distribution according to meniscus height in the first and second groups

<b>Meniscus height</b>			
	One day after surgery	One week after surgery	One month after surgery
First group	0.57	0.64	0.60
Std. deviation	0.38322	0.471852	0.309878
Second group	0.26	0.30	0.49
Std. deviation	0.194079	0.194235	0.243869
value P	0.02	0.03	0.37

Table 4  
patient's distribution according FTBUT in the first and second groups

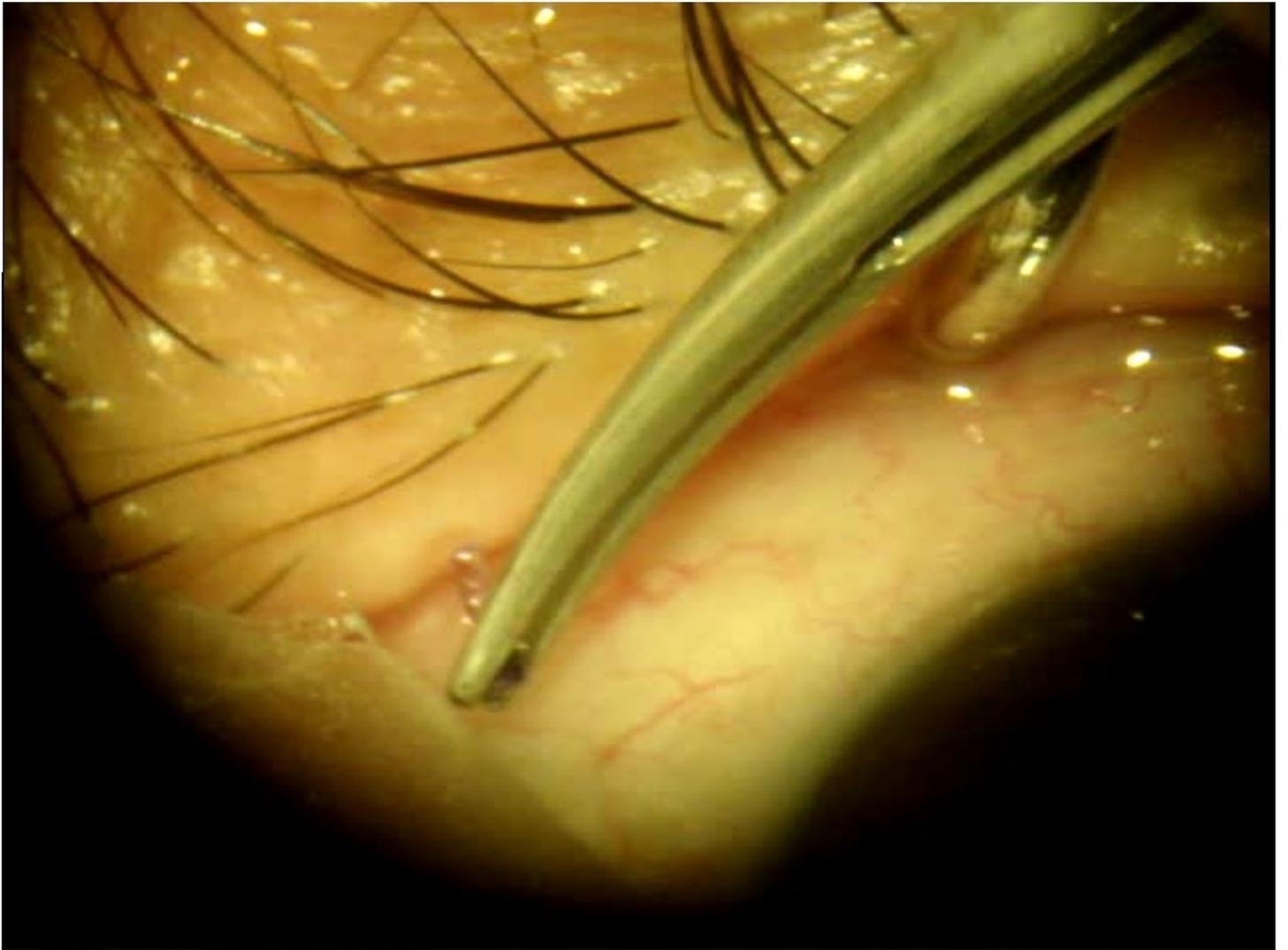
<b>FTBUT</b>	<b>Before surgery</b>	<b>One day after surgery</b>	<b>One week after surgery</b>	<b>One month after surgery</b>
First group	9.26	7.94	12.63	18.38
Std. deviation	6.287517	3.685753	8.70255	9.538573
Second group	11.15	9.64	8.64	10
Std. deviation	6.491612	10.0923	6.03776	7.334848
P value	0.44	0.53	0.21	0.02

Table 5

Distribution according to patient's satisfaction in the first and second groups

<b>Patient's satisfaction</b>			
	One day after surgery	One week after surgery	One month after surgery
First group	0.71	0.72	0.56
Std. deviation	0.665512	0.789952	0.609175
Second group	0.92	0.55	0.5
Std. deviation	0.668558	0.687552	1
P value	0.42	0.57	0.84

## Figures



**Figure 1**

Temporary punctal plugs insertion technique