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Assessment of Ocular Surface Dryness in Type 2 Diabetes Mellitus Patients

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) is a major public health issue related to ocular complications, including dry eye disease because of impaired tear film function and stability, particularly in cases with non-proliferative diabetic retinopathy (NPDR).

Aim: To improve the quality of life and vision of controlled type 2 diabetes mellitus cases with non-proliferative diabetic retinopathy and prevent the complications of ocular dryness cases.

Patients and methods: This cross-sectional, case-control research has been performed at the outpatient clinic, Ophthalmology Department, Suez Canal University Hospital, Ismailia, Egypt, from September 2022 to September 2023. In this study, we included 104 eyes from 52 participants and then divided them into two groups: Group A included 26 participants diagnosed with controlled T2DM with non-proliferative diabetic retinopathy. Group B included 26 healthy controls. **Results:** Insignificant variances have been observed in age or gender among groups. HbA1c was significantly higher in Group A (6.55±0.54%) vs. Group B (5.25±0.26%; (p-value under 0.001). But they showed no difference. Tear Meniscus Height(TMH). was lower in Group A's left eye (0.22±0.11 millimeters versus 0.3±0.17 millimeters; p-value equal 0.037). Schirmer tests (with/without anesthesia) were significantly lower in Group A (p-value under 0.05). FCT was delayed in Group A, especially in the left eye (p=0.012).

Conclusion: Controlled T2DM patients with NPDR exhibit significant ocular surface dryness, evidenced by reduced tear production and delayed clearance, highlighting the need for early screening and management to prevent complications.

Keywords: Type 2 diabetes mellitus, Ocular surface dryness, Tear film, Schirmer test.

INTRODUCTION

T2DM (non-insulin-dependent) represents one of the largest public health problems globally, particularly among developing nations, because of alterations to diet preferences and lifestyle in current years [1]. It is a collection of metabolic disorders defined by elevated blood glucose concentrations due to relative deficiency of insulin and insulin resistance [2].

Many studies pointed out that diabetes mellitus greatly affect the tear film stability and function. Furthermore, the reduced function of tear film was more severe in cases with proliferative diabetic retinopathy (PDR) than in cases with NPDR [3].

The tear film lubricates and covers the cornea, palpebral conjunctiva, and bulbar conjunctiva. It protects the ocular surface from mechanical forces when blinking and preserves ocular surface health. The tear film comprises 3 layers: the inner mucous layer, the outer lipid layer, and the middle aqueous layer [4]. The International Dry Eye Workshop 2017 identified diabetes mellitus as a risk factor for aqueous-deficient dry eye [5]. In diabetes mellitus, hyperglycemia induces microvascular damage to the lacrimal gland, accompanied by diminished lacrimal innervation from autonomic neuropathy, diminished trophic support to lacrimal tissue, impaired reflex tearing because of compromised corneal sensitivity, and diminished corneal epithelial integrity [6].

The Schirmer test is an effective evaluation of aqueous tear production. The assessment evaluates the wetting of a specialized filter paper measuring five millimeters in width and thirty-five millimeters in length [7]. Schirmer 1 is conducted without topical anesthetic and assesses maximum reflex and basic tear production. Schirmer 2 is conducted with topical anesthetic and assesses basic tear production [8].

The fluorescein clearance test is a dynamic test to assess tear secretion and drainage. It can be performed through adding five microliters of fluorescein on the ocular surface and determining the residual dye in a Schirmer strip on the lower lateral lid margin [9].

Our study aimed to enhance the quality of life and vision of controlled T2DM patients with NPDR and prevent the complications of ocular surface dryness.

PATIENTS AND METHODS

This cross-sectional, case-control research has been carried out at the outpatient clinic, Ophthalmology Department, Suez Canal University Hospital, Ismailia, Egypt, from September 2022 to September 2023. The research was conducted on controlled type 2 diabetes mellitus cases with NPDR and healthy non-diabetic matching controls. In this study, we included 104 eyes from 52 participants and then divided them into two groups: Group A included 26 participants diagnosed with controlled type 2 diabetes mellitus with NPDR. Group B included 26 healthy, non-diabetic age- and gender-matching controls.

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Inclusion criteria: Both genders were included, patients aged over 40 years old were included, and the study included patients with a history of controlled diabetes mellitus type 2 with non-proliferative diabetic retinopathy.

Exclusion criteria: Patients with chronic ocular diseases, vernal keratoconjunctivitis, or eyelid pathology, e.g., entropion, ectropion, keratoconus, or corneal ectatic disorders; ocular trauma or previous ocular surgery; contact lens wearing or smoking; utilization of topical drugs or eye drops that contain preservatives; systemic diseases, e.g., vitamin A deficiency, thyroid disorders, systemic autoimmune diseases, e.g., SLE; and pregnancy, lactation, or use of oral contraceptive pills.

The healthy non-diabetic controls who were age- and gender-matched with cases were included in our study, and we excluded healthy non-diabetic controls with one of the same exclusion criteria as cases.

Type of sample: Convenience sample.

Sample size: The required sample size has been determined depending on the following equation [10]**:**

$$n = 2\left[\frac{\left(Z_{\alpha/2} + Z_{\beta}\right) * \sigma}{\mu_1 - \mu_2}\right]^2$$

n= is the sample size needed in each group.

$Z_{\alpha/2}$ = 1.96 (the critical value that divides the central ninety-five percent of the Z distribution from the five percent in the tail). = 0.84 (the critical value that separates the lower twenty percent of the Z distribution from the upper eighty percent). σ = the estimate of the standard deviation of the tear breakup time test (TBUT) in control eyes (3.48). µ1= mean (TBUT) in control eyes (7.71). µ2 = mean (TBUT) in diabetic eyes (5.0) [11]. Thus, the calculated sample size equaled 26 eyes per group, and by adding a 10% probability of dropout, the required sample size equals at least 29 eyes per group and 58 in both groups. We examined 75 patients, and 23 were excluded (14 didn't meet our inclusion criteria, and nine declined to participate in our study).

PATIENTS AND METHODS

All patients were subjected to the following:

Complete history taking: Personal history, history of any ocular diseases, and presence of systemic illnesses; ocular examination, including external examination, visual acuity assessment, measurement of refractive error, slit lamp biomicroscopic examination, intraocular pressure measurement, fundus examination, and laboratory investigation, including the glycosylated hemoglobin (HbA1c) to estimate the control of diabetes mellitus in the last 3 months and to rule out diabetes mellitus in healthy, non-diabetic matching controls.

Procedure

Preparation of the patient: The nature and purpose of the procedure were clarified to the case, and informed consent has been gathered. The case was told that the procedure was painless and was completed in a matter of minutes.

Tear meniscometry: The inferior tear meniscus has been examined at the lower corneo-lid junction with a slit lamp, and measurements from both eyes were included for analysis. All cases have been directed to refrain from using topical eye drops for a minimum of two hours prior to testing to eliminate the effect of drugs on tear film. Cases have been asked to look straight ahead. Participants have been directed to blink, and measurements have been recorded immediately post-blink to mitigate the effects of delayed blinking. The height of the tear meniscus has been determined. All measurements have been obtained from the inferior tear meniscus due to reduced visibility and diminished retention of the top tear film meniscus caused by the presence of eyelashes **(Figure 1A).**

Tear film break-up time: Fluorescein 2% or a fluorescein strip moistened using non-preserved saline has been applied to the lower fornix. The case has been instructed to blink multiple times, and the tear film has been assessed at the slit lamp with a broad beam utilizing a cobalt blue filter. Following a period, dark spots or lines manifest on the fluorescein-stained film. A break-up time (BUT) of less ten seconds was indicative of ocular surface dryness **(Figure 1 B).**

Schirmer test: Excess tears were gently dried, and the filter paper was folded five millimeters from one end and positioned at the junction of the center and outer 3rd of the lower eyelid, ensuring no contact with the cornea or eyelashes. The case was instructed to maintain his eyes gently closed. Following five minutes, the filter paper has been removed and the extent of wetness from the fold was quantified. Wetting of less than ten millimeters following five minutes without anesthesia, or less than six millimeters with anesthesia, was deemed abnormal **(Figure 1 C).**

Fluorescein clearance test: Five microliters of fluorescein were applied to the ocular surface, and the remaining dye on a Schirmer strip was positioned at the lower lateral eyelid margin at certain periods. The wetting of the strip and the fading of the dye have been assessed at 10-minute periods. A value of three millimeters or more during the initial ten-minute period was considered as the standard for normal. If the dye was undetected at the 20-minute mark, the clearing was deemed typical. Prolonged clearing was noted in ocular surface dryness **(Figure 1 D, E).**

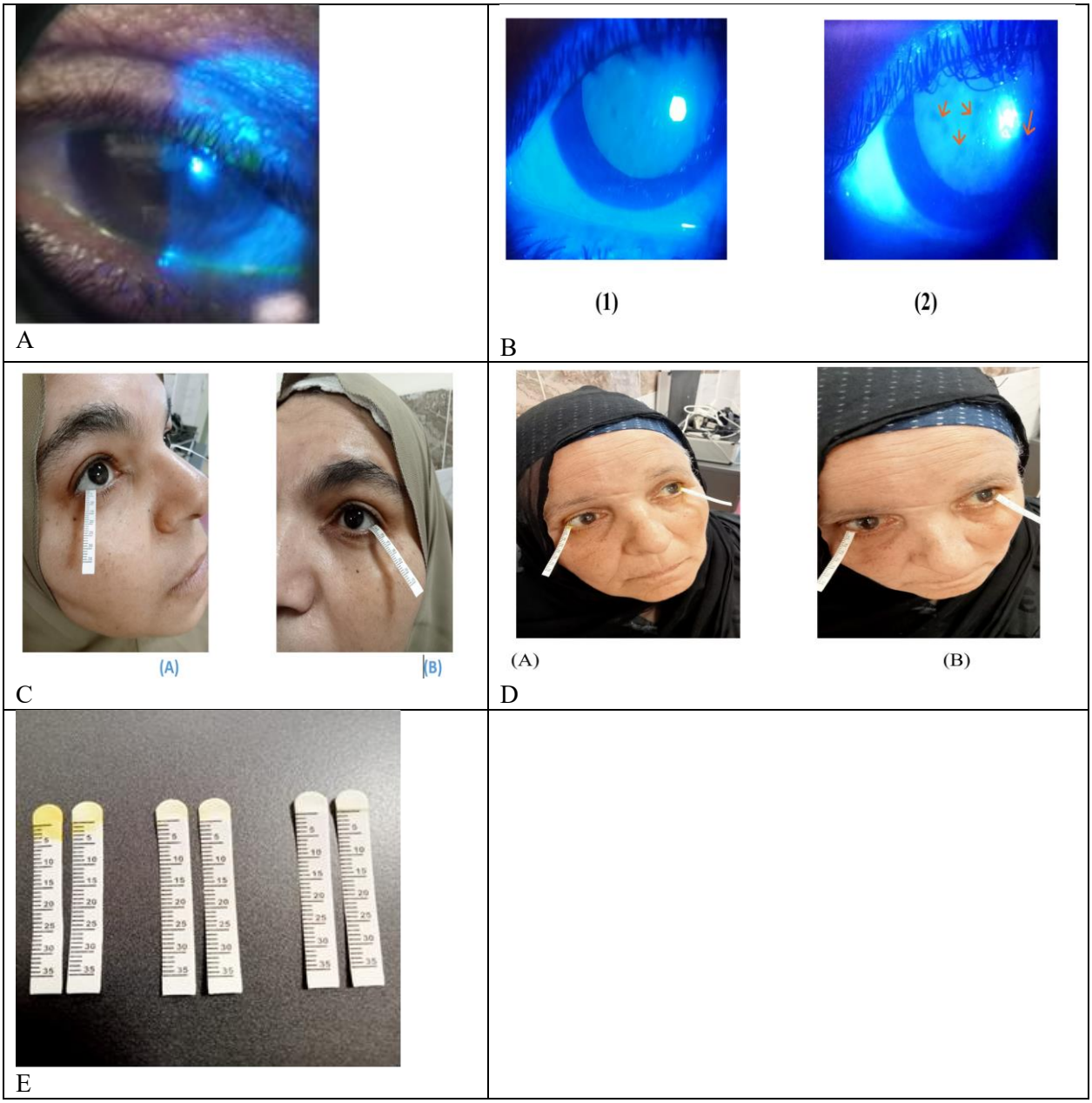

Figure 1: A: Tear meniscus height by slit lamp in a patient with type 2 diabetes mellitus. B: Tear break-up time. (1) Tear film stained by fluorescein, (2) Formation of dark spots. C: Schirmer test in a patient with T2DM. (CA) The Schirmer strip wetting of the right eye is 20 mm. (CB) The Schirmer strip wetting of the left eye is ten millimeters. D: Fluorescein clearance test (FCT) in a case with T2DM. (DA) FCT at 5-minute intervals shows Schirmer strip wetting of three millimeters of the right eye and 2 mm of the left eye. (DB) FCT at 15-minute intervals shows clearance of fluorescein dye from the ocular surface. E: Fluorescein clearance test in the same patient at 5, 10, and 15-minute intervals.

Outcome measures: The tear meniscus height (TMH) has been assessed via the vertical linear distance connecting the top corneo-meniscus junction to the lower eyelid-meniscus junction using a measurement tool on a slit lamp. Tear film break-up time is the duration between the last blink and the appearance of the first dry spot on the cornea. The degree of wetness of the Schirmer strip without anesthesia (Schirmer 1) and with anesthesia (Schirmer 2) following 5-minute durations were calculated. The extent of soaking of the Schirmer strip and the duration until the fluorescein vanishes from the ocular surface at predetermined intervals were calculated.

Ethical considerations

Approval from the Research Ethics Committee of the Faculty of Medicine, Suez Canal University has been obtained before starting the fieldwork. Informed written consents have been gathered from all participants that contained the following: The goal, procedures, and duration of the research, which were clarified simply. Participants had the right to refuse to participate in the research. The Helsinki Declaration was followed throughout the study's conduct.

Statistical analysis

The information has been fed into the computer and analyzed utilizing IBM SPSS software version 20.0 (Armonk, NY: IBM Corp). The qualitative information has been represented by percents and numbers. The Kolmogorov-Smirnov test has been utilized to assess the normality of the distribution. The quantitative information was characterized by range (maximum and minimum), mean, and standard deviation (SD). The significance of the acquired findings has been assessed at the five percent level.Chi-square test: for categorical variables, to compare between different groups. Student t-test: for normally distributed quantitative variables, to compare between two studied groups. Mann Whitney test: for abnormally distributed quantitative variables, to compare between two studied groups..

RESULTS

Table 1 illustrates that there was no statistically significant variance among both examined groups in terms of baseline data. There was high statistically significant variance has been observed among both examined groups with regard to HbA1C.

Table 1: Comparatives analysis among examined groups in terms of baseline data:

	Group A (number = 26)		**Group B (number = 26)**		**Test of significance**	**p**
Age						
Min-Max.	48 – 66		47 – 68		t= 0.403	0.689
Mean ± SD	55.69 ± 4.32		58.65 ± 6.92			
Gender	No.	%	No.	%		
Male	9	34.6	11	42.3	χ^2= 0.325	0.569
Female	17	65.4	15	57.7		
HbA1C (%)						
Min-Max.	5.6 – 7.3		4.9 – 5.6		t= 11.142	<0.001*
Mean ± SD	6.55 ± 0.54		5.25 ± 0.26			

Data are presented as frequency (%) unless otherwise mentioned, SD: Standard deviation.

Table 2 shows that there was no statistically significant variance among both examined groups regarding BUT.

Table 2: Comparatives analysis among examined groups with regard to BUT

BUT (sec)	**Group A (number = 26)**	**Group B (number = 26)**	**Test of significance**	**p**
Right eye				
Min-Max.	3 – 12	5 – 10	U=341.5	0.949
Mean ± SD	7.54 ± 3.13	7.5 ± 1.86		
Left eye				
Min-Max.	3 – 12	5 – 10	U=387	0.363
Mean ± SD	7.54 ± 3.13	8.19 ± 1.92		

BUT: Break-up time, SD: Standard deviation, U: Mann Whitney test.

Table 3 illustrates that there was no statistically significant variance has been observed among both examined groups with regard to TMH in the right, and left eye.

Table 3: Comparatives analysis among examined groups with regard to TMH

TMH (mm)	Group A (number = 26)	Group B (number = 26)	Test of significance	p
Right eye				
Min-Max.	0.1 – 0.6	0.1 – 0.6	U=299.5	0.466
Mean ± SD	0.31 ± 0.18	0.28 ± 0.19		
Left eye				
Min-Max.	0.1 – 0.5	0.1 – 0.6	U=431.5	0.07
Mean ± SD	0.22 ± 0.11	0.3 ± 0.17		

TMH: Tear Meniscus Height, SD: Standard deviation, U: Mann Whitney test.

Table 4 illustrates that there was no statistically significant variance among both examined groups with regard to the Schirmer test with anesthesia in right eye. A statistically significant variance has been observed among both examined groups with regard to the Schirmer test with anesthesia in left eye.

Table 4: Comparatives analysis among examined groups with regard to the Schirmer test with anesthesia

Schirmer test @ anesthesia (mm)	Group A (number = 26)	Group B (number = 26)	Test of significance	p
Right eye				
Min-Max.	3 – 10	2 – 20	U=410	0.186
Mean ± SD	6.92 ± 2.02	10.5 ± 6.71		
Left eye				
Min-Max.	4 – 9	4 – 16	U=563	<0.001*
Mean ± SD	6.92 ± 1.41	10.77 ± 3.35		

SD: Standard deviation, U: Mann Whitney test.

Table 5 illustrates that a statistically significant variance has been observed among both examined groups with regard to the Schirmer test without anesthesiain right, and left eye.

Table 5: Comparatives analysis among examined groups with regard to the Schirmer test without anesthesia

Schirmer test without anesthesia (mm)	Group A (number = 26)	Group B (number = 26)	Test of significance	p
Right eye				
Min-Max.	3 – 12	6 – 22	U=518.5	0.001*
Mean ± SD	7.42 ± 3.25	13.31 ± 6.39		
Left eye				
Min-Max.	4 – 14	6 – 19	U=552	<0.001*
Mean ± SD	7.85 ± 3.55	13.12 ± 4.17		

SD: Standard deviation, U: Mann Whitney test.

Table 6 illustrates that a statistically significant variance has been observed among both examined groups with regard to the fluorescein clearance test in left eye.

Table 6: Comparative analysis among examined groups with regard to the fluorescein clearance test

Fluorescein clearance test (min)	Group A (number = 26)		Group B (number = 26)		Test of significance	p
Right eye	No.	%	No.	%		
Cleared	9	34.6	13	50.0	χ^2= 1.261	0.262
Delayed after 20 min	17	65.4	13	50.0		
Right eye						
Min-Max.	15 – 25		15 – 25		U=267	0.171
Mean ± SD	20.08 ± 3.65		18.69 ± 3.59			
Left eye						
Cleared	9	34.6	18	69.2	χ^2= 6.240	0.012*
Delayed after 20 min	17	65.4	8	30.8		
Left eye						
Min-Max.	15 – 25		15 – 20		U=184.5	0.002*
Mean ± SD	20.08 ± 3.65		17.12 ± 2.52			

SD: Standard deviation, U: Mann Whitney test.

DISCUSSION

This study included (104) eyes of (52) studied subjects separated into 2 groups: Group (A) included 52 eyes of controlled diabetes mellitus type 2 patients with NPDR with mean age (55.69 ± 4.32) and group (B) included 52 eyes of healthy non-diabetic matching controls with mean age (58.65 ± 6.92). There was no statistically insignificant variance among the examined groups with regard to age and gender (p-value equal to 0.689). The research involved nine men (34.6%) and seventeen women (65.4%) in the controlled type 2 diabetes mellitus with non-proliferative diabetic retinopathy group and 11 males (42.3%) and 15 females (57.7%) in the healthy non-diabetic matching controls (p = 0.569). **Yoon *et al.*** [12] showed insignificant statistical variances in age or gender among the diabetes mellitus and normal control groups. Moreover, **De Cilla *et al*.** [13] illustrated that the mean age and gender weren't significantly different in the diabetes mellitus and control groups. The present research illustrated a high statistically significant variance among both groups with regard to the mean HbA1c; in the type 2 diabetes mellitus group, it was 6.55 (± 0.54 SD). The mean HbA1c in the controls was 5.25 (± 0.26 SD), ($p < 0.001$). In the current research, there was no statistically insignificant variance among both examined groups with regard to BUT. In the type 2 DM group, the mean BUT in both eyes was 7.54 ± 3.13 sec, and in the controls, the mean BUT in the right eye was 7.5 ± 1.86 sec (p = 0.949), and in the left eye, it was 8.19 ± 1.92 sec (p = 0.363). This can be owing to tear secretion deficiency, tear composition alterations, and meibomian gland dysfunction due to the old age of our participants and exposure to confounding factors like wind or hot climate [14]. In a previous study, the BUT was significantly lower in the type 2 DM group (5.0 ± 2.17 seconds) compared to in the control group (7.71 ± 3.48 seconds) [11].

Yoon *et al.* [12] showed that BUT was significantly shorter in the type 2 DM group (7.82 ± 2.12 seconds) in comparison with the control group (10.95 ± 1.56 seconds). Based on their findings, the authors hypothesized an aqueous deficiency in dry eyes among the subjects in their study.

In the current research, no statistically significant variance has been observed among both examined groups with regard to TMH in the left eye, as TMH in the type 2 DM group was 0.22 ± 0.11 millimeters and in the control group was 0.3 ± 0.17 millimeters (p-value equal to 0.07). In our research, there was no statistical variance among both groups with regard to TMH in the right eye, as TMH in the T2DM group (0.31 ± 0.18) and in the control group (0.28 ± 0.19) (p-value equal to 0.466). The variance among the two eyes may be owing to the severity of ocular surface dryness, decreased corneal sensitivity, and meibomian gland dysfunction in our participants.

Badr *et al.* [11] demonstrated that TMH was considerably reduced in the type 2 DM group (0.25 ± 0.10 millimeter) compared to the control group (0.40 ± 0.15 millimeter). These results may suggest a reduction in tear production and atypical tear composition, leading to superficial ocular lesions and subjective complaints in cases with T2DM.

In the current research, a statistically significant variance has been observed among both study groups in terms of the Schirmer test with anesthesia in left eye; the right eye in the type 2 DM group (6.92 ± 2.02 mm) and the control group (10.5 ± 6.71 mm) (p = 0.186), and the left eye in the T2DM group (6.92 ± 1.41 mm) and the control group (10.77 ± 3.35 mm) ($p < 0.001$).

Our research illustrated a statistically significant variance among both study groups in terms of the Schirmer test without anesthesia in both eyes. The right eye in the type 2 DM group was (7.42 ± 3.25 mm) and the control group (13.31 ± 6.39 mm) (p-value= 0.001), and

the left eye in the T2DM group was (7.85 ± 3.55 mm) and the control group (13.12 ± 4.17 mm) ($p < 0.001$).

Badr *et al.* [11] showed a highly significant decrease in the value of the Schirmer test with and without anesthesia. Their mean values in the type 2 DM group were (6.21 + 3.33 mm) and (8.96 + 3.80 mm), respectively, compared with (12.42 + 5.36 mm) and (14.73 + 5.97 mm), respectively, in the control group.

Yu *et al.* [15] showed a statistically significant variance between the type 2 diabetes mellitus group with NPDR or PDR and the control group. The percent of cases with a Schirmer I test less than five millimeters was 8.82% (3/34 eyes) in the NPDR group, 15% (6/40 eyes) in the PDR group, and only 2.78% (1/36 eyes) in the control group. In our study, there was a statistically significant variance among both examined groups with regard to the fluorescein clearance test. **Barton *et al.* [16]** indicated that a reduction in tear clearance correlates with an elevation in the concentrations of the pro-inflammatory cytokine interleukin-1α (IL-1α) in tear fluid. Results indicate that delayed tear clearing results in chronic ocular surface inflammation, which heightens the sensitivity of the nerves associated with irritation feelings.

CONCLUSION

Cases with T2DM had significantly lower tear meniscus height than healthy controls. Patients with type 2 diabetes mellitus had significantly delayed fluorescein clearance tests, and there was a statistically significant variance in the Schirmer test compared with healthy controls. Cases with type 2 diabetes mellitus are more likely to experience a variety of alterations to the ocular surface. Therefore, early diagnosis and effective management of ocular surface dryness are important to prevent serious ocular complications.

RECOMMENDATIONS

Cases with type 2 diabetes mellitus should be counseled about the ocular surface dryness and examined regularly. Ocular surface dryness is a serious disease that should be treated promptly.

DECLARATIONS

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