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A Comparative Study of Dry Eye Disease in Diabetics and Non-Diabetic Population at National Eye Centre, Kaduna

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Abstract

Background: Dry eye is a multifactorial pathology caused by a progressive dysfunction of the lacrimal and Meibomian glands which often leads to reduced aqueous tear production and increased tear evaporation. All these disorders are associated with ocular discomfort such as watering and redness of the eyes resulting from irritation of the ocular surface particularly the cornea. Dry eye is identified as one of the complications of diabetes. Diabetes mellitus is a systemic risk factor for dry eye disease. ***Objective:*** To determine the prevalence of dry eye disease in diabetics compared to non-diabetics at National Eye Centre Kaduna. ***Methods:*** This study is a comparative cross-sectional study. The study population comprised of types 1 and 2 diabetic patients who are 18years and above attending National Eye Centre Kaduna and non-diabetics age and sex matched subjects. The ocular surface disease index (OSDI) questionnaire was used to subjectively identify subjects with DED. All participants underwent Schirmer's test and a Tear break-up time to objectively make a diagnosis of DED. ***Results:*** A total of 200 participants were assessed in this study. Their ages ranged from 32-74 years (mean 53.2±9.7). Respondents within the age range of 56-65 years had higher frequency of dry eye disease (DED) 43.5%. More females had DED 61.35%. Those with secondary educational status had the highest frequency of DED 40.3%. Diabetic subjects within the age range of 56-65 years old had higher frequency of DED 88.6%. Females have higher rates of DED 80.8%, as against 61.8% among males' non-Diabetic subjects. Subjects with secondary educational status had the highest frequency of DED 87.5% in diabetic subjects while 71% in non-diabetic. The housewives had the highest percentage of DED 89.5% in diabetic subjects while 95% in non-diabetic subjects. The result further revealed the prevalence of 76% among diabetic patients while prevalence of 48% for non-diabetic patients. A significant positive correlation between subjective assessment and objective clinical tests. ***Conclusion:*** Patients with diabetes have a higher prevalence of DED than non-diabetic population in National Eye Centre, Kaduna. Women were found to have a higher prevalence. There was a significant association between DED and duration diabetes. There is a correlation between objective clinical tests and subjective assessment in both diabetic and non-diabetic population.

Keywords: Dry eye, dysfunction, lacrimal and Meibomian glands, Diabetes mellitus.

INTRODUCTION

Dry eye disease is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface [1]. Several population-based studies have reported the prevalence of dry eye disease (DED) ranging from 5% to 35%. This wide disparity has been attributed to racial differences in the epidemiology of DED [2]. Diabetes Mellitus is one of the leading causes of morbidity and mortality worldwide. Globally, 425million people were diagnosed with diabetes in 2017, and this figure is expected to exceed 629million by 2045 [3] Diabetes mellitus has been identified as one of the systemic risk factors for DED. Both DED and DM increases the risk of corneal infections and scarring, in advanced disease, corneal perforation and irreversible tissue damages [4]. The reported prevalence of DED in diabetics is 15-33% in those over 65years of age and increases with age [5].

It is important to rule out dry eye status in diabetics whether the patient is symptomatic or not. This is because some patients can be asymptomatic

especially during the early stages of dry eye due to reduced corneal sensitivity, hence the need to specifically look for objective signs of dry eye [6]. Majority of the studies done on dry eye in diabetics are in developed countries such as that done by Yazdani-Ibn et al in Glasgow, UK and amongst the elderly populations [3]. Available studies done in Nigeria are in the South West which may not be fully reflective of the picture in the entire country [7] However, there is no published data to demonstrate prevalence of dry eye amongst diabetics in the Northern part of the country.

The purpose of this study was to determine the prevalence of dry eye disease in diabetics compared to non-diabetics at National Eye Centre Kaduna.

METHODOLOGY

This study was a comparative cross-sectional study involving diabetic patients aged 18years and above attending vitreoretinal clinic of the National Eye Centre, Kaduna and age/sex matched non-diabetics who were selected in the General outpatient department based on expected age distribution and sociodemographic matching of the cases. It was conducted between 1st December 2020 to 28th February 2021. A total of 200 participants were involved in the study. Ethical approval was given by Research and Ethics committee of National Eye Centre Kaduna. Simple random sampling technique by balloting was used to select the participants.

A general health talk was given at the vitreoretina clinic on each clinic day before clinic commenced. Clinic was twice a week (Mondays and Wednesdays) and about 12-15 participants were seen on each clinic day. The comparison group was recruited at the General out patient department (GOPD) of the hospital on other days of the week. Adults who met the criteria and consented were recruited. The Ocular surface disease index questionnaire was administered to all participants and those who could not read were assisted. Visual acuity, Anterior segment examination was done on the slit lamp including the tear breakup time (TBUT) and schirmers test were all done. Pupils were dilated and the posterior segment examination was done. A structured interviewer administered questionnaire was used to obtain the demographic data, medical history on diabetes (type, duration, Fasting blood sugar (FBS) on that day and a recent Glycated hemoglobin (HBA1C) from the participant's records. For non-diabetic participants, they were sent to the laboratory where the research assistant did FBS. For FBS that was equal to or >126mg/dl (7.0mmol/l), patients were retested on another day to confirm the diagnosis. For FBS that was <126mg/dl (7.0mmol/l), an Oral glucose tolerance test (OGTT) was performed and the result was obtained.

The operational definition for diabetes was

1. Diabetes Mellitus – defined as FBS ≥7mmol/litre (126mg/dl) or a RBS of ≥11.1mmol/litre (200mg/dl), according to the1999 WHO diagnostic criteria. A glycated hemoglobin (HbA1c) value of ≥6.5% is diagnostic of DM according to 2010 American diabetic association (ADA).
2. Type 1 diabetes– defined as childhood-onset and insulin-dependent in individuals with absolute insulin resistance.
3. Type 2 diabetes -defined as adult-onset and non-insulin dependent in individual with relative insulin resistance.
4. Diagnostic Criteria for dry eye – OSDI scores that confirm dry eye from the questionnaire, abnormal TBUT, abnormal Schirmer's test in adults 18years and above.
   A. A positive OSDI score of ≥13 and above.
   B. An abnormal Schirmer's test is <10mm wetting in 5 minutes
   C. Abnormal TBUT: appearance of the first dry spot around the central cornea in <10 seconds

The inclusion criteria were as follows

- New and returning Patients diagnosed of diabetes (according to WHO criteria with a FBS of >7.0mmol/l or 126mg/dl and HBA1c of >6.5%) attending the vitreoretinal clinic of National Eye Centre, Kaduna.
- Non-diabetic patients of same age group attending General out-patient department with FBS of 3.6-5.6mmol/l (65-100mg/dl) in the absence of any medical treatment for diabetes.
- Adults 18years old and above who consented to participate in the study
- No previous ocular surgery
- No known history of ocular surface disease

Evaluating the OSDI score

The OSDI was assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI is a valid and reliable instrument for measuring dry eye disease severity (normal, mild to moderate and severe) and effect on vision-related function.

Assessing the patient's dry eye disease

Patient was asked the questions based on symptoms, and asked to circle the number that best represented each answer. Then, fill in boxes A, B, C, D and E according to the instructions beside each. Patient's score was placed accordingly, corresponding to normal, mild, moderate, or severe dry eye disease.

RESULTS

Two hundred (200) participants equally divided between diabetics and non-diabetics were examined

given a 100% response rate. The study participant ages ranged from 32-74 years (mean 53.2±9.7). Majority of the respondents were females 107(53%) and had tertiary level of education 90 (45.0%). Occupationally, most of the respondents were civil servants, housewives, traders, retirees. Tear breakup time (TBUT) was used to determine dry eyes. Respondents within the age range of 56-65 years had higher frequency of dry eye disease (DED) 54 (43.5%). Females were the higher number of respondents with DED 76 (61.35%) as against 48 (38.7%) in males, which is statistically significant (P=0.005). Respondents with secondary educational status had the highest frequency of DED 50 (40.3%), which is statistically significant (P=0.001). Housewives had the highest percentage of DED 36 (29.0%) which is statistically significant (P=0.000). Occupation that constituted 'others' with overall percentages <10% are accountants, artisan, legal practitioner, driver and journalist (Table 1).

Table 1: Distribution of DED with socio-demographic characteristics

Variable	No DED (%)	DED (%)	Total	χ^2	P value
Age					
26-35	9 (11.8)	1 (0.8)	10 (5.0)		
36-45	23 (30.3)	9 (7.3)	32(16.0)	44.42	<0.0001
46-55	26 (34.2)	36 (29.0)	62(31.0)		
56-65	16 (21.2)	54 (43.5)	70(35.0)		
>65	2 (2.6)	24 (19.4)	26(13.0)		
Total	76 (100.0)	124(100.0)	200(100.0)		
Sex					
Male	45 (59.2)	48 (38.7)	93 (46.5)		
Female	31 (40.8)	76 (61.35)	107 (53.5)	7.96	0.005
Total	76 (100.0)	124(100.0)	200(100.0)		
Occupation					
Trader/business	13 (17.1)	5 (20.2)	38 (19.0)		
Teacher	8 (10.5)	2 (1.6)	10 (5.0)	44.512	<0.0001
Farmer	4 (5.3)	11 (8.9)	15 (7.5)		
Civil servant	25 (32.9)	17 (13.7)	42 (21.0)		
Retiree	10 (13.2)	24 (19.4)	34 (17.0)		
Housewife Others	3 (3.9) 13 (17.0)	36 (29.0) 20 (7.2)	39 (19.5) 22 (10.5)		
Total	76(100.0)	124(100.0)	200(100.0)		
Level of education					
None	0 (0.0)	4(3.2)	4(2.0)		
Primary	18(23.7)	25(20.2)	43(21.5)	16.288	0.001
Secondary	13(17.1)	50(40.3)	63(31.5)		
Tertiary	45(59.2)	45(36.3)	90(45.0)		
Total	**76(100.0)**	**124(100.0)**	**200(100.0)**		

*statistically significant at p<0.05

Diabetic subjects within the age range of 56-65 years old had higher frequency of DED 31 (88.6%) while non-diabetic subjects aged 65 years and above had the highest DED. Females have higher rates of DED 42 (80.8%) as against 34(61.8) among males' Non-Diabetic subjects, which is statistically significant with (p<0.0001). Subjects with secondary educational status had the highest frequency of DED 28 (87.5%) in diabetic subjects while 22(71%) in Non-diabetic, which is statistically significant (p<0.0001). The housewives had the highest percentage of DED; 17/36 (89.5%) and 19/36 (95%) among subjects with diabetics non-diabetics, respectively. which was statistically significant (p<0.0001) (Table 2).

Table 2: Distribution of DED by Sociodemographic characteristics in Diabetic and Non-Diabetic subjects

	DIABETIC			NON-DIABETIC		
Variable	**DED**	**NON DED**	**P**		**NON DED**	**P**
Age						
26-35	1(20)	4(80)		0(0)	5(100)	
36-45	8(50)	8(50)		1(6.2)	15(93.8)	
46-55	25(80.7)	6(19.4)	0.001	11(35.5)	20(64.5)	<0.0001
56-65	31(88.6)	4(11.4)		23(65.7)	12(34.3)	

>65	11(84.6)	2(15.4)		13(100)	0(0)	
Total	76(76)	24(24)		48(48)	52(52)	
Sex						
Male	34(70.8)	14(29.2)	0.245	14(31.1)	31(68.9)	0.002
Female	42(80.8)	10(19.2)		34(61.8)	21(38.2)	
Total	76(76)	24(24)		48(48)	52(52)	
Occupation						
Trader/business	15(79)	4(21)		10(52.6)	9(47.4)	
Teacher	2(28.6)	5(71.4)		0(0)	3(100)	
Farmer	9(100)	0(0)	0.01	2(33.3)	4(66.7)	<0.0001
Civil servant	14(73.7)	5(26.3)		3(13)	20(87)	
Retiree	11(84.6)	2(15.4)		13(61.9)	8(38.1)	
Housewife	17(89.5)	2(10.5)		19(95)	1(5)	
Others	8(57.1)	6(42.9)		1(12.5)	7(87.5)	
Total	76(76)	24(24)		48(48)	52(52)	
Level of education						
None	4(100)	0(0)				
Primary	17(77.3)	5(22.7)		8(38.1)	13(61.9)	
Secondary	28(87.5)	4(12.5)	0.004	22(71)	9(29)	<0.0001
Tertiary	27(64.3)	15(35.7)		18(37.5)	30(62.5)	
Total	**76(76)**	**24(24)**		**48(48)**	**52(52)**	

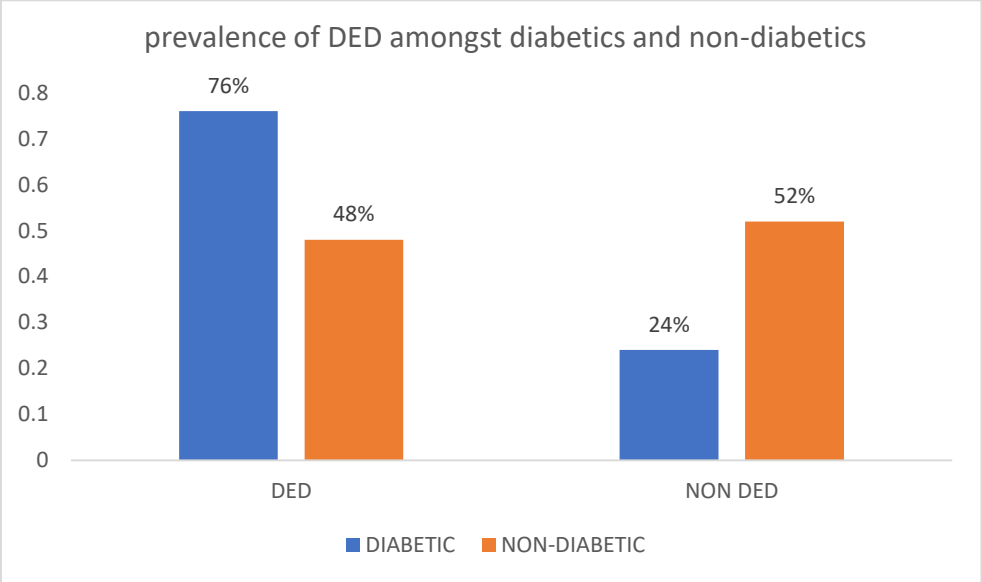

Figure 1: Distribution of prevalence of Dry Eye Disease among Diabetics vs Non-diabetic population

Majority of participants had moderate DED 50 (25.0%); seen in Diabetic patients 27 (27.0%) and non-diabetic population 23 (23.0%). One hundred (80.6%) participants with DED had normal FBS while 24 (19.4%) had elevated FBS. However, is not statistically significant (P=0.54). Sixty-three (82.9%) of patients with DED had elevated HBAIC while 17.7% had normal HBAIC, though the result is not statistically significant with (P= 0.19) (Tables 3&4).

Table 3: Distribution of DED severity among diabetics and non-diabetics using OSDI

DED	**Diabetic (%)**	**Non-diabetic (%)**	**Total**	χ^2	**P**
Normal	24(24.0)	52(52.0)	76(38.0)		
Mild	26(26.0)	19(19.0)	45(22.5)	21.69	<0.0001
Moderate	27(27.0)	23(23.0)	50(25.0)		
Severe	23(23.0)	6(6.0)	29(14.5)		
Total	100(100.0)	100(100.0)	200(100.0)		

Table 4: Recent FBS, HBA1C category and DED in diabetic patients

FBS(mmol/dl)	**No DED(%)**	**DED (%)**	**Total (%)**	χ^2	P
Normal (</=7)	69(90.8)	100(80.6)	169(84.5)		
Elevated(>7)	7(9.2)	24(19.4)	31(15.5)	3.702	0.54
Total	**76(100.0)**	**124(100.0)**	**200(100.0)**		

HBA1C					
Normal (</=7)	7(29.2)	13(17.7)	20(20.0)		
Elevated(>7)	17(70.8)	63(82.9)	80(80.0)	1.658	0.19
Total	**24(100.0)**	**76(100.0)**	**100(100.0)**		

Twenty-two (29.0%) of DM patients diagnosed 10years and above had DED while 54 (71.0%) diagnosed less than 10 years had DED. This finding is statistically significant (P<0001) (table 5).

Table 5: Duration of diabetes and DED

	No DED (%)	**DED (%)**	**Total (%)**	χ^2	P
</=10yrs	21(87.0)	54(71.0)	75(75.0)		
>10yrs	3(12.5)	22(29.0)	25(25.0)	18.676	<0.0001
Total	**24(100.0)**	**76(100.0)**	**100(100.0)**		

The logistic regression analysis was done for possible predictors of DED in studied patients. The result revealed that female patients were 6.8 times more likely to develop DED; aged patients were 344 times more likely to develop DED than young patients. Risk of DED increase among diabetic patients after adjustment for other variables, the risk of DED was 8.08 times more likely among Diabetic patients than non-diabetic patient (table 6).

Table 6: Logistic regression analysis of possible predictors of DED

	Unadjusted		**Adjusted**	
Variable	**OR(CI)**	**P**	**OR(CI)**	**P**
Age				
26-35	1		1	
36-45	3.52(0.39-31.9)	0.263	2.2(0.17-28.1)	0.541
46-55	12.46(1.48-104.5)	0.02	2.18(1.33-215.9)	0.03
56-65	30.38(3.51-258.2)	0.002	52.3(3.6-755.6)	0.004
>65	108(8.69-134.9)	<0.0001	344.9(13.9-867.3)	<0.0001
Sex				
Male	1		1	
Female	2.3(1.28-4.12)		6.8(2.2-20.8)	0.001
Occupation				
Trader/business	1		1	
Teacher	0.14(0.02-0.733)	0.02	0.08(0.006-1.12)	0.061
Farmer	1.49(0.4-5.62)	0.557	2.07(0.35-12.4)	0.425
Civil servant	0.37(0.15-0.92)	0.032	0.78(0.14-4.48)	0.781
Retiree	1.3(0.48-3.5)	0.607	1.15(0.13-10.48)	0.898
Housewife	5.96(1.53-23.2)	0.01	1.29(0.22-7.54)	0.778
Others	0.38(0.13-1.11)	0.08	1.2(0.22-6.7)	0.834)
Level of education				
Primary	1		1	
Secondary	2.77(1.17-6.5)	0.02	2.41(0.6-9.68)	0.215
Tertiary	0.72(0.35-1.5)	0.38	0.98(0.18-5.16)	0.979
Total				
Group				
DIABETIC	3.43(1.89-6.27)	<0.0001	8.08(3.2-20.4)	<0.0001
NON-DIABETIC	1		1	

Table 7, depicts correlation coefficient from Eta for association between subjective assessment and objective clinical tests, the result shows a significant positive correlation between OSDI and schirmers

(0.684) among diabetic patients, 0.881 among non-diabetic patients and 0.796 among all the patients. There is also a positive correlation between OSDI and TBUT 0.725 among diabetic patient, 0.881 among non-diabetic and 0.816 among all the patients (see table 9). The coefficients were all significant at ($p<0.0001$). Therefore, there is significant correlation between subjective assessment and objective clinical tests.

Table 7: Eta correlation between subjective assessment (OSDI) with objective clinical tests (schirmer's and TBUT) for DED among diabetic patients and non-diabetic population

	Diabetic(p<0.0001)		**non-diabetic (p<0.0001)**		**Total (p<0.0001)**	
	TBUT	Schirmer's	TBUT	Schirmer's	TBUT	Schirmer's
OSDI	0.725	0.684	0.881	0.881	0.816	0.796

DISCUSSION

This study had 100% response rate. The minimum sample size of 200 participants was achieved, 100 diabetic patients and 100 non-diabetic participants. One hundred and seven (53%) were females. Most of the participants had tertiary level of education, 90 (45.0%) which was similar to findings in other studies [7,8]. The mean age was 53.2 ± 9.7 with majority of the participants found to be between the ages of 32-74 years. The mean age is slightly similar to what was observed in the study by Onyekwelu et al [9]in south east Nigeria.

In this study, respondents with age range 56-65 years had the highest frequency of DED 54 (43.5%). This is slightly comparable to studies done by Olaniyan et al [2] in southwest Nigeria and Onwubiko et al [10], this may be due to normal age-related decrease in tear production and an increase in evaporative tear loss [10] Females were the highest number of respondents with DED 76 (61.35%). This is comparable to other studies [11,10]. In post-menopausal women, there is reduction in tear production due to low levels of androgen, which is known to promote the secretion of Meibomian gland and increase osmolarity of tears [8]. Generally women tend to have lower levels of androgen which has a stimulatory influence on tear production [10] Civil servants (21%) formed a greater percentage of participants followed closely by housewives (19.5%) and then traders (19%). However, this study showed higher percentage of DED in house-wives (39.0%) which was statistically significant. This is similar to a study in Pakistan by Ayub et al which showed a significant high percentage of DED amongst house-wives [12]. However, this study is in contrast to a study by Onyekwelu et al [9] that showed a higher percentage of DED in outdoor workers.

Prevalence of DED among diabetic patients was 76% while that in non-diabetic population is 48%. The high prevalence of DED in diabetic patients is comparable with the study done by Deepti et al who in Uttarakhand, India, reported the prevalence of 68% in diabetics and 32% in non-diabetic population [13]. while Aljarousha et al reported a prevalence of DED to be 63% in diabetic patients [14]. Other studies reported lower incidence such as that done by Waris et al [15] who in India reported the prevalence of DED in diabetics to be 43%. There is a decrease in corneal sensation in diabetic diabetes due to neuropathy involving the innervations of the lacrimal gland [16] The high prevalence may also be due to the tropical and dry climate in Nigeria. The wide range of differences may be due to our environmental conditions and variation in state of the weather at the time of conducting the study.

Diabetic patients within the age range 56-65 years old had a higher frequency of DED 31 (88.6%). This is similar to a study in Egypt by Jahanzeb et al [8] who also found DED being commoner amongst diabetics with >50yrs of age. While in the non- diabetic population, this study found a higher frequency of DED amongst individuals above 65years of age. This further shows that DED occurs earlier in diabetics. Moderate DED was more commonly seen in diabetic patients 27 (27.0%) than non-diabetic population 23 (23.0%) in this study as reported elsewhere [15] which was 25%. In this study, only 24 (19.4%) participants with elevated FBS had DED. 82.9% of participants with elevated HBA1c had DED, even though not statistically significant. This was a similar observation in a study by Olaniyan et al [7], which also showed that there was no statistical significant correlation between HBA1c and DED. However, this is in contrast to previous studies by Zou et al [17] who found a positive correlation between HBA1c values and presence of DED. This may be because HBA1c is a marker of the average blood glucose level of not less than the previous 3months, and it may not necessarily correlate with ocular surface abnormalities that occurs over the years. This study also revealed a significant associated of DED and duration of diabetes of <10yrs which was similar to a study done by Devi et al [11] and Waris et al [15]. This was however in contrast with the study by Olaniyan et al [7] which showed a greater association of DED with duration of diabetes >10yrs. This is however possibly because more elderly patients with longer duration of diabetes were seen in their study. The most prevalent comorbidity amongst the study participants was hypertension (81.5%), Onwubiko et al [10] found that patients that had both diabetes and hypertension had a greater risk of developing DED. This study showed a significant positive correlation between schirmer's and OSDI in diabetic patients, inferring that as Schirmer's test value increases, OSDI value also increases. This is similar to a study by Divya et al [18] who also found

schirmer's test and OSDI to be worse in poorly controlled diabetes. There is also positive correlation between TBUT and OSDI. The non-diabetic population in this study also showed similar correlations between the subjective and objective tests seen in the diabetic patients that was significant. Therefore, there is a significant correlation between subjective assessment and objective clinical tests.

CONCLUSION

Patients with diabetes have a higher prevalence of DED than non-diabetic population in National Eye Centre, Kaduna. Women were found to have a higher prevalence. There was a significant association between DED and duration diabetes. There is a correlation between objective clinical tests and subjective assessment in both diabetic and non-diabetic population. However, there was no correlation between HBA1c levels and DED status in patients with diabetes.

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APPENDIX

Ocular Surface Disease Index (OSDI)

Ask your patient the following questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D and E according to the instructions beside each.

Have you experienced any of the following during the last week?

	All of the time	Most of the time	Half of the time	Some of the time	None of the time
• Eyes that are sensitive to light?	4	3	2	1	0
• Eyes that feel gritty?	4	3	2	1	0
• Painful or sore eyes?	4	3	2	1	0
• Blurred vision?	4	3	2	1	0
• Poor vision?	4	3	2	1	0

Subtotal score for answers 1to5

Have problems with your eyes limited you in performing any of the following during the last week:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
• Reading?	4	3	2	1	0	N/A
• Driving at night?	4	3	2	1	0	N/A
• Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
• Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9

Have your eyes felt uncomfortable in any of the following situations during the last week:

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	
• Windy conditions?	4	3	2	1	0	N/A
• Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
• Areas that are air-conditioned?	4	3	2	1	0	N/A

Subtotal score for answers 10 to12

Add subtotals A, B, and C to obtain D
(D = Sum of scores for all questions answered)
Total number of questions answered
(Do not include questions answered N/A)