DRY EYE STATUS BASED ON THE SCHIRMER TEST AND TEAR FILM BREAK UP TIME RESULTS FOLLOWING USE OF SOFT CONTACT LENS IN KERALA

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Abstract

Prospective two years study of the dry eye status following use of soft contact lens. Based on the Schirmer test results, 10 % soft contact lens wearers developed mild dry eye at the end of 1 year and 15 % developed mild dry eye at the end of 2 years. No patient had moderate or severe dry eye. Based on the Tear film break up time results, 17 % soft contact lens wearers developed mild dry eye at the end of 1 year and 30 % developed mild dry eye at the end of 2 years. 1% had moderate dry eye at the end of 2 years. No patient had severe dry eye.

Keywords: Schirmer test, Tear film break up time, soft contact lens, dry eye

Introduction:

The precocular tear film is a complex three layer structure resting on the corneal and conjunctival surfaces of the eye. Disturbance in this tear film structure can cause dry eye and will affect the anatomical, physiological and visual functions provided by tears.

Contact lens are widely used for visual improvement and cosmetic reasons. Many of the patients especially the younger patients are now using contact lens for long duration. The presence of a contact lens causes many changes in the precorneal tear film like thinning of the tear film, lipid layer disruption, increase in mucous secretions and changes in the blink characteristics and increased tear evaporation. As a result of these changes, some patients experience dry eye symptoms associated with contact lens wear which are referred to as contact lens-induced dry eye.

The most common objective test used for dry eye diagnosis is the Schirmer test. The low cost of strips and their ease of application has led to the Schirmer test being the most commonly applied clinical test for lacrimal secretory function in dry eye. The tear film break-up time (TBUT) describes the stability of the tear film. This test is considered to be more reliable than the Schirmer test as it is repeatable (1) and minimally invasive. The test is very simple, interpretation is easy and far superior qualitatively to

other available tests as tear film is studied under magnification.

Schirmer test and Tear film break up time test are two common tests which can be done in most eye hospitals. So these two tests were chosen to determine the contact lens induced dry eye status.

Review of literature

The use of contact lens for visual rehabilitation and cosmetic reasons is constantly increasing in our society. James Key (2) in his article stated that most of the 125 million global contact lens wearers were young females and soft lenses was the dominant type of contact lens prescribed. The presence of a contact lens causes thinning of the tear film (3), lipid layer disruption, changes in the blink characteristics and increased tear evaporation. The 2007 International Dry Eye Workshop defined dry eye as a multi factorial 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. The Workshop identified use of contact lens as one cause for dry eye. Contact lens-related dry eye typically maintains an example of "evaporative" dry eye.

Dryness is the most frequently reported symptom among soft contact lens wearers. Studies by Guillon et al (4) and Nichols JJ et al (5) have found contact lens induced dry eye symptoms in 40 - 50% of soft contact lens wearers. A study by Richdale K et al (6)

found that 24.1% had permanently discontinued contact lens wear due to dryness.

Studies by Savini G *et al* (7) and Lemp MA *et al* (8) have shown that the Schirmer test has low reproducibility and the reliability of the test can be affected by environmental conditions like temperature and humidity. In the study by Bron AJ, less than 10 mm of wetting was considered as mild DED while less than 5mm of wetting was considered to indicate severe DED. The studies done by Schaumberg DA *et al* (9) considered a Schirmer test result of 10 mm or less as abnormal. However the test lacks standardization, is inaccurate and unrepeatable because of the reflex secretion produced by its invasive nature. It measures only tear production and the evaporative aspects of dry eye are overlooked.

The study done by Jacobi C *et al* (10) found that TBUT values below 10 seconds were definitely pathological. Studies by Cardona G *et al* (11), Downie L E *et al* (12), Turner A W *et al* (13), Graham JE *et al* (14) have found that TBUT still remains one of the most commonly used diagnostic tests for DED in clinical practice and is the most frequently used diagnostic test to determine tear film instability. TBUT measurements give moderately high sensitivity (83%) with good overall accuracy (85%).

Review of literature did not find any prospective study conducted on contact lens induced dry eye in Kerala. This study will help provide new scientific knowledge regarding dry eye developing in contact lens wearers in Kerala.

Methodology

Aim

To determine the dry eye status based on the Schirmer test and Tear film break up time test results following 1 year and 2 years use of soft contact lens.

Study design

Prospective study

Study population and study setting

Patients attending the contact lens clinic in a tertiary eye care hospital in Kerala, India.

Inclusion criteria

a) Patients in the age group 18 -40 years with refractive error who were prescribed soft contact lens as part of their treatment.

b) Patients who were willing to participate in the study.

Exclusion criteria

- a) Patients with dry eye, eye infections.
- b) Patients with past history of contact lens use or refractive surgery.
- c) Patients not willing to give consent for the study or to come for the followup visits.
- d) Pregnant or lactating patients.

Sample size

According to a study done by Nichols (5), the frequency of contact lens induced dry eye is 50 percent. This data was used to calculate the required sample size. Assuming a precision of 80% and a confidence interval of 95 %, sample size $N = 4 PQ / d^2$ where $P = 50$, $Q = 100 - P = 50$, $d = 20/100 \times P = 10$. Thus the sample size was calculated to be 100.

Sampling technique

Consecutive sampling technique of the patients meeting the inclusion and exclusion criteria.

Study period

Two years follow up period.

Study procedure

All procedures were conducted in accordance with the Declaration of Helsinki and Ethics committee approval got. The following details were collected and filled in the proforma.

- a) Demographic details like age, sex and occupation.
- b) Schirmer test - A calibrated Whatman's filter paper No. 41 strip (35 × 5 mm) was placed in the conjunctival sac of the temporal third of the lower eyelid. The patient's eyes are kept closed and the wetting of the strip after 5 minutes was measured.

Schirmer test result (mm / 5 minutes)	Dry eye severity
≥ 10	No dry eye
7 - < 10	Mild dry eye
5 - < 7	Moderate dry eye
< 5	Severe dry eye

c) Tear film break up time test - Tear breakup time was measured by instilling a 1 % Fluorescein Ophthalmic diagnostic strip in the inferior lateral fornix of the eye. The cornea was examined under slit

lamp using blue cobalt filter light. The patient was asked to blink several times and then hold the eye open. A dry area was indicated by appearance of a black spot or line. The time in seconds between the last blink and the appearance of a random dry spot was recorded as the tear film breakup time. The test was repeated 3 times and the average was recorded. The normal range lies between 20 and 30 seconds. The test was considered positive if the average tear film breakup time was less than 10 seconds.

TBUT (seconds)	Severity of dry eye
≥ 10	No dry eye
7 - < 10	Mild dry eye
5 - < 7	Moderate dry eye
< 5	Severe dry eye

Each patient was followed up after 1 year and 2 years. Based on test results, the severity of dry eye (no / mild / moderate / severe) was determined. The association of dry eye status with demographic factors was noted.

Data analysis

The data was entered in Excel format and was analysed using SPSS version 22 (SPSS Inc., Chicago, IL, USA). Pearson X2 test and Fisher exact tests were used to find out the statistical significance between variables. A p value less than 0.05 was considered statistically significant.

Results

1) Age distribution

The mean age of the patients was 24.6 years. The youngest patient was 18 years old and the oldest patient was 35 years old.

Age in years	Frequency	Percent
10-20	11	11.0
20-30	60	60.0
30-40	29	29.0

2) Gender distribution

The male: female ratio was 1: 1.77.

Gender	Frequency	Percent
Male	36	36.0
Female	64	64.0

3) Distribution based on occupation

Most (47 %) of the patients were students.

	Frequency	Percent
Student	47	47.0
Teacher	9	9.0
Computer professional	24	24.0
Other Professionals	9	9.0
Housewife	3	3.0
Office work	8	8.0

4) Distribution based on systemic disease

77 % had no systemic disease.

Systemic disease	Frequency	Percent
No systemic disease	77	77.0
Arthritis	4	4.0
Hypothyroidism	6	6.0
Asthma	9	9.0
Collagen Vascular disease	4	4.0

5) Distribution based on refractive error

Most of the patients had a refractive error of ≤ 8 dioptres .

Refractive error	Frequency	Percent
0.25-4	43	43.0
4.25-8	44	44.0
8.25-12	8	8.0
>12	5	5.0

6) Distribution based on number of hours of contact lens use /day

Most of the patients (69 %) used the contact lens for 6-12 hours a day.

Number of hours of contact lens use per day	Percentage
< 6 hours	10
6 -- < 12 hours	69
≥ 12 hours	21

7) Distribution based on Schirmer test

Based on the Schirmer test results, mild dry eye was seen in 10 % contact lens wearers after 1 year and in 15 % contact lens wearers after 2 years. There were no moderate and severe dry eye patients at the end of 2 years.

Schirmer test	Before		After year		1 After year		2 After year	
	N	%	N	%	N	%	N	%
≥10 (No dry eye)	10	100.	90	90.0	85	85.0		
	0	0						
7-10 (Mild dry eye)	0	0	10	10.0	15	15.0		
5-7 (Moderate dry eye)	0	0	0	0	0	0		
<5 (Severe dry eye)	0	0	0	0	0	0		
Total	10	100.	10	100.	10	100.		
	0	0	0	0	0	0		

8) Distribution based on Tear film break up time test

Based on the Tear film break up time test results, mild dry eye was seen in 17 % contact lens wearers after 1 year and in 30 % contact lens wearers after 2 years. 1 % contact lens wearers had moderate dry eye at the end of 2 years. There were no severe dry eye patients at the end of 2 years.

Tear film break up time result	Before		After 1 year		After 2 years	
	N	%	N	%	N	%
≥10 (No dry eye)	100	100.0	83	83.0	69	69.0
7-10 (Mild dry eye)	0	0	17	17.0	30	30.0
5-7 (Moderate dry eye)	0	0	0	0	1	1.0
<5 (Severe dry eye)	0	0	0	0	0	0
Total	100	100.0	100	100.0	100	100.0

Discussion

Before the use of contact lens, the average values obtained in this study were TBUT 15.3 ± 4.6 seconds and Schirmer test 18.7 ± 6.1 . These values represent the average tear parameters in the normal population without dry eye in Kerala. No published studies are available from Kerala to compare these results. A study done by Harvinder Nagpal in 2017 in Patiala, Punjab yielded normal tear parameters as TBUT 11.0 ± 2.45 seconds and Schirmer test 12.33 ± 3.0 . In Ghaziabad, Uttar Pradesh the control normal subjects in a dry eye study conducted by Kumar J et al (15) had Schirmer test values 17.17 ± 2.97 and TBUT values 13.53 ± 2.12 . Study done by Benjamin D Sullivan, et al (16) found the following normal values - TBUT 11.8 ± 6.4 seconds, and Schirmer test 19.3 ± 10.4 . The other normal tear parameters mentioned in literature are TBUT 12.8 ± 1.3 seconds (Krenzer KL, et al 2000) and Schirmer test 20.2 ± 11.3 (Arita R, et al 2009).

After two years of contact lens use, the average tear parameters obtained in this study were TBUT 10.1 ± 3.6 seconds and Schirmer test 11.4 ± 3.1 . These results indicate that use of contact lens has caused dry eye in some patients. Results of similar longitudinal contact lens induced dry eye studies in Kerala /India are not available. Harvinder Nagpal (2017) studied the different types of dry eye patients attending a hospital in Patiala, Punjab and found the following tear parameters in the mild dry patients - TBUT 9.50 ± 2 and Schirmer test 10.19 ± 2.81 . Study done by Kumar J, et al (15) in Uttar Pradesh found the TBUT result in dry eye patients as 8.88 ± 3.54 . The study by Benjamin D Sullivan, et al (16) found the

following values in mild dry eye patients -Schirmer test 13.9 ± 9.5 and TBUT 6.1 ± 4.9 .

The above results show that the tear parameters obtained in this study is different from the parameters obtained from studies conducted in North India and in Western countries. The average Schirmer test and TBUT results are more in normal subjects in Kerala compared to the normal subjects in North India and Western countries. The results got after two years use of contact lens show a similar difference. The average tear parameters got from this study population in Kerala suggest a lower dry eye status in Kerala compared to other parts of the world. This may be explained by the higher humidity in Kerala compared to other parts of India. According to the Meteorology department, the annual average humidity values in Thiruvananthapuram is 78 compared to the values of 54 in Delhi, 63 in Ghaziabad (place where Kumar et al study was conducted) and 63 in Punjab (state where Harvinder Nagpal conducted his study in 2017). Low humidity was found to be a risk factor for dry eye in the study conducted by Harvinder Nagpal in 2017. Low humidity leads to increased evaporation of tears and more chance of dry eye. However the other studies had older subjects and did not study only contact lens induced dry eye. So in addition to low humidity, age and other patient related factors may be responsible for the difference in the tear parameter results.

The following factors were found to have statistically significant association with contact lens induced dry eye - female gender (p value 0.35), age (p value 0.021), occupation (computer professionals, p value = 0.002) and high refractive error (p value < 0.001). Systemic diseases (p = 0.165) and systemic medications (p = 0.114) did not have any statistically significant association with contact lens induced dry eye. No contact lens induced dry eye studies from India were available for comparison. However dry eye studies done by Shah S et al (14) in Gujarat and Gupta N et al (15) in Delhi have found a greater prevalence of dry eye in females. Dry eye studies by Chia EM et al (16) have shown that females are 1.5 -2 times more likely to report dry eye symptoms compared to males.

Conclusions

This is the first longitudinal study in Kerala to determine the dry eye test results before and after use of contact lens. Based on the Schirmer test results, 10 % soft contact lens wearers developed

mild dry eye at the end of 1 year and 15 % developed mild dry eye at the end of 2 years . No patient had moderate or severe dry eye. Based on the Tear film break up time results, 17 % soft contact lens wearers developed mild dry eye at the end of 1 year and 30 % developed mild dry eye at the end of 2 years. 1% had moderate dry eye at the end of 2 years. No patient had severe dry eye. Tear film break up test was able to detect more contact lens induced dry eye patients than Schirmer test. The following patients will require regular and frequent follow up dry eye evaluation after prescription of contact lens -- females, older patients, patients working with computers, long continuous use of contact lens and high refractive correction.

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