

Assessing Tear Osmolarity to Determine Dry Eye Status Following the use of Soft Contact Lenses

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Abstract:

Background and Objectives: Prospective two years study of the dry eye status following use of soft contact lens. At the end of 1 year of soft contact lens use, 20% soft contact lens wearers developed mild dry eye. Contact lens is widely used for visual improvement and cosmetic reasons. Many of the patients especially the younger patients are now using contact lens for long duration. No patients had moderate or severe dry eye. One year, between June 2017 to July 2018. after use of soft contact lens, 33% wearers developed mild dry eye and 2% had moderately severe dry eye. Tear Osmolarity values were used to assess dry eye status.

Conclusion: 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.

Keywords: Tear Osmolarity, soft contact lens, dry eye.

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Introduction

The precorneal 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 is 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. A statistical meta-analysis of the literature on Tear Osmolarity over the last twenty years revealed that Tear Osmolarity is one of the most accurate diagnostic tests for dry eye, with a 90% accuracy rate when compared with other standard diagnostic tests. Studies to determine the Tear Osmolarity values in normal and contact lens wearers have been done in different parts of the world. However, there are no studies available regarding the Tear Osmolarity values in normal persons and contact lens wearers. The warm climate may contribute to values different from the values got from studies in other parts of the

world. This study hopes to provide scientific data regarding the dry eye status based on the Tear Osmolarity values before and after contact lens use in Bihar.

Material and Methods

Prospective study, to determine the dry eye status in soft contact lens wearers based on the Tear Osmolarity.

Patients attending the contact lens clinic in a tertiary eye care hospital in Bihar. Ophthalmology department at Nalanda medical college and Hospital Patna, Bihar Study duration is one year. Between June 2017 to July 2018.

Inclusion criteria

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

Exclusion criteria

- Patients with dry eye, eye infections.
- Patients with past history of contact lens use or refractive surgery.
- Patients not willing to give consent for the study or to come for the followup visits.

d) Pregnant or lactating patients.

According to a study done by Nichols (2006), the frequency of contact lens induced dry eye is 50 percent. This data was used to calculate the required sample size. Assuming a power 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

sampling technique of the patients meeting the

Tear Osmolarity value (mOsm / liter)	Dry eye status
Less than 308	No dry eye
308 – 315	Mild dry eye
316 – 324	Moderate dry eye
More than 324	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

inclusion and exclusion criteria.

a) Demographic details like age, sex, educational status and occupation.

b) Tear Osmolarity determination was done using the Tear Lab Osmolarity System. This lab-on-a-chip system simultaneously collects and analyses the electrical impedance of a 50-nanolitre tear sample from the inferior lateral meniscus

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 dioptries.

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) **Contact lens induced dry eye patients based on Tear Osmolarity results:** Based on the Tear Osmolarity results at the end of one year contact lens use, it was found that 80 % had no dry eye and 20 % had mild dry eye. None of the patients had moderate or severe dry eye. At the end of 2 years of contact lens use, it was found that the proportion of patients with dry eye had increased to 35 %. 2 % had moderate dry eye. None of the patients had severe dry eye.

Tear Osmolarity	Before		After 1 year		After 2 year	
	N	%	N	%	N	%
No dry eye	100	100.0	80	80.0	65	65.0
Mild dry eye	0	0	20	20.0	33	33.0
Moderate dry eye	0	0	0	0	2	2.0
Severe dry eye	0	0	0	0	0	0
Total	0	0	100	100.0	100	100.0

8) **Relation between the contact lens induced dry eye status and gender of the patient:** Based on the Tear Osmolarity results, at the end of 2 years of contact lens use, females were found more affected with dry eye than males. This was found to be statistically significant ($p < 0.05$).

9) **Relation between the contact lens induced dry eye status and refractive error correction:** Based on Tear Osmolarity results at the end of 2 years, it was found that there was a statistically significant difference in the proportion of patients developing dry eye based on the power of the prescribed contact lens ($p < 0.001$). All the patients with refractive error correction more than 8 dioptries developed dry eye.

Refractive error correction	Tear Osmolarity after 2 year				Total		χ^2	df	p
	No dry eye		Dry eye						
	N	%	N	%	N	%			
0.25-4	35	81.4	8	18.6	43	100	29.419	3	<0.001
4.25-8	30	68.2	14	31.8	44	100			
8.25-12	0	0	8	100	8	100			
>12	0	0	5	100	5	100			
Total	65	65	35	35	100	100			

Discussion

In this study, a Tear Osmolarity cut-off score of ≥ 308 mOsm/L was used for the diagnosis of dry eye - Foulks GN et al (11), Lemp et al (6). Before the use of soft contact lens, the average Tear Osmolarity value obtained in this study was 290 ± 6 mOsm/ litre. This value represents the average Tear Osmolarity value in the normal population without dry eye in Bihar. No published studies are available from Kerala to compare these results. Dhiman et al (12) did a study on A meta-analysis by Tomlinson et al (13) of 13 dry eye studies done in the West obtained a combined average normal Tear Osmolarity value

of 302 ± 9.7 mOsm /litre. Thus, the average Tear Osmolarity in normal subjects in Bihar is lower than the results in North India and Western countries. At the end of 1 year of soft contact lens use, the proportion of soft contact lens wearers developing dry eye was found to be 20 % based on the Tear Osmolarity results. The dry eye was of mild severity in all these tests. No patients had moderate or severe dry eye. Two years after use of soft contact lens, the average Tear Osmolarity was 308 ± 9.2 mOsm /litre. The proportion of soft contact lens wearers developing dry eye was found to be 35 % based on the Tear Osmolarity results. Most of the dry eye patients had

only mild dry eye. Moderately severe dry eye was detected in 2% patients. Results of similar longitudinal contact lens induced dry eye studies in India are not available. 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 Bihar to determine the dry eye test results before and after use of contact lens. It was found that contact lens do cause dry eye in 35% contact lens users after 2 years of use. In most cases, the severity of dry eye was only mild. 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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