

A Study to Compare the Influential Factors of Contact Lens Discomfort in First -Time Soft Contact Lens Wearers

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ABSTRACT

Background: Contact lens discomfort (CLD) remains a predominant reason for contact lens dropout globally, despite advancements in lens materials and designs. The multifactorial nature of CLD—including ocular surface changes, dry eye symptoms, and visual fatigue—demands comprehensive evaluation.

Objective: This study aims to compare anterior ocular surface health and subjective symptom questionnaires among three groups of first-time soft contact lens users to identify key contributors to CLD and develop evidence-based strategies for its management.

Methods: A prospective, experimental, and comparative study was conducted on 90 healthy contact lens neophytes (aged 18–30), divided into three equal groups using Omafilcon-B (hydrogel), Comfilcon-A, and Fanfilcon-A (both silicone hydrogels). Anterior segment health was assessed using the Efron grading scale, Schirmer's test, Tear Break-Up Time (TBUT), and AS-OCT-based corneal epithelial thickness. Subjective symptoms were evaluated using the Ocular Surface Disease Index (OSDI) and Convergence Insufficiency Symptom Survey (CISS). Baseline (pre-contact lens wear) and Follow-up assessments(post contact lens wear) were done at 1, 2, and 3 months respectively.

Results: All groups showed a statistically significant reduction in Schirmer's test scores and TBUT over time ($p < 0.01$), with Group 3 demonstrating the greatest decline. Efron grading indicated transient mild inflammation at 1 month, which resolved by month 3. Corneal epithelial thickness decreased significantly (statistically) in all groups ($p < 0.001$), most notably in Group 3. CISS scores indicated a notable increase in eye strain, especially in Groups 1 and 3. Group 2 showed comparatively better ocular surface stability and symptom control.

Conclusion: CLD in neophyte soft lens users is multifactorial, with tear film instability, mild redness, dryness, corneal epithelial thinning, and visual fatigue as significant contributors. Silicone hydrogel lenses, especially Comfilcon-A, may offer better ocular surface compatibility. Early detection and individualized management protocols, integrating both objective and subjective assessments, are essential to reduce contact lens dropout rates and enhance user satisfaction.

Keywords: Contact lens discomfort, ocular surface health, tear film, dry eye, convergence insufficiency, AS-OCT, soft contact lenses, contact lens dropout

1. INTRODUCTION

Contact lenses (CL) wearers who use CL for refractive corrections are estimated to be around 140 million people worldwide [1]. Comfort and intolerance with contact lenses may be challenging to diagnose. Type of CL material, design, adaptation, wearing schedule, CL solution, care products, ocular surface dysfunction, dry eye, exposure to wind, humidity, temperature and devices display, age, gender and drugs etc. are amongst the several factors indicating soft **Contact lens discomfort (CLD)** [2]. The early hydrogel soft contact lens materials lacked oxygen transmissibility provided by the modern silicone hydrogel contact lenses [3]. In 1999 when silicone hydrogel material was launched in the market it revolutionised contact lens industry because it met the oxygen transmissibility requirement as recommended by Holden and Mertz [4] to eliminate corneal hypoxic (less oxygen) changes due to extended wear of contact lenses [5]. But solution induced corneal staining (SICS) was observed as per early reports due to the fact that contact lens solutions (used for cleaning, rinsing and storing contact lenses) interacted with silicone hydrogel material [6,7,8]. Thereafter contact lens solutions and materials have evolved [9] rapidly and left no evidence of SICS events in the literature. Controlling the rate of contact lens dropouts worldwide was difficult in spite of inception of better contact lens materials and designs [10,11].

As contact lens dropouts due to contact lens discomfort has become a worldwide problem understanding the associated factors is the need of the hour and design a strategy to help overcoming pitfalls of current contact lenses. Since the last 20 years CL industry has been continuously modifying lens designs, materials, care products, manufacturing processes, CL replacement frequency to increase physiological performance of CL, Comfort and wearers convenience [9]. Approximately 90% CL wearers in the world are soft contact lens wearers [12]. Silicone hydrogel (SiHy) CL is the most popular choice now-a-days [13]. In case of a chance given, it is estimated that 74% of CL dropouts are able to resume CL wear successfully [14]. CL discomfort (CLD) is the most prevalent incident reported by CL wearers to ophthalmologists and optometrists. Reportedly, 50–75 percent of CL wearers experience CLD [2]. Henceforth, it is now very important to ensure that people are effective contact lens users. The goal of this study is to comprehensively examine **ocular surface health parameters / Objective methods** like Efron grading scale, Tear break-up time (TBUT), Schimmmer's test-1, and central corneal epithelium thickness measured with advanced Non-invasive device like Anterior segment Optical Coherence Tomography (AS-OCT), **Subjective methods** like open access validated dry eye patient symptoms questionnaires (OSDI), eye strain symptoms questionnaire (CISS) in 3 groups of contact lens designs to understand the associated factors contributing to soft contact lens drop-outs due to contact lens discomfort/dissatisfaction. This may help to minimise contact lens dropouts rate and thus reduce patients chairtime to a greater extent.

The main aim of the study is to identify the associated factors responsible for contact lens dropouts due to **multifactorial contact lens discomfort** in order to construct a strategy plan for contact lens fitting, better contact lens materials and designs which may help the ophthalmologists and optometrists to meet the refractive (good and stable vision), quality of life and ocular health requirements of the contact lens wearers with an evidence based and a scientific approach.

Subjective parameters (Subject Reported Symptoms Questionnaires)

1.1[a] Ocular surface disease index (OSDI)

To quantify symptoms of ocular discomfort related to dry eye OSDI open access questionnaire is used. OSDI is a previously validated questionnaire and a reliable tool [15]. It consists of 12 questions regarding dryness and symptoms of ocular discomfort. Questions 1 to 5 are regarding vision related symptoms, questions 6 to 9 are regarding ocular discomfort symptoms and questions 10 to 12 are regarding environmental stimuli. Total score range is from 0 to 100. If the score obtained is between **0 to 12 points then it indicates a normal ocular surface**, between 13 - 22 points indicate mild, 23 - 32 points indicate moderate and 33 - 100 points indicate severe DED.

1.1[b] Convergence Insufficiency Symptom Survey (CISS) :

Convergence insufficiency leads to headache, asthenopic symptoms, blurred vision, diplopia and eye strain after prolonged near work [16]. The convergence insufficiency treatment trial group (CITTG) developed CISS questionnaire as a reliable and valid method of quantifying and monitoring convergence insufficiency symptoms [17]. The group found that score of ≥ 16 could distinguish children with convergence insufficiency symptoms from children with normal binocular vision [18]. Recent studies have questioned this value [19,20] and now the recommended cutoff for the adults is ≥ 21 [21]. Both binocular vision disorders (BVD) and CLD contribute to CL dissatisfaction but BVD

contributes to CL dissatisfaction irrespective of CLD [22]. CISS has 15 questions regarding the frequency of eye tiredness and comfort during a prolonged near work. **CISS Questionnaire Score >21 is cut off value.**

1.2 Objective parameters (Anterior Ocular Surface health parameters)

Objectively measurable and an approach to evaluate disease process which helps the researchers to discover early indicators of the disease and risk factors hence aids in giving early treatment and better health outcomes.

Researcher's ability to identify early illness signs and risk factors which facilitates early diagnosis, effective treatment, and improved health outcomes [23].

1.2[a] Efron gradings:

The Efron grading scale is used to monitor the anterior segment ocular health. These include Blepharitis, conjunctival, limbal redness, conjunctival staining, papillary conjunctivitis, corneal neovascularization, corneal staining and Meibomian gland dysfunction (MGD) [24].

Efron [25] said in 2016 that the lens built-in component causes contact lens irritation. Redness, heat, swelling, discomfort, and discontinuing to use contact lenses are the five clinical signs of contact lens inflammation. Most common contributing factor to evaporative dry eye disease is Meibomian gland dysfunction (MGD) [26] and dryness is linked to majority of CL dropouts [27]. More than 40% of established soft CL wearers reported dryness as their main reason to discontinue CL wear in a Cross-sectional survey by Chalmers et-al 2006[28]. Diagnosing SCL related dryness is challenging as it is a symptomatic condition which is influenced by modifications in SCL[29,30,31] material and lens care products[32,33] which ameliorates symptoms. Ocular surface changes based on **Efron grading >2** is considered subnormal.

1.2[b] Tear break-up time (TBUT)

According to the TFOS 2013 CLD report which was made by considering biophysical and biochemical aspects of tear film, a low TBUT and tear ferning was reported to be associated with Contact lens discomfort [35]. TBUT (whether measured with fluorescein or with non-invasive techniques) has been an important tool in differentiating between successful contact lens users and contact lens dropouts mainly due to contact lens wettability issues [36]. Guillon-et al., [37] evaluated pre-lens tear film kinetics both in symptomatic and asymptomatic contact lens users. During the inter-blink period symptomatic contact lens users were identified by a low TBUT and less tear film coverage but at the time of blink greater surface exposure was found [37]. Screening soft contact lens users with low TBUTs and timely management of their tear quality may help in preventing CL dropouts. **TBUT greater than 10seconds is considered normal** and less than 10seconds is considered subnormal indicating dry eye.

1.2[c] Schirmers test(1):

Dry eye disease (DED) is a disorder in which the quality or production of tears is compromised and the ocular surface is inflamed, resulting in various symptoms such as ocular weariness, irritation, a burning feeling in the eyes, visual disruption, or fluctuating eyesight. Therefore, the evaluation of visual quality and the tear film ocular surface are related. Schirmer's test and tear film break-up time are two of the most used techniques for evaluating the tear film (TBUT) [39,40]. Due to the fact that DED can cause significant morbidity by interfering with a patient's everyday activities and has an economic impact on the individual and the community, it is essential to analyse this in depth. [41,42]. A score of **more than 10mm in 5minutes is accepted as normal**. Score less than 5mm in 5minutes duration indicates lesser tear production and dry eye.

1.2[d] Central Epithelial Thickness by Anterior segment Ocular coherence tomography (AS-OCT):

In AS-OCT non-invasive measurement of central (corneal) epithelial thickness is indicator of corneal health [43]. Corneal epithelial thickness measured by AS-OCT includes the tear film and the mean thickness of central corneal epithelium is $52.2 \pm 3.6 \mu\text{m}$ according to Li and Huang.[44]

Fig 4: Classification of dry eye syndrome according to 4 Epithelial thickness maps : Normal ocular surface, mild dryness, moderate dryness, severe dryness [45]

This study was inspired by the awareness of contact lens-related complications, compliance, care requirements, mixed literature review, confusion and myths regarding effective /associated factors of contact lens intolerance and

dropouts. Dilemma leading to generalised treatment for contact lens dry eye and discontinuation of contact lens wear especially in Neophytes compared to Established soft CL wearers.

Literature states that **74% of contact lens dropout cases can resume contact lens wear successfully[14] in case of a chance given**, inspired the researchers to choose this topic. Our evidence-based study focuses on each influential element contributing to contact lens dropouts (both objective and subjective parameters) and as a result, we may reach to a conclusion that can provide a novel, evidence based individualised treatment for the many reasons causing contact lens dropouts, dissatisfaction, intolerance and obtain a better visual outcome with contact lenses.

Research Gaps

Several studies documented dynamic alterations of ocular inflammation in contact lens (CL) users. According to Maldonado-codina-et al.,(2004) [46] corneal limbal hyperaemia increased significantly after 2weeks of CL wear and then decreased after 4weeks of CL wear. Efron(2018) stated that contact lens discomfort (CLD) variations and the relationship of discomfort and ocular inflammation need further exploration[47].

The International Workshop on Contact Lens intolerance hosted by the Tear Film and Ocular Surface (TFOS) Society proposed that inflammation may play a role in the genesis of discomfort experienced during uncomplicated CL usage [48]. CL discomfort (CLD) is the most prevalent incident reported by CL wearers to ophthalmologists and optometrists. Reportedly, **50–75 percent of CL wearers experience CLD** [2, 49]. In addition, 12–51 percent of CL wearers cease or drop-off wearing CLs due to CLD [50,51]. According to Richdale-et al.,(2007) CLD is the leading cause of CL dropout [52].

It is challenging for ophthalmologists and optometrists to treat CLD because its genesis and clinical manifestations are not completely known. Insights regarding eye's response to CL wear and its association with CLD has been elaborated in several studies but further studies are required regarding the combination of all these elements(multifactorial) to simplify the complexity of discomfort in an uncomplicated CL wear. Other factors like contact lens care and maintenance, digital eye strain, dryness of eye, convergence insufficiency influencing contact lens dissatisfaction were not included in the previous studies which is most important as contact lens discomfort is multifactorial and complex.

Aim: To compare the anterior ocular surface health and patient symptoms questionnaires in detecting the underlying factors of Contact Lens Discomfort in the first time soft contact lens users.

4.1 Objectives

To evaluate anterior ocular surface health of first-time contact lens users from baseline to 3months in all 3 types of soft contact Lenses.

To assess patient symptoms using valid and reliable questionnaires (OSDI, and CISS) from baseline to 3months in all 3 types of soft contact Lenses.

3. To compare Anterior ocular surface findings and Patient symptoms questionnaire score for determining the causes of Contact Lens Discomfort amongst all 3 types of soft contact lenses.

4.2 Methodology For Objective 1: To evaluate anterior ocular surface health of first-time contact lens users from baseline to 3months in all the three types of contact lenses.

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Study Design :Experimental and Comparative study

Sampling method : Convenience sampling method.

Hypothesis

(H₁) : Contact lens usage affects the integrity of anterior ocular surface health. (Allergy/inflammation/redness of eye, dryness of eye)

(H₀) : Contact lens usage doesnot affect the integrity of anterior ocular surface health (Allergy/inflammation/redness of eye, dryness of eye)

Sample size: sample size is **90 subjects**.

[30 participants were allotted **Omafilcon-B** and 30 participants allotted **Comfilcon-A** contact lens and 30 participants allotted **Fanfilcon-A**]. Sample size calculation not required as the researchers are doing census study and all the population walking into the OPD.

Study duration For the Study : 3months

Ethics clearance was obtained.

After explaining the participants about the study content in the language that they understand(**English/Hindi/Kannada**), written informed consent was obtained and written consent form was kept confidential. Patient was free to withdraw from the study at any point of time if not willing to continue for follow-up or for any personal reason.

The researchers recruited only Normal healthy subjects with no systemic or ocular diseases within the age group of **18 years and 30 years** and those who have never worn contact lenses (CL Neophytes).

Objective 2: To assess patient symptoms using valid and reliable questionnaires (OSDI and CISS) from baseline to 3 months.

2. METHODOLOGY FOR THE STUDY:

To achieve objective 2 of the study the researchers relied on Questionnaires methodology from baseline to 3 months. The questionnaires are open access, previously validated, reliable and are of the International standard.

Hypothesis

(H₁) : Contact lens usage influences Dryness of eye and Digital eye strain .

(H₀) : Contact lens usage doesnot influence Dryness of eye and Digital eye strain .

Objective 3: To Compare Anterior ocular surface findings and Patient symptoms questionnaire score for determining the causes of Contact Lens Discomfort amongst all the three types of soft contact lenses .

Hypothesis

(H₁) : Dryness, redness and digital eye-strain are the main causes of contact lens discomfort amongst all three types of soft contact lenses.

(H₀) : Dryness, redness and digital eye-strain are not the main causes of contact lens discomfort amongst all three types of soft contact lenses.

Contact lens solution used by all participants in the study was **Renu Advanced** Formula Multi-Purpose Contact Lens Solution.

Comparison was analysed and new guidelines could be obtained to tackle contact lens dropout rate due to Multifactorial Contact Lens Discomfort and co-management with ophthalmologists in treating complications of contact lens if any .

Inclusion criteria:

Age group **18 years to 30 years** with good general health and normal sighted participants and those who are first time contact lens wearers(Neophytes).

Participants willing to wear contact lens and willing to and able to spend time for the study .

Participants with best corrected visual acuity of 6/6 ; N6 in both eyes were only recruited.

Participants with **Spherical power of -0.50DSph to -10.0DSph and +0.50DSph to +10.0DSph with or without cylinder power upto -1.0DCyl** were only included.(Spherical equivalent was considered in case of astigmatism upto -1.0DC only). No toric contact lenses was dispensed.

General Visual assessment like Uncorrected Visual Acuity, Pinhole Vision, Vision with Spectacles (if participant was already using spectacles), Objective refraction (undilated retinoscopy) with Heine Retinoscope (Germany) and Subjective Refraction with Fogging method, Duochrome test, Jackson cross cylinder , worths four dot test were done.

Eligibility test for contact lens trial :

(Efron gradings with slitlamp biomicroscopy, Schirmer's test(1), TBUT, OSDI & CISS questionnaire analysis) was done/conducted for participants fulfilling the inclusion criteria.

After the routine baseline investigations like visual examination and Anterior segment Examination with slitlamp biomicroscopy and Posterior segment examination(dilated fundus examination) with Indirect Ophthalmoscope ,Contact lens trial was done on next day(because of dilated pupil) for the participants eligible for contact lens trial .

Only participants with an **Ideal contact lens trial fitting** were included in the study.

Insertion and removal techniques was explained by the Principal investigator and only participants willing for strict care and maintenance of contact lens were included in the study.

Exclusion criteria :

Subjects with previous history of any systemic or ocular diseases, with previous history of systemic or ocular allergies, with previous history of systemic or ocular surgeries, with previous history of systemic or ocular medications were excluded.

Subjects with **Amblyopia**(lazy eye) **High Myopia** more than -10DS, High Hypermetropia more than +10.DS, Astigmatism >1.0Dcyl power and Presbyopes, wearing near vision glasses for reading(above 40years of age) were excluded.

Children below 18years of age were also excluded. Adults above 30years were also excluded due to chances of age related changes in anterior ocular health and accommodation status of eye.

Dry eye subjects based on **Schirmers test(1) value < 10mm** in 5minutes duration, **OSDI SCORE ≥ 13 ; TBUT <5sec and central corneal epithelial thickness <50 μ m** were excluded.

Eye strain subjects based on subnormal values of CISS Questionnaire score **>21 were excluded.**

Subjects with subnormal ocular surface changes based on **Efron grading >2(infection)** and central corneal thickness **< 470 μ m** (ectasia) were excluded and referred to an ophthalmologist for clinical interventions and further management .

Mentally unstable ,Lactating mothers or pregnant women, smokers and alcoholic subjects were excluded.

Testing procedures:

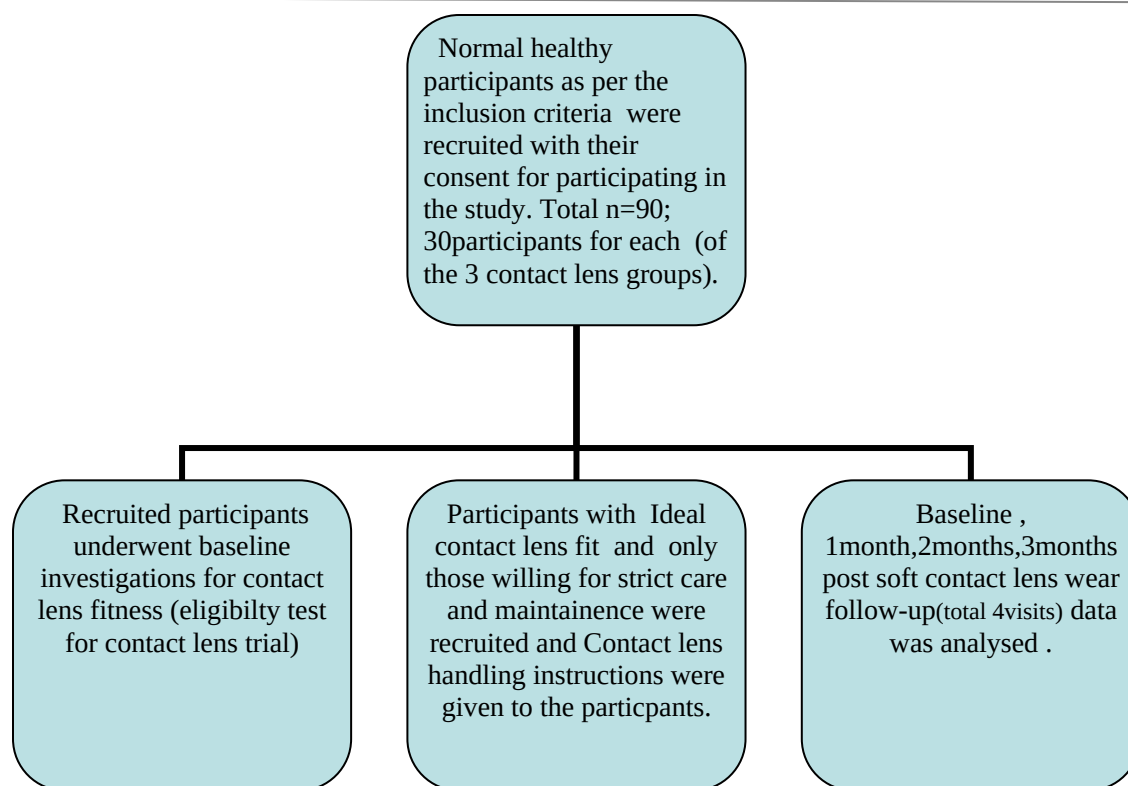
Group1 (Hydrogels) contact lens wear modality was 8 to 10hours daily wear and monthly replacement lens. The lens was recommended to be removed each evening, cleaned and safely stored in the clean lens case with ReNU Advanced formula multi-purpose solution (all purpose rinsing, cleaning and storing contact lens solution). Group 2 and Group 3 (Silicone hydrogels) contact lens wear modality was 12 to 14hours daily wear and monthly replacement lens. Participants were strictly instructed not to sleep /take a short nap with contact lens .care regime was same as group 1.

All the procedures were performed on both eyes in all the 3 groups.First Efron gradings were checked with slitlamp biomicroscopy then central Corneal epithelium with AS-OCT were tested followed by schirmers -1 performed with a sterile tear test strips “opstrip” and TBUT which was tested with a sterile fluoro strip .At last 2 questionnaires forms OSDI (dry eye and contact lens discomfort assessment) and CISS (eye strain assessment) were given to the participants to fill up with honest feedback.

All the procedures were performed without contact lens .Participants were instructed not to wear contact lenses on the day of follow-up .However after all the test procedures were done participants were instructed to wear contact lens to check the lens insertion and removal techniques followed by participants then lens case examination, solution bottle hygiene and fit assessment were done before the participants left the Out Patient Department.

All visits baseline and subsequent 3 follow-ups were performed between 10am and 1pm.OSDI questionnaire analyses contact lens discomfort and is used widely because it is stable , most reliable surveys in contact lens related comfort research [22].

Work flow



All the 3 designs of soft contact lenses used in the study were of **clear tint, spherical monthly disposables of the same International brand**. **Participants were assured about care** in any events of contact lens complications/dropouts due to Contact lens discomfort and informed that such cases will be intervened and referred to an ophthalmologist for necessary clinical procedures and treatment. Informed participants that Such events will be noted down/recorded and such participants shall be excluded from the study. The study period was uneventful and no dropouts.

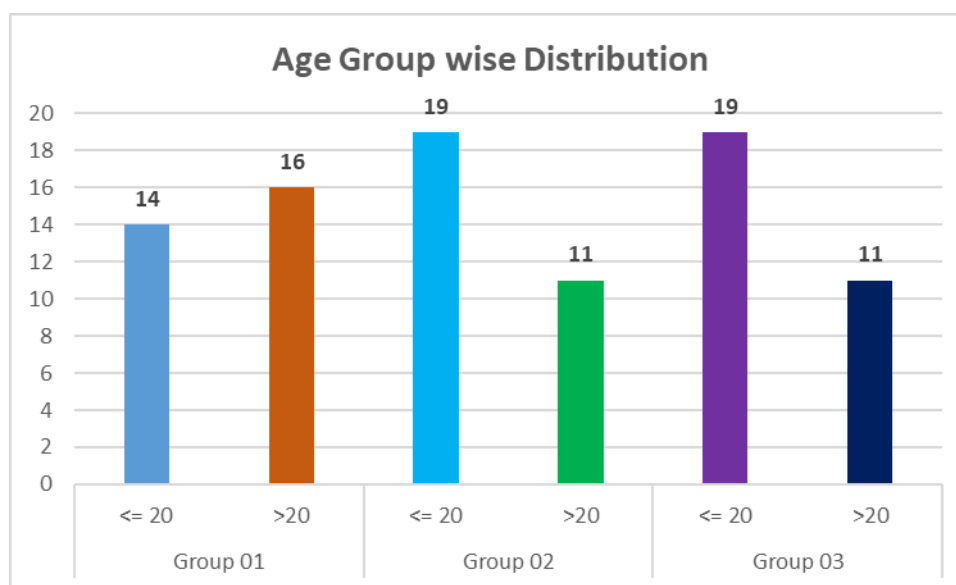
3. RESULTS

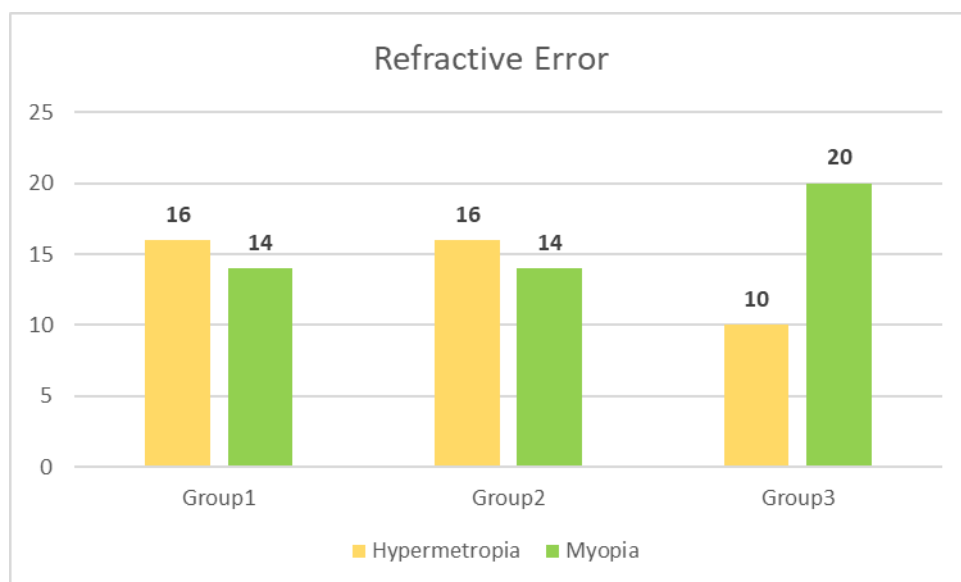
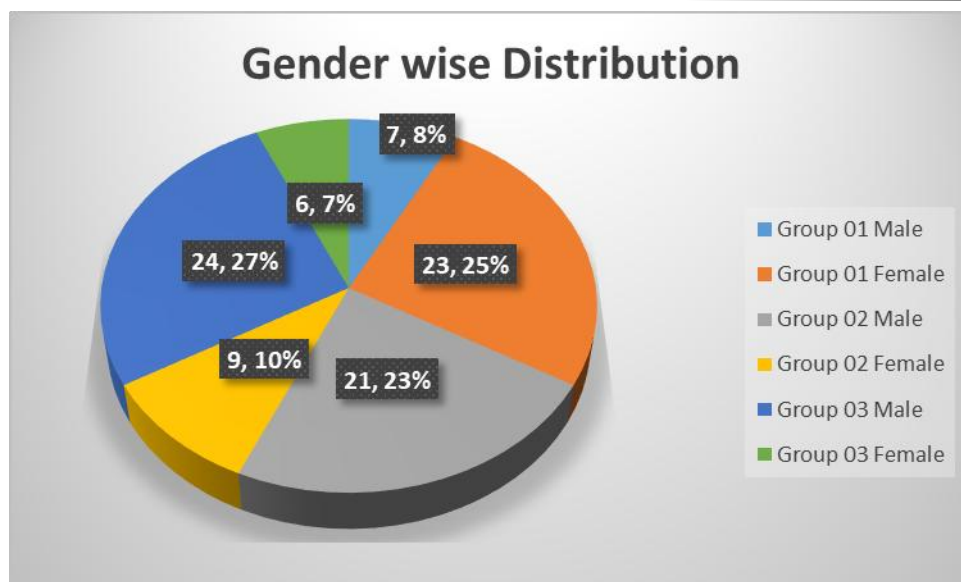
Researchers have included total 90 participants in the study. Among 90 participants, 30 were in each of the 3 groups.

Table:1. Comparison of Demographic Variable between groups

Group	Demographic Variable		No.of. Patients	Mean	Standard Deviation	P-Value
Group 01	Age Group	<= 20	14	21.76	3.31	
		>20	16			
Group 02		<= 20	19	20.23	1.50	
		>20	11			
Group 03		<= 20	19	20.1	1.47	
		>20	11			

Group 01	Gender	Male	7			*0.027*S
		Female	23			
Male		21				
Female		9				
Group 03		Male	24			
		Female	6			
Group 01	Refractive errors (spherical equivalent)	Myopia	14	-0.45	2.366	*0.881*NS
		Hypermetropia	16			
Myopia		14	-0.52	2.312		
Hypermetropia		16				
Group 03		Myopia	20	-0.85	1.887	
		Hypermetropia	10			





Interpretation:

Age: A statistically significant difference ($p = 0.042$) was observed in age distribution among the three groups. Group 1 had older participants on average compared to Groups 2 and 3. This may influence outcomes related to visual parameters and must be considered in analysis.

Gender: There was a significant gender difference among the groups ($p = 0.027$). Group 1 had predominantly females, while Groups 2 and 3 had more males. Gender-based physiological differences might affect the ocular surface and tear film stability.

Age	Mean	SD	Range
Group 1	21.76	3.31	18-30years
Group 2	20.23	1.50	18-30 years
Group 3	20.1	1.47	18-30years

Gender	Male	Female
Group 1	07	23
Group 2	21	09

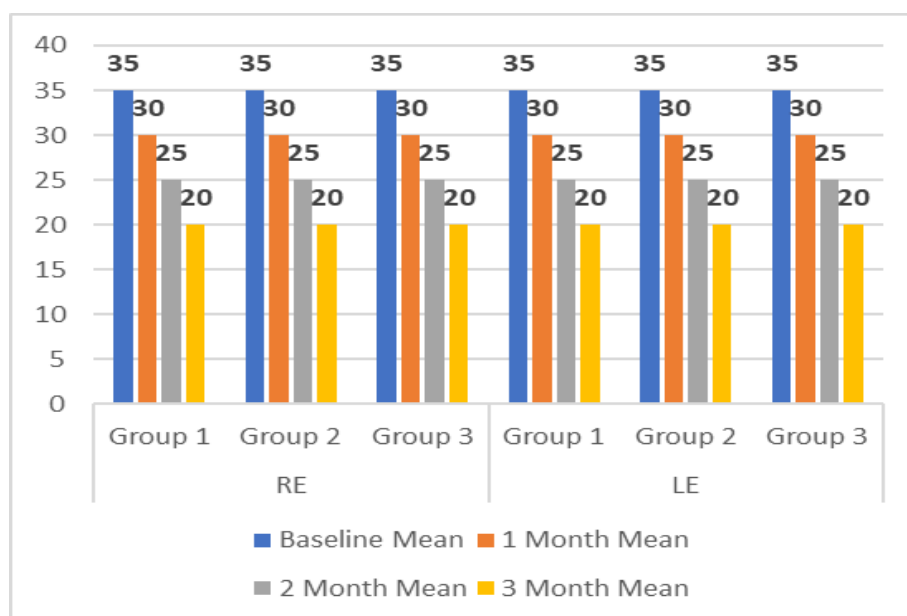
Group 3	24	06
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Refractive error	Group1	Group2	Group3
Hypermetropia	16	16	10
Myopia	14	14	20

Table 02: Comparison of Schirmmers test findings from baseline to different post findings within the groups

Eye	Schirmmers test findings	Baseline Mean± SD	1 Month Mean± SD	2 Month Mean± SD	3 Month Mean± SD
RE	Group 1	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0
	Group 2	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0
	Group 3	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0
LE	Group 1	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0
	Group 2	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0
	Group 3	35.0±0.0	30.0±0.0	25.0±0.0	20.0±0.0

Graph 01: Comparison of Schirmmers test findings from baseline to different post findings within the groups



Interpretation:

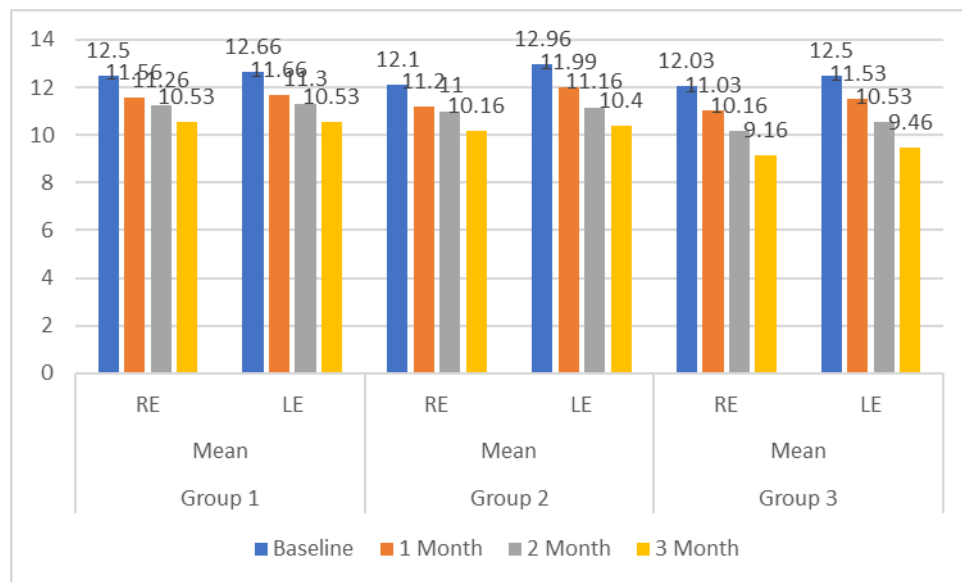
All groups (RE and LE) showed a progressive decrease in Schirmer's test values from baseline to 3 months. Although p-values are not individually listed, the consistent trend across all groups suggests a gradual decline in tear production over time.

This decline could be due to post-procedural or intervention-related ocular surface changes, supporting the hypothesis of intervention-induced dry eye symptoms.

Repeated measures ANOVA confirms statistical significance overall ($p < 0.05$).

Table :03 Comparison of Tear break-up time on right eye and left eye at different months between groups

TBUT(sec)	Group 1 Mean± SD		Group 2 Mean± SD		Group 3 Mean± SD		p value	
	RE	LE	RE	LE	RE	LE	RE	LE
Baseline	12.5±1.04	12.66±1.24	12.1±0.43	12.96±0.92	12.03±0.18	12.53±0.81	0.057	0.271
1 Month	11.56±1.07	11.66±1.54	11.2±0.48	11.99±0.92	11.03±0.18	11.53±0.81	0.001	0.065
2 Month	11.26±0.82	11.3±0.87	11±0.52	11.16±0.79	10.16±0.37	10.53±0.81	<0.01	<0.01
3 Month	10.53±0.86	10.53±0.97	10.16±0.46	10.4±0.62	9.16±0.37	9.46±0.68	<0.01	<0.01
One way ANOVA test, p value <0.05 considered as statistically significant								



Interpretation:

At baseline, TBUT values were comparable between groups with no significant difference, indicating similar ocular surface stability before intervention.

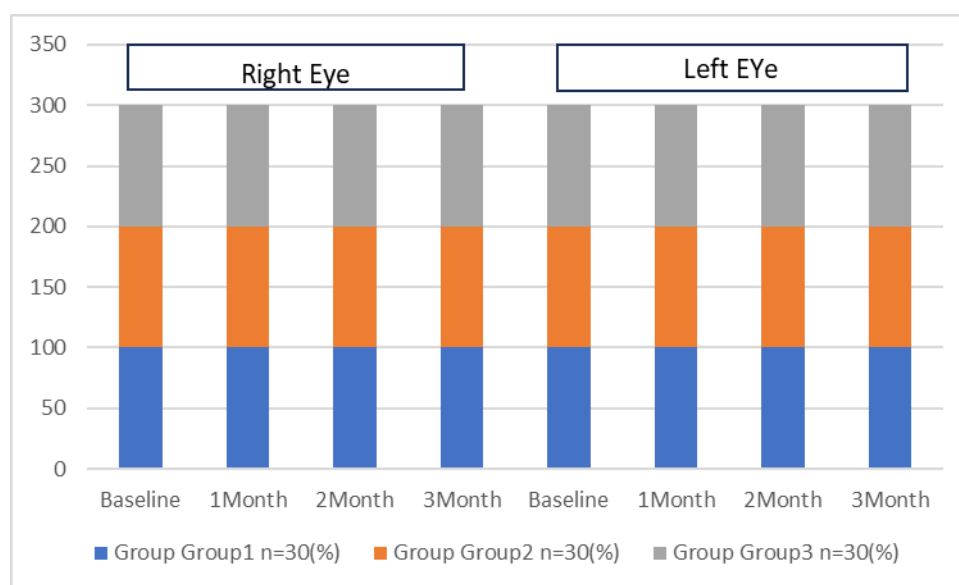
By 1 month, significant differences emerged in RE TBUT ($p = 0.001$), indicating early ocular surface disruption, particularly in Group 3.

At 2 and 3 months, both RE and LE TBUT showed highly significant reductions ($p < 0.01$), especially in Group 3, indicating persistent and possibly worsening tear film instability.

Group 3 consistently showed the lowest TBUT values, suggesting it experienced the most significant ocular surface changes.

Table : 04 Comparison of Efron grade at different months between groups

Side	Efron grade	Category	Group		
			Group1 n=30(%)	Group2 n=30(%)	Group3 n=30(%)
Left Eye	Baseline	Normal	30(100)	30(100)	30(100)
	1Month	Mild allergy/redness	30(100)	30(100)	30(100)
	2Month	Trace	30(100)	30(100)	30(100)
	3Month	Trace	30(100)	30(100)	30(100)
Right Eye	Baseline	Normal	30(100)	30(100)	30(100)
	1Month	Mild allergy/redness	30(100)	30(100)	30(100)
	2Month	Trace	30(100)	30(100)	30(100)
	3Month	Trace	30(100)	30(100)	30(100)
Chisquare test, p value <0.05 considered as statistically significant					



Interpretation:

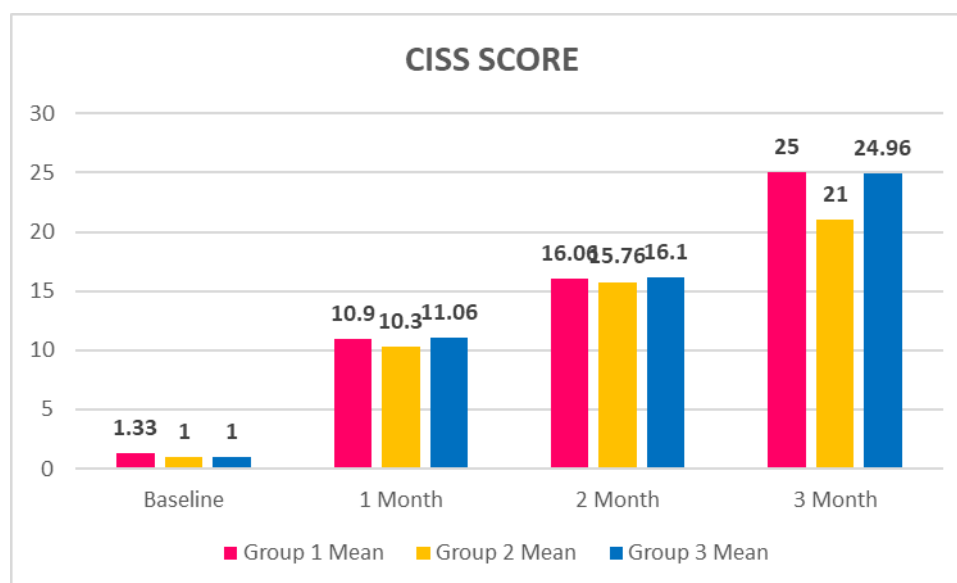
All participants in all groups had normal conjunctival appearance at baseline.

By 1 month, 100% of participants showed mild allergy/redness, and this reduced to trace findings by 2nd and 3rd months.

The uniformity of findings (100%) across groups suggests that the intervention had a universal mild inflammatory effect on the ocular surface, which later subsided, possibly due to tissue adaptation or healing.

Table:5 Comparison of CISS score at different months between groups

CISS	Group 1 Mean± SD	Group 2 Mean± SD	Group 3 Mean± SD	p value
Baseline	1.33±0.57	1.00±0.0	1.00±0.0	0.304
1 Month	10.9±1.9	10.3±0.83	11.06±1.89	0.04
2 Month	16.06±1.11	15.76±0.72	16.1±1.12	0.38
3 Month	25±2.51	21±0.48	24.96±2.32	<0.001
One way ANOVA test, p value <0.05 considered as statistically significant				



Interpretation:

Baseline scores were low and similar across groups (not significant).

By 1 month, Group 3 showed a slightly higher symptom score ($p = 0.04$), indicating early onset of asthenopic symptoms.

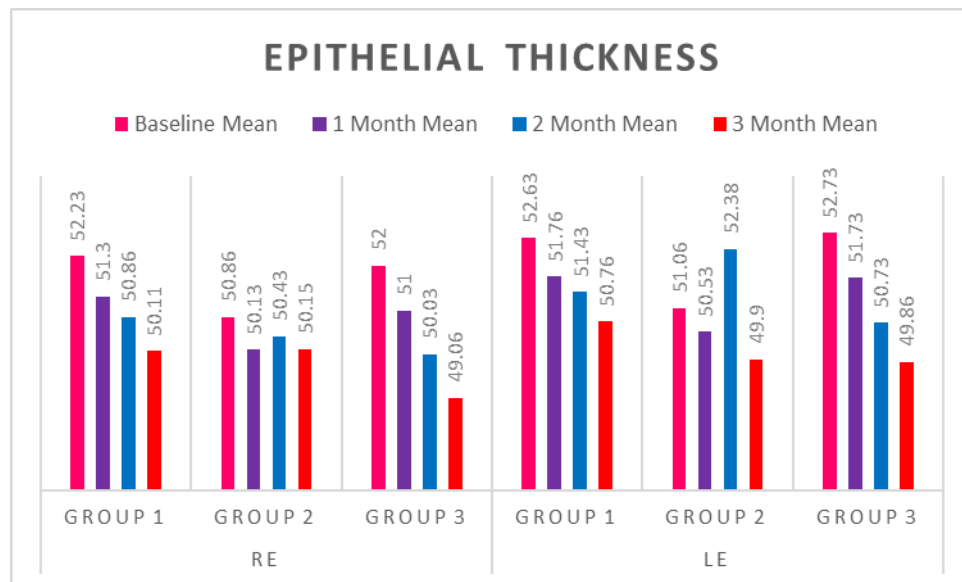
At 2 months, no significant difference was observed between groups.

At 3 months, Group 1 and 3 had significantly higher CISS scores compared to Group 2 ($p < 0.001$), suggesting persistent or worsening visual fatigue or discomfort, particularly in Group 1 and 3.

The results indicate that the intervention may have contributed to increased visual symptoms over time, especially in select groups.

Table:6 Comparison of Epithelial thickness (µm)from baseline(pre-contact lens wear) to different post contact lens wear follow-up months between groups

	Epithelial thickness	Baseline Mean± SD	1 Month Mean± SD	2 Month Mean± SD	3 Month Mean± SD	p value
RE	Group 1	52.23±3.59	51.3±3.61	50.86±2.7	50.11±2.6	<0.001
	Group 2	50.86±1.66	50.13±1.60	50.43±1.25	50.15±1.6	<0.001
	Group 3	52±1.31	51±1.31	50.03±1.29	49.06±1.25	<0.001
LE	Group 1	52.63±3.65	51.76±3.60	51.43±2.7	50.76±2.6	<0.001
	Group 2	51.06±1.58	50.53±1.61	52.380±2.8	49.9±3.1	<0.001
	Group 3	52.73±1.48	51.73±1.48	50.73±1.48	49.86±1.50	<0.001
Repeated measures ANOVA test, p value <0.05 considered as statistically significant						

**Interpretation:**

All groups showed a statistically significant reduction in corneal epithelial thickness over time in both RE and LE ($p < 0.001$).

Group 3 exhibited the most pronounced decrease, indicating possible epithelial remodeling or damage due to the intervention.

Group 2 showed the least variation, suggesting better epithelial preservation or recovery.

The trend aligns with tear film instability and supports the development of ocular surface changes post-intervention.

Discussion

This study assessed and compared tear film parameters, conjunctival changes, corneal epithelial thickness, and visual discomfort symptoms across three groups over a three-month period. The findings indicate that ocular surface parameters, especially Schirmer's test and TBUT, significantly declined over time across all groups, while epithelial thickness and symptom scores also reflected deteriorating ocular surface health, particularly in Group 3. The age and

gender distributions showed statistical differences between groups, which is consistent with earlier studies showing that age-related tear function decline and gender differences in hormonal balance may influence dry eye pathophysiology (53,54). Our findings that Group 1 had a greater female representation, and Group 3 had more males, highlight the need to control for such demographic variables. Tear film stability assessed by Schirmer's test and TBUT showed a consistent and significant decline post-intervention. These results align with previous research indicating that ocular procedures or screen exposure can disrupt tear homeostasis and lead to evaporative dry eye (55,56). TBUT values were particularly reduced in Group 3, consistent with studies identifying that long-term exposure or surgical intervention may impair mucin layer function (57). The uniform conjunctival findings across all groups, progressing from mild redness at one month to trace by three months, suggest a transient inflammatory response, likely due to ocular surface stress (58). Previous studies have shown that minor inflammatory changes following ocular procedures typically resolve within weeks with appropriate tear film recovery (59). The progressive thinning of the corneal epithelium noted across all groups, especially Group 3, corresponds with clinical findings in patients with chronic dry eye and poor ocular surface protection (60). Corneal epithelial thinning is a recognized biomarker of ocular surface disease severity and has been associated with reduced tear film quality and goblet cell density (61). Visual discomfort and fatigue symptoms, as measured by CISS scores, increased significantly over time, particularly in Group 1 and Group 3. This echoes earlier findings that tear film instability is correlated with asthenopia and reduced visual performance, especially in dry eye sufferers (62,63). Group 2's relatively stable CISS scores suggest a protective factor that may be inherent to the treatment protocol or baseline ocular health. Despite the absence of statistically significant variation in refractive error and baseline TBUT values, the progressive deterioration in test scores over time in all groups supports the conclusion that the intervention had a universal impact on ocular surface integrity and visual function (64). These results reinforce the understanding that stress to the ocular surface—whether mechanical, environmental, or chemical—can have widespread consequences on tear film dynamics and patient comfort (65,66). The findings also emphasize the importance of early monitoring and proactive management in high-risk individuals. Interventions such as lubricating drops, environmental modifications, and screen time limitation may be warranted to mitigate long-term ocular surface damage (67).

Summary

What was known before

- Contact Lens Discomfort and Dry-eye can be diagnosed with several Sophisticated and Invasive clinical tests, but correlation with patients symptoms is poor.

What this study adds

- Contact lens discomfort can be also tested with simple and non-invasive instruments and both objective and subjective (CISS, OSDI) methods of testing may yield a better and accurate diagnosis.

Imaging of ET maps (central corneal epithelial profile) with ultrahigh resolution anterior segment OCT and extrapolation of central corneal epithelial thickness variance can offer a reliable index for diagnosis of dry-eye disease, evaluate severity, and follow-up soft contact lens wearers.

4. CONCLUSION

The Efron grading, Schirmers test (1), Tear breakup time, OSDI, CISS questionnaire scores, central corneal epithelial thickness measured by anterior segment OCT machine were analysed in pre-contact lens wear in all the 3 groups. In addition, the researchers found AS-OCT and questionnaires to be simple, economical tools and quick techniques for detecting any changes in the eye. AS-OCT is a simple, quicker and novel method of measuring central corneal epithelial thickness non-invasively. In the present study the researchers conclude that though statistically significant changes were found between pre contact lens wear (baseline) and post contact lens wear (3 months follow-up period), there were no clinically significant changes (both subjective and objective parameters) noticed in pre and post contact lens wear in all 3 groups except CISS score. In Group 1 and Group 3 both statistically and clinically significant values

(of CISS) were found at the end of 3rd month of post contact lens wear. To conclude on the comparison between results obtained from various studies is very hard because of the lens type and methods of measurements being different in each study. So, minimum 3 months follow-up studies are required (good enough) to confirm the results and establish a reasonable conclusion.

Limitation of the study

Further multicentre studies with longer follow-ups are required to provide more clinical evidence on underlying factors of contact lens discomfort as it is multi-factorial. Longer follow-up studies are required to confirm the ocular surface changes and mainly follow-up after discontinuing contact lens wear for a month as most of the clinical signs recover after discontinuing contact lens wear.

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