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Original Research Article

Unveiling the impact of refitting with new daily wear silicone hydrogel lenses on dryness and discomfort

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Abstract

Background: Contact lens wear offers convenient vision correction, but dryness and discomfort remain common, affecting ocular health and quality of life. This study aims to assess dryness and discomfort in symptomatic silicone hydrogel lens wearers and evaluate symptom improvement following refitting with new silicone hydrogel lenses.

Materials and Methods: Symptomatic participants attended two clinical visits: those wearing habitual contact lenses (Balafilcon A or Lotrafilcon B) during the initial visit and those transitioning to study silicone hydrogel lenses (Samfilcon A) at the first follow-up. Symptoms related to contact lens dryness and discomfort was measured using the Contact lens dry eye questionnaire-8 (CLDEQ-8) during both visits. A thorough examination of the eyes and contact lenses was performed, followed by an assessment of dry eye. Subsequently, all participants were fitted with the study silicone hydrogel lenses and re-evaluated after two-weeks.

Results: Sixty participants completed the trial. Participants reported higher CLDEQ-8 scores while wearing their habitual contact lenses compared to when wearing study silicone hydrogel lenses (12.8 ± 2.6 vs. 3.2 ± 2.9, P <.0001). Upon comparing two visits, significant increases were noted in Schirmer 1 (22.0 ± 3.4 vs. 22.4 ± 2.9, P<.05), Schirmer 2 (19.7 ± 3.2 vs. 20.4 ± 2.9, P<.01) and Tear Breakup Time (TBUT) (7.4 ± 0.9 vs. 10.0 ± 0.8, P<.0001). Notably, moderately negative correlations were observed between CLDEQ-8 and TBUT (r = -0.39 vs. -0.34), Schirmer 1 (r = -0.07 vs. -0.07), and Schirmer 2 (r = -0.17 vs. -0.07) during both visits.

Conclusion: The current study demonstrated that the tear function profile and CLDEQ-8 scores significantly improved after a two-week study lens usage, indicating improved subjective dryness and discomfort.

Keywords: Contact lens induced dryness and discomfort, CLDEQ-8, Tear function profile.

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1. Introduction

Contact lens wearing is a popular vision correction method used by millions of people around the world, and it offers convenience and visual clarity. On the other hand, besides its benefits, contact lens users usually encounter problems, such as dryness and discomfort. These symptoms can seriously affect the quality of life and eye health of the wearer. Dry eye disease (DED) is common among all age groups and cause chronic discomfort and pain.[1] Additionally, the attitudes and habits of wearers of contact lenses towards their care can negatively affect their ocular health, including not adhering to lens care instructions.[2] Furthermore, meibomian gland dysfunction like changes caused by contact lens wear can provoke tear anomalies resulting in dryness and discomfort.[3]

Contact lens dryness, as specified by the tear film and Ocular surface society international workshop (TFOS),[4] is a condition where discomfort, irritation, or a feeling of dryness is usually experienced by contact lens wearer. This situation is often associated with tear film dysfunction, which causes insufficient lubrication between the lens and the surface of the eye. These factors, including tear film instability, lesser tear production, increased tear evaporation, and friction

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between the contact lens and ocular surface, contribute in the pathogenesis of contact lens-related dryness.[5]

In 2013, the TFOS on Contact lens discomfort (CLD) defined contact lens discomfort as a condition resulting from the incompatibility between the lens and the ocular environment associated with adverse ocular sensations.[6] Reduced satisfaction and discontinuity of contact lens wear significantly associated with dryness and discomfort.[5] Kojima et al.[4] found a strong connection between contact lens discomfort and dry eye, which is why it is important to deal with dryness-related symptoms.

Moreover, a survey of university students in Malaysia showed that a substantial proportion of lens wearers (73.5%) had dry eye symptoms, which is further evidence of the influence of dryness on wearing comfort.[7]

Recent advancements in silicone hydrogel contact lenses in the form of newer materials and surface chemistry to tackle dehydration with contact lens wear that results in dry eye.[8] One strategy used by lens manufacturers to improve water retention in contact lenses and to provide a smooth optical surface is to integrate wetting agents into lens polymers.[9]

Despite advances in silicone hydrogel contact lens materials and surface treatments, limited studies have directly compared the effects of refitting habitual lens wearers with new generation silicone hydrogel lenses on both subjective symptoms and objective tear function parameters. There remains a lack of conclusive evidence regarding the clinical benefits of switching to newer lens materials in symptomatic wearers. Based on this identified gap, this study hypothesizes those refitting habitual symptomatic contact lens wearers with a newer generation silicone hydrogel lens (Samfilcon A) will significantly reduce subjective dryness and discomfort and improve tear film parameters compared to their habitual lenses.

The aims of the study were twofold: first, to assess the degree of dryness and discomfort in symptomatic silicone hydrogel contact lens wearers; second, to refit the wearers with a new silicone hydrogel lens (Samfilcon A) and evaluate the potential improvement in these symptoms.

2. Materials and Methods

2.1. Recruitment and enrollment

Participants were recruited from the Department of Optometry, Sapthagiri Institute of Medical Sciences and Research Center, Bangalore, India, during routine outpatient visits to the contact lens department. The study was approved by the Institutional Ethics Committee, registered with the Clinical Trials Registry-India (CTRI/2024/05/067491), and conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants after explaining the study's nature, procedures, and potential consequences.

Participants who experience symptoms of dryness and discomfort, especially towards the day's end with their habitual contact lens wear, were recruited for this study and were required to be 18 years or older but younger than 36 years, designed to minimize the contribution of vision-related factors from presbyopia with 1 to 12 diopters of myopic spherical error. Participants wore their lenses daily for at least 9 hours a day, at least for a period of 6 months preceding the study. They were advised to discontinue wearing their lenses for at least 3 days before commencing the study. This approach was taken to ensure that participants who previously wore different designs of contact lenses achieved a more consistent baseline result before fitting them with the study lenses. Participants were also required to be currently wearing either Balafilcon A or Lotrafilcon B silicone hydrogel spherical single-vision contact lenses; to have a visual acuity of at least 0.10 logMAR in each eye at 6 m with full refractive correction. The exclusion criteria were any systemic or ocular conditions that may adversely affect contact lens wear, no ocular surgery, not strabismic, and not pregnant. In addition, subjects were withdrawn from the study if they experienced any contact lens related complications during the duration of the study.

2.2. Study overview

A total of 60 participants completed a single-masked crossover study involving two clinic visits: a baseline assessment and a follow-up two weeks after study lens fitting. At baseline, medical, ocular, and lens history were recorded, including lens type, wear schedule, care solutions, visual display use, allergies, and lifestyle factors.

Visual acuity was measured at 6 m (I Chart HD Smart) and 30 cm (MNREAD Card), followed by subjective refraction. Keratometry was performed using the IOL Master 500, averaging three readings with SNR $\geq$ 100.

Anterior ocular assessment was conducted with an Appasamy slit lamp using the cornea and contact lens research unit grading scale for hyperemia, staining, and roughness (0–4 scale, 0.5 steps). The ocular surface was evaluated for abnormalities, including meibomian gland dysfunction and lid-parallel conjunctival folds. Fluorescein sodium strips were used to assess corneal staining, lid wiper epitheliopathy (graded as present/absent), and tear breakup time (TBUT). All staining assessments were performed by a masked examiner.

2.3. Outcome measures

2.3.1. TBUT

TBUT was measured by applying a minimum amount of fluorescein to the superior temporal bulbar conjunctiva, and after waiting 60 s, participants were asked to blink three times before measuring breakup time using a stopwatch. The time (in seconds) between a blink and the appearance of the first dark spot in fluoresceinwas recorded as the tear breakup time.

>10 seconds was considered normal, 5-10 seconds, marginal, and <5 seconds was considered low.[12] Breakup time measurements were performed at least twice per eye and the results were averaged.

2.3.2. Schirmer 1 and Schirmer 2

After a 10-minute break, bilateral Schirmer 1 (without anaesthesia) and Schirmer 2 (with 0.5% Proparacaine) tests were performed using Tear Strips (Whatman No. 41) placed in the inferior temporal conjunctival sac for 5 minutes. Tear wetting length was measured in millimetres; values of 5 to <10 mm (without anaesthesia) and <8 mm (with anaesthesia) were considered abnormal.[13]

Following a 30-minute break, the study contact lenses were fitted directly from blister packs and worn for approximately one hour. Distance and near visual acuity, over-refraction, and lens fitting parameters were assessed, including centration (≤0.2 mm decentration), corneal coverage (1.0–2.0 mm beyond the limbus), horizontal lag (0.5–1.0 mm), blink movement (0.25–0.50 mm), and push-up test (2–4 mm/s).[14]

Participants were instructed to wear the study lenses for two weeks, 9–12 hours daily. Lens care instructions, including insertion, removal, and cleaning, were provided verbally and in writing.

2.3.3. CLDEQ-8

The CLDEQ-8 was administered at baseline to assess dryness and discomfort with habitual silicone hydrogel lenses; a score ≥12 indicated significant symptoms. The CLDEQ-8 was repeated after 15 days of study lens wear to evaluate symptom changes.

At the follow-up visit, participants underwent CLDEQ-8 assessment, TBUT, Schirmer 1 and 2 tests (without lenses), and anterior ocular examination by a masked examiner.

2.4. Statistical analysis

Statistical analysis was conducted using SPSS v20. The Wilcoxon signed-rank test evaluated changes in TBUT, Schirmer tests, and CLDEQ-8 scores. Spearman's Rank Correlation assessed the relationship between CLDEQ-8 scores and tear film parameters. Significance was set at $P \leq 0.05$.

3. Results

3.1. Demographic data

The study recruited 60 healthy young habitual contact lens wearers (41 females, 68.8%; 19 males, 31.2%), with no dropouts. The mean age was 26.6 ± 5.1 years (range: 17–35 years). Of these, 32 (53%) wore Balafilcon A and 28 (47%) wore Lotrafilcon B lenses for at least six months prior to the study.

Participants reported wearing their habitual lenses an average of 5.6 ± 1.8 days per week (range: 2–7 days), 11.8 ± 3.4 hours per day (range: 6–19 hours), with an average of 7.2 ± 3.5 comfortable hours daily (range: 1–14 hours).

The interval between baseline and follow-up visits averaged 15.36 ± 1.42 days (range: 13–19 days).

Table 1: Demographics of the study population (n = 60)

Factor	**Result**
Age (y), mean ± SD (range)	26.6 ± 5.1 (17 to 35)
Sex (%)	
Female	68.8
Male	31.2
Contact lens Brand (%)	
Balaficon A	53
Lotrafilcon B	47
Lens care solution (%)	
Multipurpose	95
Hydrogen Peroxide	05
Subjective Spherical refraction (D), mean ± SD (range)	
Right Eye	-4.8 ± 2.7 (-11 to -1.5)
Left Eye	-4.9 ± 2.8 (-11.5 to -1.5)
Average keratometry (D), mean ± SD (range)	
Right Eye	44.2 ± 1.4 (40.5 to 46.7)
Left Eye	44.3 ± 1.4 (41.0 to 46.5)
Contact lens wear (d/wk), mean ± SD (range)	5.6 ± 1.8 (2 to 7)
Contact lens wear (h/d), mean ± SD (range)	11.8 ± 3.4 (6 to 19)
Comfortable contact lens wear (h/d), mean ± SD (range)	7.2 ± 3.5 (1 to 14)

D = Diopters; d/wk= Days/week; h/d = Hours/day; SD = Standard deviation.

3.2. Quantitative assessment of tear breakup time, schirmer 1, and schirmer 2

Participants wearing their habitual contact lenses showed a significant difference in mean ± standard deviation in Schirmer 1 (22.0 ± 3.4 millimeters vs. 22.4 ± 2.9 millimeters, P <.05) and Schirmer 2 (19.7 ± 3.2 millimeters vs. 20.4 ± 2.9 millimeters, P < .01) values, and a significant longer fluorescein tear breakup time (7.4 ± 0.9 seconds vs. 10.0 ± 0.8 seconds, P <.0001) compared after two weeks post study lens wear. The significant differences in the parameters are listed in **Table 2**.

Table 2: Mean ± SD and 95% confidence interval for Schirmer 1, Schirmer 2 and TBUT parameters showing a significant difference ($P < .05$) when compared with baseline and first follow-up visit

Parameters (95% CI)	Mean ± SD	p-value
Schirmer 1 (mm)		
Baseline	22.0 ± 3.4 (20.7-23.2)	
First follow-up	22.4 ± 2.9 (21.4-23.5)	<.05
Schirmer 2 (mm)		
Baseline	19.7 ± 3.2 (18.5-20.9)	
First follow-up	20.4 ± 2.9 (19.3-21.4)	<.01
TBUT (sec)		
Baseline	7.4 ± 0.9 (7.0-7.8)	
First follow-up	10.0 ± 0.8 (9.7-10.3)	<.0001

During the first follow-up visit, measurements were taken after removing the study contact lens. mm = Millimeter; Sec = Second; SD = Standard deviation; CI = Confidence interval; TBUT = Tear break-up time.

3.3. Questionnaire

The mean ± standard deviation and 95% confidence interval for the CLDEQ-8 are shown in **Table 3**.

Participants wearing the study contact lenses scored significantly lower, indicating improved symptoms when compared to their scoring during their baseline visit (12.8 ± 2.6 vs. 3.2 ± 1.9, $P< .0001$).

Table 3: Mean ± SD and 95% confidence intervals for CLDEQ-8 questionnaire according to contact lens comfort status

Questionnaire (Range)	Mean (95% CI)	p-value
CLDEQ-8		
Baseline (12 to18)	12.8 ± 2.6 (11.8-13.8)	<.0001
First follow-up (1 to 7)	3.2 ± 1.9 (2.4-3.8)	

A higher score for questionnaire indicates increased symptoms. CI = Confidence interval; SD = Standard deviation; CLDEQ-8 = Contact lens dry eye questionnaire-8.

3.4 Correlation between questionnaire with tear breakup time, schirmer 1, and schirmer 2

The CLDEQ-8 showed a moderately negative and significant correlation with tear breakup time ($r = -0.39$, $P < .02$ vs. $r = -0.34$, $P< .05$) between two study visits.

There was a less significant but moderately negative correlation with Schirmer 1 ($r = -0.07$, $P = .68$ vs. -0.07, $P = .70$), and Schirmer 2 ($r = -0.17$, $P = .36$ vs. -0.07, $P = .67$). The correlations of TBUT, Schirmer 1, and Schirmer 2 with the CLDEQ-8 are shown in **Table 4** and **Table 5**.

Table 4: *r* value between CLDEQ-8 with TBUT, Schirmer 1 and Schirmer 2 showing a moderately negative correlation during baseline visit

Parameter	r-value	Correlation	p-value
CLDEQ-8 and TBUT	-0.39	Moderately Negative	< 0.02
CLDEQ-8 and Schirmer 1	-0.07	Moderately Negative	0.68
CLDEQ-8 and Schirmer 2	-0.17	Moderately Negative	0.36

A negative correlation indicates two parameters move in opposite direction. Significant *P* value is shown in bold font. TBUT = Tear break up time; CLDEQ-8 = Contact lens dry eye questionnaire-8.

Table 5: *r* value between CLDEQ-8 with TBUT, Schirmer 1 and Schirmer 2 showing a moderately negative correlation during first follow-up visit

Parameter	r-value	Correlation	p-value
CLDEQ-8 and TBUT	-0.34	Moderately Negative	<0.05
CLDEQ-8 and Schirmer 1	-0.07	Moderately Negative	0.70
CLDEQ-8 and Schirmer 2	-0.07	Moderately Negative	0.67

A negative correlation indicates two parameters move in opposite direction. Significant *P* value is shown in bold font. TBUT = Tear break up time; CLDEQ-8 = Contact lens dry eye questionnaire-8.

4. Discussion

Globally, around 140 million people use contact lenses,[15] yet dropout rates remain high, with 26% discontinuing within the first year, mainly due to discomfort from dryness, irritation, and fatigue.[16] Factors such as lens material, design, care regimen, and patient characteristics influence comfort,[17] making improved comfort critical to reducing dropout rates.[15]

Contact lens comfort depends largely on lens wettability and its interaction with the tear film.[5] Tear film instability, lipid layer disruption, and increased friction during blinking contribute to contact lens discomfort (CLD).[18] Reduced pre-lens tear film and lipid layer elimination further destabilise the tear film, increasing evaporation and discomfort.[19-22] Ocular surface disorders like dry eye can exacerbate these issues.[4,17]

This study found significant improvements in TBUT ($P < .0001$), Schirmer 1 ($P < .05$), and Schirmer 2 ($P < .01$) after two weeks of study lens wear. Reduced TBUT is strongly linked to CLD, as highlighted by TFOS in 2013,[23] with non-invasive TBUT recognised as a key indicator of lens dropout.[24] Guillon et al. reported reduced tear film coverage and increased blinking surface area in symptomatic

wearers.[18] Giannaccare et al. similarly found lower TBUT, Schirmer scores, and higher corneal staining among those who discontinued lens use.[25] Kastelan et al. noted a positive correlation between TBUT and Schirmer 2, linking tear film instability to increased evaporation.[22]

In contrast, Garcia Montero et al. found no significant ocular surface or tear film changes after 15 days of silicone hydrogel lens wear.[26]

The CLDEQ-8 questionnaire, validated for assessing CLD and contact lens-induced dry eye,[27,28] showed significantly higher scores with habitual lenses, which reduced significantly ($P < .0001$) after two weeks of study lens wear.

A moderate negative correlation was observed at baseline between CLDEQ-8 scores and TBUT ($P < .02$), Schirmer 1 ($P = .68$), and Schirmer 2 ($P = .36$), indicating higher symptom scores with reduced tear film values. A similar negative correlation was found after study lens wear, with decreased CLDEQ-8 scores as TBUT ($P < .05$), Schirmer 1 ($P = .70$), and Schirmer 2 ($P = .67$) values improved.

Reduction in discomfort and dryness with silicone hydrogels extends beyond improved oxygen supply.[29] Though silicone and conventional hydrogels have similar wettability, continuous wear leads to tear film component deposition, enhancing surface wettability.[30] Laboratory studies report significantly less protein deposition on silicone hydrogels.[31,32] which may reduce friction.[29]

Participants in this study previously used first-generation materials (Balafilcon A or Lotrafilcon B).[33] Balafilcon A employs TRIS-based plasma surface oxidation, while Lotrafilcon A incorporates siloxy macromers and TRIS, both requiring surface treatments to improve wettability. Newer lenses, like Samfilcon A, include advanced features such as internal wetting agents and modified chemistry to enhance clarity and wettability.[33] Samfilcon A utilises Moisture Seal technology, combining a high DK/t silicone matrix with low bulk modulus and a permanent internal wetting agent to improve water content and surface wetting.[34]

5. Limitations

This study has limitations; including a small sample size, limited demographic diversity, and the absence of certain diagnostic tools like tear osmolarity measurements, which may affect the generalisability and interpretation of the findings. These factors should be considered when interpreting results and planning future research.

6. Conclusions

Wearing Samfilcon A lenses for two weeks significantly improved dryness, discomfort, and tear function, enhancing overall lens comfort and reducing end-of-day symptoms, potentially supporting longer wear time. However, proper clinical assessment remains essential to ensure safety, comfort, and minimise dropout due to lens-related dryness and discomfort.

7. Source of Funding

None.

8. Conflict of Interest

None.

9. Ethical Approval

Ethical No.: SIMS & RC/IEC/10/2024

10. Ethical Approval and Registration Database

This study was reviewed and approved by the Sapthagiri Institute of Medical Sciences and Research Center Institutional Ethics Committee, Bangalore, India. Prospectively registered in Clinical Trials Registry – India (CTRI). Registration Number: CTRI/2024/05/067491.

11. Author Contributions

The authors have substantially contributed to the design of the framework, acquisition, analysis and interpretation of data for the work.

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