



Temporal changes in contact lens comfort over a day of wear

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Abstract

Purpose: Contact lens discomfort continues to be reported as the primary reason for soft lens discontinuation, regardless of new modalities and materials. The purpose of this analysis of comfort related data from a series of clinical studies was to review whether there was a difference between symptomatic and asymptomatic habitual lens wearers' comfort responses over the course of the day.

Methods: Data from five independent non-dispensing clinical studies were pooled and analysed. Participants in these studies were assigned to one of two groups depending on whether they were classified as symptomatic or asymptomatic contact lens wearers according to a modified Subjective Evaluation of Symptoms of Dryness (SESOD) questionnaire. Masked participants were randomised to wear either a hydrogel or a silicone hydrogel contact lens and their ocular comfort was rated using a visual analogue scale on insertion and 2-hourly during an 8-hour period of a single lens wearing day.

Results: Data from 103 participants were used, 58 in the symptomatic group and 45 in the asymptomatic group as determined by the SESOD questionnaire. There was no effect of lens material on comfort ($p = 0.43$). However, there was a significant interaction between symptoms and time. The difference in mean comfort between the symptomatic and asymptomatic group was significant at each time point ($p < 0.05$). However, comfort did not vary significantly over the day for the asymptomatic group ($p = 0.87$), whereas, there was a significant decline in mean comfort ratings for the symptomatic group from 84.6 ± 13.2 (S.D.) at insertion to 73.0 ± 18.5 at 8 hours ($p < 0.001$).

Conclusions: In our study, changes in contact lens comfort over a day were independent of lens material but not symptoms. Symptomatic lens wearers reported a progressive decrease in comfort, whereas asymptomatic wearers did not. Therefore, asymptomatic wearers should not be used when measuring contact lens comfort in clinical studies. The exclusion of asymptomatic lens wearers would likely increase the sensitivity of comfort ratings as a measure in contact lens research.

Introduction

Contact lens discomfort (CLD) has been reported as the primary reason for discontinuation of soft lens wear.^{1–3} This is despite the introduction of innovations such as silicone hydrogel materials⁴ and single use daily disposable lenses.³ In a recent review of the contact lens literature some authors reported an improvement in comfort by changing lens materials while others reported an alternate

effect.⁵ At best CLD reduces the comfortable wearing time of the patient, both over the day as well as over the life of the lens. The use of lubricating drops may help the patient to sustain wear and/or the patient simply has to tolerate lens discomfort.^{6–8}

CLD has been such a challenge to the contact lens industry that the Tear Film and Ocular Surface Society (TFOS) conducted a workshop to review the condition by staging a discussion platform for clarification of CLD and to

establish a knowledge base.⁹ The TFOS International Workshop on Contact Lens Discomfort developed a definition of contact lens discomfort as ‘a condition characterised by episodic or persistent adverse ocular sensations related to lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation from contact lens wear’. The conclusion was that CLD is a poorly characterised condition with little known about its temporal progression.¹⁰

CLD is associated with ageing of the lens but it also occurs over the day of wear.^{3,11–15} Patients have been reported to wear their lenses for total wearing times that exceed their comfortable wearing time.¹⁶ It is not unreasonable to suspect that both end of day discomfort and discomfort associated with the lens age would contribute to patient dissatisfaction from lens wear.^{11,13} Papas *et al.*¹¹ demonstrated that lens discomfort towards the end of the day was not influenced by lens replacement midway through the day of wear, suggesting comfort decrements were not caused by changes occurring to the lens but may be a fatigue like response in neophyte participants. In analysis of a number of clinical studies investigating the performance of silicone hydrogel lenses Truong *et al.*¹⁷ concluded that excessive lens movement, poor fit, detrimental surface characteristics, inferior corneal staining and the Asian eye were all factors contributing to CLD.

The Centre for Contact Lens Research at the University of Waterloo conducted a series of contact lens studies investigating lens comfort over a day of wear. These studies utilised the same study design but investigated a variety of different lenses, both hydrogel and silicone hydrogel. The purpose of the analysis reported here was to assess CLD over the course of a day from five of these studies that included ‘successful’ habitual contact lens wearers. From this analysis it was hoped to contribute additional information to the literature on:

- how contact lens comfort changed over a day of wear;
- whether the change in comfort could be characteristic of specific lens materials and;
- whether the change in comfort differed between symptomatic and asymptomatic lens wearers.

To our knowledge this is the first time all of these factors have been addressed in a single analysis from a pooled data source.

Methods

Study design

A review of the data from five studies conducted within a 12-month period at the Centre for Contact Lens Research

was undertaken. These studies followed similar protocols with regard to masking, randomisation, lens wearing periods, comfort rating collection and participant recruitment. In these studies, two different lens types were worn for a single day over an 8-hour period. Lens fit, vision and physiological responses were monitored as well as the study participants’ comfort rating at insertion and every 2 hours thereafter up to the 8-hour time point.

The lenses under investigation were approved medical devices fabricated in either hydrogel or silicone hydrogel materials. For this manuscript the data relating to contact lens comfort are reported.

Study participants

For all studies, ethics clearance was obtained through the Office of Research Ethics at the University of Waterloo. Participants provided written informed consent before entering the study. All participants were treated in accordance with the tenets of the Declaration of Helsinki and the studies were conducted according to Good Clinical Practice Guidelines. Successful habitual soft lens wearers were recruited. Habitual was defined as having worn lenses for more than the 6 months prior to recruitment. Study group assignment (*Figure 1*) was based on a declaration that the participants were able to wear their habitual contact lenses for more than 8 hours. The participants were stratified into two groups: Those that developed symptoms relating to lens wear after 8 hours, the symptomatic group and those that did not report symptoms relating to lens wear, the asymptomatic group.

For participant recruitment, the intensity of symptoms from lens wear was assessed using an adapted version of

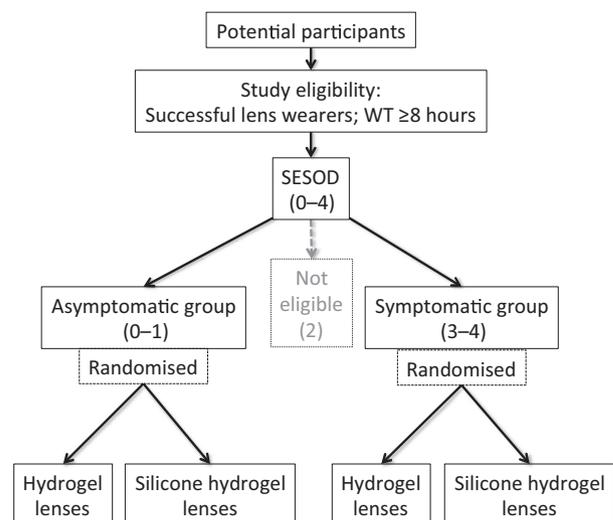


Figure 1. Flow chart of participant review and group assignment.

the Subjective Evaluation of Symptoms of Dryness (SESOD) questionnaire.¹⁸ The adaptation of the SESOD questionnaire was within the stem of the question only, where ‘your contact lenses’ replaced ‘the symptoms of dryness’, see *Figure 2*.

The SESOD questionnaire was selected as it has been demonstrated to be an effective screening tool to discriminate study participants.¹⁹ The group assignment was based on the intensity of their symptoms as follows:

- SESOD grading of 0 or 1 = Asymptomatic group,
- SESOD grading of 2 = not assigned to a study group and,
- SESOD grading of 3 or 4 = Symptomatic group.

Randomisation and masking

For all studies, once participants were classified as either symptomatic or asymptomatic they were randomised to wear either hydrogel lenses or silicone hydrogel lenses. Both the participant and the investigator were masked from group assignments; Asymptomatic or Symptomatic group and Hydrogel or Silicone hydrogel lens group (*Figure 1*).

Comfort ratings

Participants were asked to rate the comfort of the study lenses using a visual analogue scale, which was then converted to a numerical 1–100 rating, where 1 was very poor (unwearable) and 100 represented excellent (not aware of

the lens). After lens insertion, lens comfort was then assessed every 2 hours for an 8-hour period.

Data review and statistical analysis

Data were collated using Microsoft Excel, with statistical analyses being performed using SPSS (IBM). A two-way repeated measures ANOVA was conducted to determine whether or not there were statistically significant differences in comfort, with ‘time’ as the within factor, and ‘symptom group’ and ‘lens material’ as the between factors.

Interaction terms were investigated and, where significant, simple main effects were determined and analysed. *Post-hoc* tests of all pair-wise comparisons were conducted using the Bonferroni test. An α level of less than or equal to 0.05 was considered statistically significant. Finally, error bars in figures represent the 95% confidence intervals ($\pm 1.96 \times S.E.$).

Results

Data from 103 participants were eligible for analysis. Fifty-eight participants formed the symptomatic group and 45 formed the asymptomatic group, as determined by the SESOD questionnaire. Participants were then randomly assigned to wear hydrogel or silicone hydrogel contact lenses, *Table 1*.

All participants completed the study by wearing the assigned lenses over the 8 hours on the study day, with comfort ratings (1–100) successfully recorded following

Evaluate your end of day ocular discomfort due to your contact lens wear on a scale of 0 (none) to 4 (severe). You may use the following descriptions to assist in your score.			
Discomfort	Grade	Description	Study group assignment
None (0)		I do not have this symptom	Asymptomatic participant
Trace (1)		I seldom notice this symptom, and it does not make me uncomfortable	
Mild (2)		I sometimes notice this symptom, it does make me uncomfortable, but it does not interfere with my activities	Not eligible for study
Moderate (3)		I frequently notice this symptom, it does make me uncomfortable, but it sometimes interferes with my activities	Symptomatic participant
Severe (4)		I always notice this symptom, it does make me uncomfortable, but it usually interferes with my activities	

Figure 2. The adapted SESOD questionnaire.

Table 1. The distribution for study participants between lens material and their Symptomatic and Asymptomatic study groups

	Symptomatic group	Asymptomatic group
Total (n)	58	45
Hydrogel material group (n)	29	24
Silicone hydrogel material group (n)	29	21

insertion and then at 2, 4, 6 and 8 hours of lens wear by all participants.

Comfort ratings

For the comfort rating data the assumptions for use of repeated measures ANOVA were checked and it was found that the assumption of sphericity was violated, as assessed by Mauchly’s test of sphericity, ($\chi^2 = 145.3, p < 0.001$). Therefore, a Greenhouse-Geisser correction was applied ($\epsilon = 0.60$).

The results of the repeated measures ANOVA for the comfort ratings as the dependent variable are reported in Table 2.

There was no significant main effect of lens material ($p = 0.43$). However, there was a statistically significant interaction between symptom group and time ($p < 0.001$), as evident in Figure 3. An analysis of the simple main effects and pairwise comparisons showed a statistically significant difference between the Symptomatic and Asymptomatic groups at each time point ($p < 0.01$), from lens

Table 2. Results of the repeated measures ANOVA for comfort over time, with between group factors of ‘symptom group’ and ‘lens material’

Source of variation	Sums of squares	df	Mean square	F	p
Time	3819.8	2.4	1589.9	15.4	<0.001
Time × Symptom Group	2282.1	2.4	949.9	9.2	<0.001
Time × Lens Material	112.2	2.4	46.7	0.5	0.67
Time × Symptom Group × Lens Material	376.4	2.4	156.7	1.5	0.22
Error (Time)	24 564.6	237.9	103.3		
Symptom Group	16 872.3	1	16 872.3	34.4	<0.001
Lens Material	314.6	1	314.6	0.6	0.43
Symptom Group × Lens Material	93.3	1	93.3	0.2	0.66
Error (Symptom Group × Lens Material)	48 503.2	99	489.9		

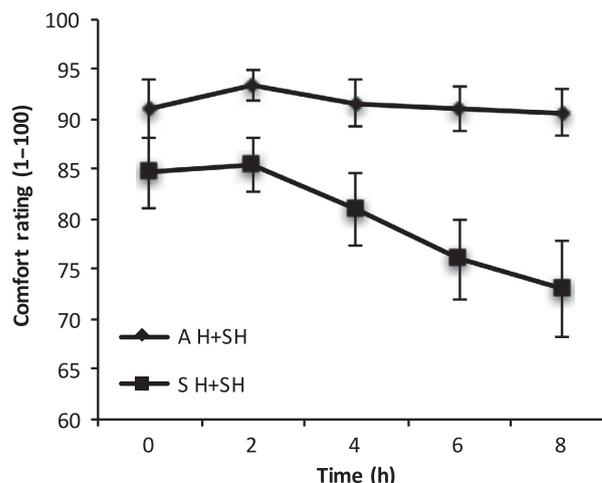


Figure 3. The comfort ratings for both the asymptomatic participant group (A H+SH) and the symptomatic participant group (S H+SH) with the lens materials combined.

insertion to the 8-hour time point. However, the change in comfort with time for the Asymptomatic group was not statistically significant, from a mean of 91.0 ± 9.8 (S.D.) at insertion to a mean of 90.6 ± 7.8 at 8 hours ($p = 0.87$). Whereas, there was a statistically significant decline in comfort ratings for the Symptomatic group, from a mean of 84.6 ± 13.2 at insertion, to a mean of 73.0 ± 18.5 at 8 hours ($p < 0.001$).

Discussion

The analysis presented here suggests that decreasing contact lens comfort over the first 8 hours of wear is not related to material type, hydrogel vs silicone hydrogel. In the literature the view is mixed regarding a comfort advantage between hydrogel and silicone hydrogel materials.^{5,20,21}

Considering our comfort data combined for both materials it appears that the Asymptomatic group remained comfortable during the 8 hours of wear as there were no time dependent differences. However, the Symptomatic group was different from the Asymptomatic group as their comfort ratings obviously decreased over the course of the day. It is important to appreciate that while comfort decayed during the 8 hours for the Symptomatic group the rating after 8 hours of lens wear was still reasonably high at 73 ± 18.5 . This high score probably reflects the fact that these participants were able to wear their lenses habitually in a satisfactory manner. An oddity of this study was the apparent lower comfort rating for the Symptomatic group (84.6 ± 13.2) compared to the Asymptomatic group (91.0 ± 9.8) at the lens insertion time point. Although this difference was statistically significant, it might not be considered clinically meaningful. Papas et al.²² reported that

the just noticeable difference between groups needed to be 7–8 points on a similar 1–100 numerical scale.

The decay in comfort in the Symptomatic group did not occur until after the 2-hour time point, the decay progressing thereafter. Changes in comfort over the day may occur in several ways including being confined to the end of the day or a gradual decline over the day. Our data supports a gradual decline, suggesting that ‘comfortable wearing time’ does not reflect the graded nature of the change in comfort. Our study suggests a level of discomfort exists in symptomatic lens wearers throughout the day and supports previously reported data suggesting lens wearers persist with lens wear beyond their comfortable wearing time.¹⁶

Some studies investigating lens comfort choose not to recruit participants by their experience and level of symptoms, often combining habitual lens wearers with neophytes.^{11,23} The challenge is to create a participant group that is sensitive enough to demonstrate a difference or be able to notice a change in their symptoms. An experienced symptomatic group of lens wearers’ demonstrates substantial change over time compared to an asymptomatic group, as reported here. If the two groups had not been differentiated, then asymptomatic wearers comfort data would have dampened the lens comfort rating changes over time and negated the effect. The results from our study clearly show the importance of the separation of participants by symptoms. Similarly, the use of neophytes in such studies requires caution. Naduvilath *et al.*²⁴ found neophytes consistently reported lower levels of comfort in comparison to lens wearers. The reasons for the absence of a change in comfort over time for asymptomatic wearers compared to symptomatic wearers, remains unclear. Two possible considerations may be that asymptomatic participants either lack the ability or an awareness to detect change or they genuinely may not have a change in comfort.

With the majority of lens wearers discontinuing lens wear due to decreasing comfort towards the end-of-day, understanding CLD is important. Any approach to understanding CLD needs to consider a variety of factors; Dumbleton *et al.*³ reported that there was a link between comfort and over-wearing lenses beyond their expected life cycle. Papas *et al.*^{11,12} focussed on the discomfort reported over the course of a day by reviewing the impact lens replacement had on comfort. They concluded discomfort was not related to wearing recycled lenses or replacing the lens with a new lens during the course of day but more likely an ocular fatigue response and subsequently reduces the wearing time leading to lens drop-out. Navascues-Cornago *et al.*¹³ suggested that the decline in comfort over time (12 hours) was more likely due to changes to the ocular environment rather than a lens effect. Stapleton *et al.*²⁵ concluded from their literature review on neurobiological mechanisms for CLD that it

was likely multifactorial and complex. Certainly the results from our study assert that the lens material does not play a role in changes to comfort ratings, for hydrogel vs silicone hydrogel lenses.

In our analysis we used an adapted SESOD questionnaire in an attempt to produce two participant groups that were differentiated by symptoms (*Figure 1* and *Table 1*). The selection of those who graded the SESOD questionnaire as 0 or 1 were considered to be asymptomatic, those who graded 2 were excluded and those grading 3–4 as symptomatic participants has been shown here to be effective, or was at least able to successfully create two groups of participants who utilise a visual analogue scale in a similar way (*Figure 2*). The data in this study demonstrates that the adapted SESOD was an effective recruitment tool to separate symptomatic and asymptomatic contact lens wearers.

Study limitations

The conclusions drawn in this manuscript may require a modicum of caution due to some limitations in the data. While the pooled data were taken from five studies of similar protocol some variance may still have occurred between these studies, even though the same investigator was used to collect the data. The data for all hydrogel lens brands were pooled as were the data for the silicone hydrogel brands, an assumption being made that each lens material type behaved similarly, this may not have been the case. Finally, the data were only collected up to 8 hours of lens wear and so conclusions regarding what changes may occur for either study group beyond that could not be derived.

Conclusion

In our study, changes in contact lens comfort over a day were independent of lens material but not symptoms. Symptomatic lens wearers reported a progressive decrease in comfort, whereas asymptomatic wearers did not. Therefore, asymptomatic wearers should not be used when measuring contact lens comfort in clinical studies. The exclusion of asymptomatic lens wearers will likely increase the sensitivity of comfort ratings as a measure in contact lens research.

Disclosure

The authors report no conflicts of interest.

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