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Impact of soft contact lenses on lid- parallel conjunctival folds

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ABSTRACT

Purpose: Lid-parallel conjunctival folds (LIPCOF) are related to dry eye symptoms and appear to be related to mechanical forces in blinks. The primary aim of this longitudinal, parallel group study was to investigate impact of contact lens wear (CLW) on LIPCOF and secondly the impact of contact lens wear on lid-wiper epitheliopathy (LWE) and dry eye symptoms.

Methods: After a 2-week wash-out phase with a hydrogen peroxide care regimen, 30 experienced contact lens wearers (female: 25, male: 5; median age: 34.5 years) with at least LIPCOF Sum grade 1 (nasal + temporal LIPCOF, either eye) were randomised into three groups: one which discontinued CLW (SPEC), one which were refitted with senofilcon A two-weekly replacement daily wear silicone hydrogel (OAS) and one which continued to wear their habitual lenses (HCL). LIPCOF Sum and LWE were evaluated at the enrolment visit and over a period of 12 weeks. LIPCOF were classified by fold number using a four-grade scale. LWE was classified using a five-point scale after staining with lissamine green and fluorescein. Symptoms were evaluated with the Ocular Surface Disease Index (OSDI).

Results: On enrolment, there were no differences between groups for LIPCOF Sum (median 2.0), LWE (1.0) and OSDI scores (12.5) (Kruskal-Wallis, $p > 0.718$). Median changes at 12-weeks follow-up compared to the enrolment visit were (HCL-group: 0.5, 0.0, 0.0; OAS-group: −1.0, −0.5, −10.42; SPEC-group: −0.5, −0.5, −5.21; LIPCOF, LWE and OSDI, respectively). LIPCOF (Friedman-Test, $p = 0.178$), LWE ($p = 0.791$) and OSDI ($p = 0.874$) were unaltered over the period of observation in the HCL group. LWE ($p = 0.120$) was unaltered in OAS group but LIPCOF ($p = 0.001$) and OSDI ($p = 0.003$) significantly improved. In the SPEC group LIPCOF ($p = 0.031$), LWE ($p = 0.002$) and OSDI (ANOVA repeated measurements, $p = 0.034$) changed significantly.

Conclusions: Refitting experienced CLW with senofilcon A daily wear, 2-week reusable contact lenses, or ceasing lens wear, improved LIPCOF, LWE and dryness symptoms.

1. Introduction

Many soft contact lens wearers report dry eye symptoms when wearing contact lenses. [1,2]. The frequency of contact lens related dry eye is approximately 50% [1,3,4]. It can be associated with a reduction in visual acuity and wearing comfort as well as an increased risk of ocular surface alterations and infection [5]. Discomfort during contact lens wear is the major cause of discontinuation with established wearers [6]. Approximately half of patients who drop-out from contact lens wear in the UK and three-quarters in the USA, do so because of discomfort [7,8]. Furthermore, based on Pritchard et al. 12% of new contact lens patients discontinued lens wear within a five year period due to these symptoms [5]. A retrospective study reported, that during the first year of contact lens wear, the overall retention rate for neophytes was 74%, with many lapsing during the first 2 months [9].

There is evidence that the coefficient of friction (CoF) of contact lens surfaces is significantly related to the wearing comfort [10–12]. Consequently, new contact lenses materials with low CoF were developed [13].

However, to the best of our knowledge, it is unknow if clinical signs of friction in blinks improve when refitting patients with low CoF contact lens materials.

Lid parallel conjunctival epithelial folds (LIPCOF) and lid wiper epitheliopathy (LWE) are thought to be clinical indicators of mechanical forces between the sliding partners the lid wiper and the ocular surface, or in contact lens wear between the sliding partners the contact lens surface and the lid wiper plus the contact lens back-surface and the ocular surface [14]. Whilst they are relatively uncommon diagnostic

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tests in clinical practice, they have been shown to be excellent predictors of successful contact lens wear in both neophytes and habitual lens wearers [15,16]. LIPCOF and LWE grades are significantly increased in symptomatic lens wearers [17,18].

LIPCOF are small bulbar conjunctival folds along the lower lid margin and are observed as extending perpendicularly from the temporal and nasal limbus [15,19,20]. Bulbar conjunctival folds were first described by Middlemore in 1835 without any classification [21]. To our knowledge, Hughes [22] later named these prominent folds *conjunctivochalasis* (CCH). The term CCH has changed over time. Meller and Tseng [23] described CCH as being used in the 80´s to describe "moderate CCH" and in the 90´s for "mild CCH". CCH is manifested by the easy displacement of conjunctiva from the episclera and the formation of pleated folds, especially visible just over the rim of the lower lid and increases due to forced blinks [21,23]. However, LIPCOF, as described in this report, represents a much milder stage, with fold thickness of around 0.08 mm [24] and less laxity to that commonly described in CCH [25–27].

LWE is a clinically observable alteration in the epithelium of the advancing lid margin, the lid wiper. In patients with dry eye the lid wiper is assumed to be subjected to trauma during the eye movements [14,18,28]. As there is a strong correlation in the presence of LWE and LIPCOF it is thought they share a common frictional origin [15,29]. Therefore, LIPCOF and LWE are thought to represent indirect, *in-vivo* measures of ocular surface friction during eye movements [30].

The primary aim of this longitudinal study was to investigate how LIPCOF recovers or persists after the continued use of habitual lens wear, discontinuation of contact lenses, or after refitting with low CoF contact lenses. The secondary aim of this study was to analyse the impact of contact lens wear on LWE and dry eye symptoms.

2. Methods

This was an open label, longitudinal, parallel group study. After a 2-week wash-out phase with a hydrogen peroxide care regimen (AOSept, Alcon), 30 experienced daily wear contact lens wearers (female: 25, male: 5; median age: 34.5 years; Table 1) with at least LIPCOF Sum grade 1 (nasal + temporal LIPCOF, either eye) were randomised into three groups: one which discontinued contact lens wear and were fitted with glasses (SPEC), one which were refitted with senofilcon A, two-weekly replacement daily wear silicone hydrogel (OAS) and one which continued to wear their habitual lenses (HCL, Fig. 1). The coefficient of friction (CoF) of the senofilcon A silicon hydrogels lens was 0.018 [31] and the COF of the HCL group ranged from 0.091 to 0.423 [31]. However, the CoF of the "55% water content unknown HEMA (eyelike GmbH, Neuberg, Germany)" soft contact lens (Table 1) was unknown. LIPCOF Sum and lid wiper Epitheliopathy (LWE) were evaluated at the enrolment visit and over a period of 12 weeks for both eyes (Fig. 1) each time by the same observer (HP). Dry eye symptoms were evaluated with the Ocular Surface Disease Index (OSDI) [32]. The investigator was masked against observations evaluated in previous visits. All subjects were masked against treatment, except of the SPEC group. All subjects were recruited from the optometry patient pool of Horst Riede GmbH, Weinheim, Germany. All subjects gave written informed consent before participating in the study. Ethical approval was given by the 'Freiburger Ethik Kommission', Freiburg, Germany. All procedures were conducted in accordance with the Declaration of Helsinki (1983).

2.1. Lid parallel conjunctival folds (LIPCOF)

LIPCOF were evaluated in the area perpendicular to the temporal and nasal limbus on the bulbar conjunctiva above the lower lid (temporal and nasal LIPCOF, respectively) with a slit-lamp microscope using 25x magnification, and classified using the Pult LIPCOF grading scale [15,20]. A further combined LIPCOF score (LIPCOF Sum) was calculated by adding together the nasal LIPCOF grade and temporal LIPCOF grade [15]. Care was taken to differentiate between parallel, permanent conjunctival folds (LIPCOF) and disrupted micro-folds.

2.2. Lid wiper epitheliopathy (LWE)

Lid-wiper epitheliopathy (LWE) was made visible using a combination of instilled 1% lissamine green and 2% fluorescein, and evaluated for the upper lid. LWE was observed using a slit-lamp microscope with 18x magnification, classified according to Korb et al. [33] Care was taken to differentiate between the fluorescein and lissamine staining associated with Marx's line and that from staining of the lid wiper [33].

2.3. Ocular surface disease index (OSDI)

Each subject's symptoms were evaluated after objective observation by a validated German translation of the OSDI questionnaire. Total OSDI scores were calculated as recommended by Schiffman et al. [32].

$$\text{OSDI} = \frac{\textit{sum of scores x } 25}{\textit{number of questions answered}}$$

2.4. Inclusion and exclusion criteria

Subjects were enrolled in the study if they were at least 18 years old, subject's contact lens correction was in the range of −6.00 to +6.00 in each eye and refractive cylinder less than 1.00D in each eye. The subject must have best corrected visual acuity of 20/40 or better in each eye and must have demonstrated adequate mobility and 20/40 vision OD and OS with the study contact lenses or the spectacles in the SPEC group. The subject must have been an adapted soft contact lens wearer in both eyes with at least 1-years' experience in contact lens wear. The subject must have had a LIPCOF degree of at least 1.

Table 1
Percentage of contact lens material of each of the three groups worn at visit.

Contact Lens Material	Wearing Mode	Habitual Group	Senofilcon A Group	Spectacle Group
55% water content unknown HEMA (eyelike GmbH, Neuberg, Germany)	4 weeks daily	10%	0%	30%
Balafilcon A (Bausch & Lomb GmbH, Berlin, Berlin)	4 weeks daily	30%	0%	0%
Nelficon A (Alcon Pharma GmbH, Großostheim, Germany)	one day	10%	0%	10%
Lotrafilcon A (Alcon GmbH, Großostheim, Germany)	4 weeks daily	10%	10%	0%
Lotrafilcon B (Alcon GmbH, Großostheim, Germany)	4 weeks daily	50%	20%	10%
Comfilcon A (Cooper Vision GmbH, Eppertshausen, Germany)	4 weeks daily	0%	20%	20%
Hioxifilcon (Emergo Europe, The Hague, Netherlands)	4 weeks daily	0%	10%	0%
Metafilcon A (LinsenPlatz.de, Diez/Lahn, Germany)	4 weeks daily	0%	10%	0%
Oculfilcon D (Cooper Vision GmbH, Eppertshausen, Germany)	4 weeks daily	0%	20%	10%
Phemfilcon A (Alcon GmbH, Großostheim, Germany)	4 weeks daily	0%	10%	0%
Delefilcon A (Alcon GmbH, Großostheim, Germany)	one day	0%	0%	10%
Enfilcon A (Cooper Vision GmbH, Eppertshausen, Germany)	4 weeks daily	0%	0%	10%

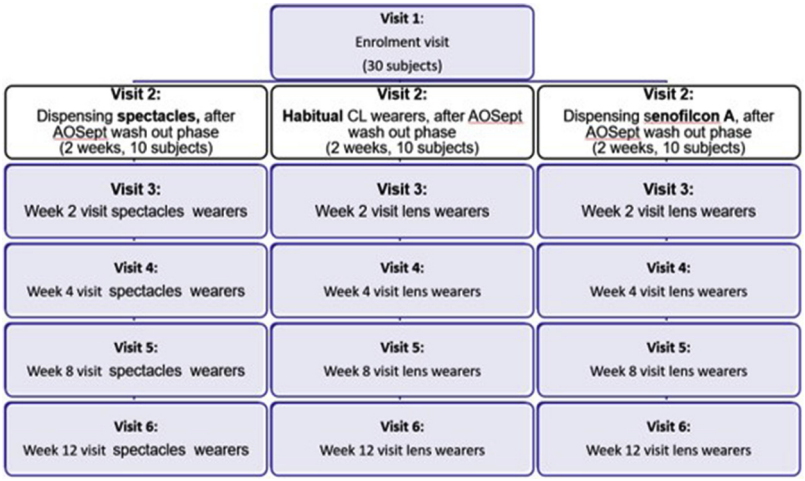

Fig. 1. Study protocol. LIPCOF, LWE of both eyes and OSDI were observed at visits 1, 3, 4, 5 and 6 (blue boxes) over a 12-week study period.

Subjects were excluded if they were currently self-reported pregnant or lactating. Further exclusion criteria were any ocular or systemic allergies or diseases that may interfere with contact lens wear as well as prior refractive surgery. Subjects were excluded with any grade 3 or greater slit lamp findings (e.g., oedema, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale, any previous history or signs of a contact lens-related corneal inflammatory event or any other ocular abnormality that may contraindicated contact lens wear, any ocular infection. Monovision or multi-focal contact lens correction were excluded, as well as participation in any contact lens or lens care product clinical trial within 90 days prior to study enrolment. They were excluded if the contact lens wearing time was less than 6 h/day and/or 5days/week, wearing of senofilcon A lenses or extended wear of any contact lenses.

2.5. Statistical analyses

Data of all eyes (LIPCOF and LWE but of each subject for the OSDI) were analysed for normal distribution using Shapiro-Wilk test. Differences between groups at the enrolment visit were analysed using Kruskal Wallis test. Repeated measurements were analysed using ANOVA repeated measurements or Friedman-Test in non-parametric data. The data were analysed using SPSS 20.0 (SPSS Inc., Chicago, USA) and BiAS 10.5 (Epsilon Verlag, Frankfurt, Germany).

3. Results

On enrolment, the median grade of LIPCOF Sum was 1.8 (1.0 and 2.75, 25% and 75% interquartile, respectively), the median LWE grade was 1.0 (0.5; 1.0) and the median OSDI score was 13.5 (6.3; 20.0) On enrolment, there were no differences between groups for LIPCOF Sum, LWE) or OSDI scores (Kruskal-Wallis, $p > 0.718$).

Median changes at 12-weeks follow up compared to the enrolment visit were in the HCL-group 0.5, 0.0, 0.0 (LIPCOF, LWE and OSDI, respectively, Figs. 2–4), in the OAS-group −1.0, −0.5, −10.42 and in the SPEC-group −0.5, −0.5, −5.21. LIPCOF (Friedman-Test, $p = 0.178$), LWE ($p = 0.791$) and OSDI ($p = 0.874$) were unaltered over the period of observation in the HCL group. LWE ($p = 0.120$) was unaltered in OAS group but LIPCOF ($p = 0.001$) and OSDI ($p = 0.003$) significantly improved. In the SPEC group LIPCOF ($p = 0.031$), LWE ($p = 0.002$) and OSDI (ANOVA repeated measurements, $p = 0.034$) changed significantly.

Post-hoc testing (Fig. 2) revealed these significant changes for LIPCOF having occurred for the OAS group between visit 1 and 3, 1 and 4, 1 and 5, 1 and 6. In the SPEC group this occurred between visit 1 and 4 as well as 1 and 6 (1 and 3 only without Bonferroni correction).

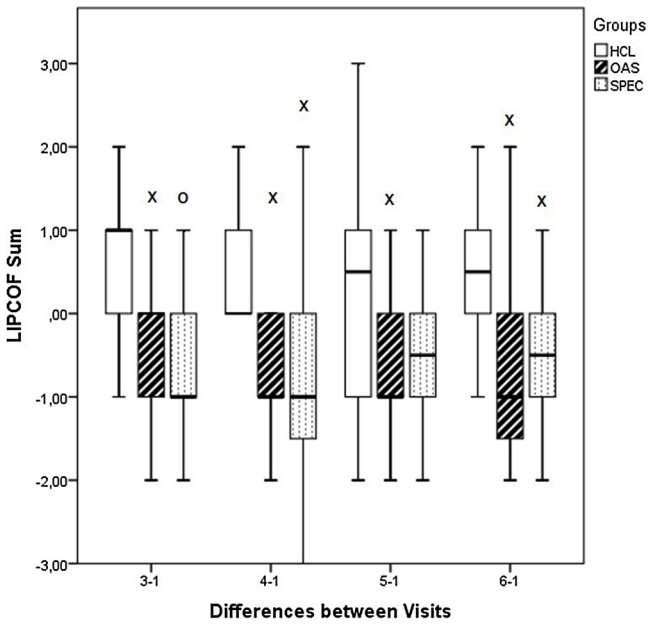

Fig. 2. Box plots of changes of LIPCOF Sum (LIPCOF Sum scores of visit 3–6 - LIPCOF Sum scores of Visit 1).

However, excluding those subjects who had LWE grades less than 1 at the enrolment visit resulted in a significant improvement of LWE in the SPEC (6 subjects) and OAS group (7 subjects) ($p < 0.032$) but not HCL group (6 subjects; $p = 0.814$).

Post-hoc testing (Fig. 3) revealed these significant changes having occurred for the OAS group between visit 1 and 3, 1 and 4, 1 and 6 (1 and 5 only without Bonferroni correction). In the SPEC group, this occurred between visit 1 and 4 as well as 1 and 6 (1 and 3 only without Bonferroni correction).

Comparing visit 6 to 1 resulted in a median improvement of LWE in the HCL-group of −0.25 (−0.5 and 0.5, 25% and 75% interquartile, respectively) in the OAS-group of −1.0 (−2.0 and −0.5, 25% and 75% interquartile, respectively) and in the SPEC-group of −1.0 (−1.0 and −1.25, 25% and 75% interquartile, respectively).

4. Discussion

In this study, habitual daily wear contact lens wearers where either refitted with senofilcon A contact lenses (group OAS), stopped wearing contact lenses (group SPEC) and wore spectacles, or continued wearing

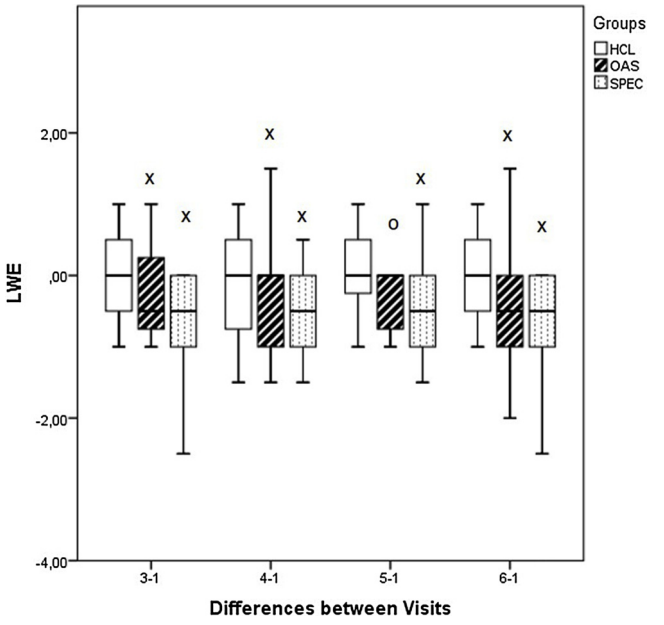

Fig. 3. Box plots of changes of LWE (LWE scores of visit 3–6 - LWE scores of Visit 1). *Asterisks indicates significant changes, bullets indicate significant changes without Bonferroni correction.*

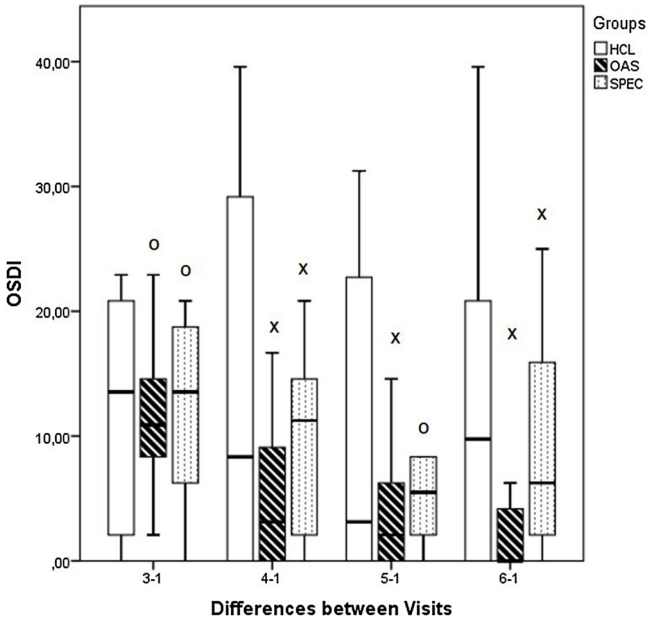

Fig. 4. Box plots of changes of OSDI scores (OSDI scores of visit 3 to 6 - OSDI scores of Visit 1). *Asterisks indicates significant changes, bullets indicate significant changes without Bonferroni correction.*

their habitual contact lenses (group HCL). Over a period of 12 weeks, the ocular signs LIPCOF and LWE, as well as dry eye symptoms, were observed. While in the HCL group no significant changes of the ocular signs or symptoms were detected in this study, LIPCOF and OSDI significantly improved in the both of the other groups after just 2 weeks; and this improvement was larger as the reported 95% coefficient of repeatability of LIPCOF (± 0.8) [24], but not of LWE (± 0.9) [34] and it was maintained throughout the study. LIPCOF may be caused by mechanical forces between the ocular surface and the lids in blinks and eye movements [14]. This mechanical interaction mainly depends on the CoF of the surfaces [14]. As the ocular surface as well the lid wiper is protected by the glycocalyx and mucins, there is likely no wear between sliding partners due to the so called brush-to-brush friction [14]. However, the core mechanism of dry eye clearly highlights a mucin deficiency in dry eye patients [35]. Consequently, there is increased friction between sliding partners in dry eye at low sliding velocity. In soft contact lens wearers, the interacting sliding partners are mainly the contact lens surface and the lid wiper in terms of LWE; and the contact lens back surface and the cornea and conjunctiva. More precisely, that area of the conjunctiva being covered and impacted by the contact lens – including that area impacted in lens movement. While that area of the bulbar conjunctiva not being covered by the contact lens is impacted by the lid wiper – this will be the very nasal and temporal lid wiper and conjunctiva region. LIPCOF are in the region covered by the soft contact lens or at least impacted by lens movements in blinks. The contact lens movement is mainly at the low sliding velocity such the brush-to-brush friction may be the main component for LIPCOF.

In this study the HCL subjects worn contact lenses with higher CoF than those fitted by senofilcon A lenses [31]. Hence, it could be assumed that LIPCOF improved because of the lower CoF (back surface) of the senofilcon A lenses compared to the other lenses. However, also in the SPEC group, LIPCOF degrees significantly decreased, while this was not observed for the HCL group. The most reasonable hypothesis may be that ceasing lens wear resulted in better brush-to-brush friction due to a better glycocalyx of the bulbar conjunctiva and lid wiper. Indeed, contact lenses disturb the tear film and may result in dry eye status in almost every second contact lens wearer [12]. Not wearing contact lenses at all may have improved the tear film status and consequently the glycocalyx of the ocular surface and lid wiper, resulting in reduced mechanical interaction between both sliding partners.

In contrast to LIPCOF, LWE did not significantly change in all the groups. The primary aim of this study was to evaluate LIPCOF. To be able to observe any improvement of LIPCOF, subjects were included for the study when they had at least LIPCOF degree 1. Such a criterion was not defined for LWE. Therefore, some of the subjects had no signs of LWE; this may be the reason not finding any significant improvements in LWE. Indeed, when excluding all subjects with less than a LWE degree 1 in the statistical analyses of the data, LWE significantly improved in the SPEC and OAS groups.

This may make sense as similar interactions between the lid wiper and the contact lens occur as already discussed for LIPCOF. However, in case of LWE, the front surface of the contact lens material needs to be considered, not the back surface as discussed for LIPCOF.

LIPCOF and LWE are significant predictors of dry eye in lens wearers and non-lens wearers [15,16,19,20,36].

Consequently, it may be reasonable that OSDI scores also decreased in both groups (OAS and SPEC).

This is supported by the evidence that wearing comfort of contact lens is significantly related to the CoF of contact lenses [11,13,37].

However, in addition or instead of the CoF theory, the contact lens edge may be a crucial factor, as the lid is wiping over the lens edge thousands of times a day with LWE, and the lens is moving up and down in any blinks and is ‘rubbing’ over the bulbar conjunctiva with LIPCOF.

Indeed, the senofilcon A lens` edge design appears one of those being most comfortable [13]. However the contact lens edges of the habitual contact lenses of this study were not all known, but as symptoms an designs improved in the SPEC group too, the contact lens edge may either not being the factor here, or not the only factor. Interestingly, the improvement in terms of LIPCOF and OSDI was highest in the SPEC group. Such further or additional effects as only the CoF may need to be investigated in future studies. Furthermore, as shown in Table 1, previous worn lens type was not consistent between groups. Possible effects need to be evaluated in a larger cohort study, as well as gender effects, as in this study the majority were female.

5. Conclusions

LIPCOF and LWE are recognized as sensitive tests to predict and to evaluate contact lens related dry eye [15,18,38]. This study is the first time that effects of low CoF contact lenses - or discontinuing contact lens wear - on LIPCOF and LWE were observed. LIPCOF and LWE significantly improved when refitting subjects with senofilcon A daily wear, 2-weekly replacement lenses, or with contact lens wear discontinuation. Both signs are assumed to be promising clinical tests indicators on the impact of lens CoF on the ocular surface.

Refitting experienced contact lens wearers with senofilcon A, daily wear, 2-weekly replacement contact lenses, or ceasing lens wear, may be a promising management option for LIPCOF, LWE and contact lens-related dryness symptoms.

Disclosure

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