**TITLE:** Changes of symptomatology, tear film and ocular surface integrity one week during Somofilcon-A and Omafilcon-A lens wear

**SHORT TITLE:** One week impact of Somofilcon-A and Omafilcon-A lens

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## ABSTRACT

**Purpose:** Clinicians play a key role in prescribing contact lenses that best suited for fitting which materials had an impact on ocular surface parameters. The present study aimed to evaluate the impact on symptomatology, tear film dynamics and ocular surface integrity of a silicone-hydrogel (Somofilcon-A) and a hydrogel (Omafilcon-A) lens before and after wearing for one week in contact lens neophyte participants.

**Methods:** A Somofilcon-A and Omafilcon-A were randomly fitted to one or other the eye on an initial group of 28 participants. Subjects were scheduled for three sessions: basal session previous fitting, second session after 4-wear hours, and final session after 7-wear days for up to 10 hours. In each session, CLDEQ-8, tear meniscus height and hyperemia with and without lenses, as well as lipid layer thickness and corneal/conjunctival staining without lenses were assessed. Values were compared between lenses and sessions.

**Results:** In intrasession comparison, there were no differences in any parameter between materials on any session with or without lenses (all $p \geq 0.176$), except on the conjunctival staining where values obtained during Somofilcon-A wear (all $p \leq 0.006$). In intersession analysis, CLDEQ-8 score, tear meniscus height and lipid layer thickness showed a statistical difference during both materials wear (all $p \leq 0.009$), while conjunctival hyperemia does not ($p=0.237$); corneal staining showed differences during Omafilcon-A wear ($p=0.037$), contrary to conjunctival staining which showed differences only during Somofilcon-A wear ($p<0.001$).

**Conclusion:** Contact lenses wear had an impact on ocular parameters that have some specific influences of the material on which lenses were manufactured.

## INTRODUCTION

In the last decades, there has been a continuous increase in contact lenses prescription as an option for refractive compensation.[1, 2] Even though new materials have been introduced in the market, complaints are still reported by contact lens-wearers, at the end of the day, or will drop-out cease lens wear.[3-5] Contact Lens Discomfort is a phenomenon that frequently affects users, leading them to reduce comfortable wearing time or shorten the duration of their lens. Until recently, there was no consensus on the definition and causes of this alteration, however, this topic has been studied by the Tear Film and Ocular Surface Society in the Contact Lens Discomfort Workshop.[6-8]

Clinicians play a key role in prescribing one or another contact lens that is best suited for fitting, as well as in the education of the patient. The use of one or other material may influence the final decision fitting, which could potentially affect the patients´ comfort during wear and may conditionate the patient to prefer one over another. The contact lenses´ water content has a major impact on this comfort such as dehydration has been shown to increase as a function of that property.[9] Silicone-hydrogel lenses are usually characterised by an inherently lower content of water; therefore, those materials are less susceptible to dehydration than traditional hydrogel lenses. The present study aimed to evaluate the impact on symptomatology, tear film dynamics and ocular surface integrity of a silicone-hydrogel (Somofilcon A) and a hydrogel (Omafilcon A) lens before and after wearing for one week in one week in young contact lens neophyte healthy participants.

## MATERIAL AND METHODS

### Sample size

For the sample size calculation, PS Power and Sample Size Calculations Software Version 3.1.2 (Copyright © by William D. Dupont and Walton D. Plummer) was used. The sample size for this study planned as a continuous response variable from paired sessions was determined based on the ability to detect differences in the Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score.[10, 11] CLDEQ-8 previous data indicate that the mean standard deviation of

repeated measures is normally distributed with a value of ±5 points while the minimal clinical difference proposed by the literature of the questionnaire is ±3 points.[10, 11] To be enabled for reject the null hypothesis with a power of 0.80, and to have a Type I error probability associated of 0.05, a minimum amount of 25 participants should be needed; adjusting for 10% loss to follow-up yielded a total sample size of 28.

Eligible participants were required to have a spherical contact lens prescription of -8.00D/+5.00D in each eye, no more than <-1.00D cylindrical correction, and must have a best-corrected visual acuity of 0.9 decimal acuity at least in the worse eye to be enrolled on the study.[12] Subjects were included if they understand and sign the Informed Consent Form (all gave their written informed consent to be included), agree to fulfil the visit schedule and be able to keep all appointments as specified in the study protocol for the duration of the study and have acceptance of random group allocation and the masked study design as well. Subjects were required to have normal eyes (no abnormality or disease that would contraindicate contact lens wear, i.e., history of conjunctival, scleral, corneal disease or prior eye surgery), were contact lenses neophytes, and had to agree to leave the use of rewetting drops throughout the study.[12] Participants were excluded if they had a systemic disease that might affect the study (i.e., diabetes mellitus), a known allergy to fluorescein or no good general health. A total of 28 young volunteer participants (22.4 ± 2.2 years old) were initially recruited for the study. The study protocol adhered to the tenets of the Declaration of Helsinki.

**Study Design**

Qualified participants were scheduled for three different sessions. In the first session, subjective refraction, best-corrected visual acuity, keratometry, Horizontal Visible Iris Diameter, tear meniscus height (TMH), conjunctival hyperemia, lipid layer thickness (LLT) and corneal/conjunctival fluorescein staining were assessed. At this point, contact lenses w randomly and double-blinded assigned by another examiner: a Somofilcon A lens (8.60 mm of radius, 14.10 mm of diameter, 56% water content and 86 Dk/t of oxygen permeability) to one eye and an Omafilcon A lens (8.70 mm of radius, 14.20 mm of diameter, 60% water

content and 28 Dk/t of oxygen permeability) to the other. After lens fitting, participants were scheduled for a second session where the evaluation was performed after 4 hours of lens wear, and a final session where the evaluations were performed after 7 days of wear (participants were requested to use the contact lenses all days the 7 days for up to 8 hours); on those visits, the CLDEQ-8 was administrated to the patients, TMH and conjunctival hyperemia were recorded again with and without lenses while LLT and corneal/conjunctival staining were obtained only without the lenses cause of the characteristics of the evaluation procedure.

**CLDEQ-8**

Subjective opinion of the contact lenses was also assessed at the same time points using the CLDEQ-8, which is validated to reflect the subjective overall opinion of the lens.[10-12] For the CLDEQ-8, lower scores indicate a more favourable response. Questionnaires were performed two times in each subject asking about one or the other eye in each session.

**Video acquisition of tear film and ocular surface parameters**

During all tests, participants were placed on the chinrest for the ocular surface recording in a video by an integrated camera on an HS-7000 slit-lamp biomicroscope (Huvitz Co., Ltd.). Except for the hyperaemia and the conjunctival staining recording protocols, in all tests participants were instructed to look at a target located to maintain a primary eye gaze during the recording procedure. Participants were also instructed to blink naturally, without squeezing to avoid other factors that could affect the visualization (for example, an excessive lipid component generated by a meibomian gland expression). In all subjects, measurements were always performed in the same order, from the least to the most invasive test to avoid the possible interferences between them.[13]

For TMH recording, the slit-lamp was set at 40x, and the lower tear meniscus was observed; to avoid reflex tearing, a short light beam (3 mm wide and 5 mm height) with moderate illumination was used to prevent the light from shining directly into the pupil during

measurements.[14, 15] Since the height of the tear meniscus varies along the length of the lower eyelid,[15, 16] videos were always recorded at the centre of the lower lid margin at the 6 o'clock position perpendicularly below the pupil centre, with the observation and illumination systems set at 0º and without tilt of the illumination column.[14-16]

The LLT was qualitatively examined using an EASYTEARview+ (Easytear s.r.l., IT)[17] attached to the slit lamp set both at x16 and x25, an instrument for the assessment of lipid thickness in clinical settings based on the projection of a cylindrical source of cool white fluorescent light onto the lipid layer (throughout the study, the illumination was provided by the device). It must note that the video acquisition procedure requires previous training to well centre and focus the LLT.

Hyperemia conjunctival images were obtained under 16x magnification with diffuse light: participants were instructed to look right and left to capture images of the nasal and temporal bulbar conjunctiva.

Five minutes later to the other recordings, non-preserved 2% sodium fluorescein was instilled using strips;[18-20] participants were then instructed to blink several times naturally, without squeezing, to evenly distribute the dye over the cornea.[18] Within 30 seconds of instillation, the eye was observed by the slit-lamp by using a cobalt blue filter and a Wratten 12 yellow filter to enhance tear film visibility.[18, 20] The upper eyelid is lifted slightly to grade the whole corneal or conjunctiva surface when the situation requires.

**Classification and evaluation procedure of tear film and ocular surface parameters**

After the study sessions, another masked examiner quantified the parameters from the video recordings.

TMH was measured by digital assistance tools provided by the slit-lamp own software: TMH was marked with a software tool that allows the user to set a line with a free size and position in the middle of the illuminated area, perpendicularly below the pupil centre and to the eyelid margin from the lowest limit to the highest one. Limits were established as the distance between the darker edge of the lower eyelid (the end of the black lower edge) and the upper

limit of the tear meniscus.[14] Then, the length size was calculated provided on pixels and converted to millimetres out of the software. To avoid interblink variations the frames were extracted 2 – 3 seconds after blinking when the meniscus was stable with minimal changes and completely expanded.[15, 16, 21, 22]

The LLT was quantitatively classified following Guillon's clinical scheme,[23] where the images were described in a five-grade pattern scale as an open meshwork, closed meshwork, wave, amorphous, and colour LLT, that are related to thin (open and closed meshwork pattern), average (wave pattern) or thick (amorphous, and colour patterns) tear film lipid layers. It is important to consider that the LLT does not follow a discrete classification but rather a continuing evolution of the lipid tear film thickness, thus, when the pictures fell between two grades, the observers classified those images as the pattern closer to following the Guillon scheme.

Conjunctival hyperaemia images were categorized following the Brien Holden Vision Institute grading scale that corresponds to 4 groups: Grade 1 (Very slight), Grade 2 (Slight), Grade 3 (Moderate) and Grade 4 (Severe).[24] Corneal and conjunctival staining were categorized following the Oxford grading scheme that corresponds to 0 to 5 different levels of ocular surface damage.[20]

**Statistical analysis**

SPSS statistical software v. 23.0 for Windows (SPSS Inc., Chicago, IL) was used for data analysis. Significance was set at a $p \leq 0.05$ for all the analyses. Previous to the analysis, the normal distribution of the different parameters was checked using the Shapiro-Wilk test.[25] A parametric analysis was performed on TMH data such it showed a continuous distribution (Shapiro-Wilk; $p \geq 0.200$), while a non-parametric analysis was assigned to CLDEQ-8, LLT, conjunctival hyperaemia and corneal/conjunctival staining cause all those parameters followed a non-continuous distribution (Shapiro-Wilk; all $p \leq 0.028$).

In the first analysis, the values obtained on each parameter between both lens was compared session by session; an unpaired t-test (parametric parameters) or a Mann-Whitney U (non-

parametric parameters) was used for the different analysis.[25] In a second analysis, the values for parameters obtained on each lens and session were compared. Differences between results obtained by the same lens in the different sessions were assessed using the Greenhouse-Geisser correction (Parametric parameters) or Friedman test (non-parametric parameters), while the Sidak test (parametric parameters) or Wilcoxon test was used to detect significant pairwise differences in parameter results obtained by the same lens in each session;[25] to avoid type I errors arising from multiple comparisons non-parametric parameters pairwise analysis, statistical significance for the Wilcoxon test was divided by the number of comparisons performed to give a $p \leq 0.017$.[25]

## RESULTS

At beginning of the study, differences between eyes were not statistically significant in baseline measurements for TMH (unpaired t-test: $p = 0.718$), LLT (Mann-Whitney U test: $p = 0.999$), conjunctival Hyperemia (Mann-Whitney U test: $p = 0.429$), corneal staining (Mann-Whitney U test: $p = 0.540$) and conjunctival staining (Mann-Whitney U test: $p = 0.954$). Thus, it was assumed that apart from the diverse types of lenses, any other factors affected both eyes equally. The values on each studied parameter during each session/lens were graphically represented in Figures 1 to 6. From the initial patients who were recruited for the basal session and fitting, one patient showed an adverse event in one of their eyes (a grade 4 corneal staining in the 5-grade Oxford Grading Scheme) in the first wear evaluation session (before the 4-hours of Somofilcon A lens wear) which obligate the examiners to stop the fitting and not be scheduled for the final seven-days wear session.

### Intrasession differences of material impact of the studied parameters

There was found no differences between material with or without lenses on any session in the CLDEQ-8 score (Mann-Whitney U test: all $p \geq 0.176$), the TMH value (unpaired t-test: all $p = 0.282$), LLT category (Mann-Whitney U test: all $p \geq 0.403$), conjunctival hyperemia (Mann-Whitney U test: all $p \geq 0.615$) or the corneal staining (Mann-Whitney U test: all $p \geq 0.337$)

(Figures 1 to 6). Contrary, a statistical difference was obtained between the conjunctival staining findings of both lenses in all sessions (Mann-Whitney U test: all $p \leq 0.006$), being higher than the values obtained during Somofilcon A wear (Figure 6).

**Intersession differences of material impact of the studied parameters on each lens**

CLDEQ-8 score showed a statistical higher value during both materials wear between the one-week session (Wilcoxon test: $p \leq 0.009$) (Figure 1). The TMH value showed a statistical difference between sessions during both material wear (Greenhouse-Geisser correction: $p \leq 0.003$) (Figure 2). In the paired analysis during both lens fitting, TMH showed a statistical lower value on measurements performed in the two sessions during lens wear regarding the basal session (Sidak test: both $p \leq 0.016$), and in the values obtained between measurements performed with and without the lens in each session (Sidak test: all $p \leq 0.022$); all the other comparison showed no statistical difference (Sidak test: $p \geq 0.105$) (Figure 2).

Both materials showed a statistical difference in impact on the LLT between sessions (Friedman test: both, $p \leq 0.001$) (Figure 3). In the analysis by pairs of sessions, with both materials, the LLT showed a statistical higher category on the basal session regarding both post-lens evaluations (Wilcoxon test: all $p \leq 0.001$), but not between the two sessions where it was categorized after lens extraction (Wilcoxon test: all $p \leq 0.168$) (Figure 3).

Conjunctival hyperemia values showed no statistical difference during both materials between sessions (Friedman test: $p = 0.237$) or in the paired analysis between sessions (Wilcoxon test: all $p \geq 0.084$) with and without the lens wear evaluation (Figure 4). The presence of corneal staining showed a statistical difference during Omafilcon A wear between sessions (Friedman test: $p = 0.037$) while during Somofilcon A wear do not (Friedman test: $p = 0.816$) (Figure 5). However, in the paired analysis between sessions both materials showed no difference in the corneal staining findings (Wilcoxon test: all $p \geq 0.107$) (Figure 5). Otherwise, the presence of conjunctival staining showed a statistical difference during Somofilcon A wear between sessions (Friedman test: $p < 0.001$) while during Omafilcon A wear do not (Friedman test: $p = 0.832$) (Figure 6). In the paired analysis of conjunctival staining between sessions, during

Somofilcon A wear was found a statistical lower value on the basal session regarding the post-lens evaluation on the other two sessions (Wilcoxon test: both $p \leq 0.001$), but not between sessions when this value was categorized after lens extraction (Wilcoxon test: $p = 0.904$); on the other hand, conjunctival staining showed no statistical difference during Omafilcon A wear between sessions (Wilcoxon test: all $p \geq 0.526$) (Figure 6).

## DISCUSSION

The use of one or another material may potentially influence the patient´s comfort or also the ocular surface integrity and tear film dynamics. In the present study, it was compared the impact of two different contact lenses materials, Somofilcon A and Omafilcon A, on comfort (CLDEQ-8), tear film dynamics (LLT and TMH) as well in the ocular surface integrity and inflammation (conjunctival hyperemia and corneal/conjunctival staining). The studied materials showed an impact in all those parameters during wear, with slight differences between them.

Contact Lens Discomfort and dryness are the most frequent reasons why contact lens wearers experience reduced wearing times, which can eventually lead to contact lens discontinuation.[4] One of the most used questionnaires to measure discomfort in contact lens users is CLDEQ-8 and its scores changes as lens wearer's global opinion indicator of lens comfort.[4, 10, 11] In the present study, similar to Sapkota et al.[3] and Diec et al.,[5] a significant reduction in comfort score with the time (intersession analysis) was found. It could be assumed that soft lens wear itself has an associated discomfort in all users, the friction between the contact lenses and the ocular surface may cause foreign body, dryness, and discomfort sensations; however, other types of material with different water content, thickness, or composition such as silicone-hydrogel should be studied such could affect the cornea differently, improving comfort. On the other hand, intrasession analysis between lenses showed no differences in the symptomology impact; the two contact lenses studied were similar except for the oxygen transmissibility, therefore it was very unlikely that different responses have been provoked (literature has shown that hydrogel and silicone hydrogel lenses lead to very similar subjective responses).[26]

TMH is the main test to detect the presence of a dry eye related to an aqueous deficiency, a condition being directly related to Contact Lens Discomfort.[13] Because of its importance as an indirect evaluation of the tear film total volume, it was widely studied during contact lens fitting assessment or dry eye diagnosis. In concordance with present results where parameters were evaluated during a certain period (intersession analysis), previous studies have found a decrease in the TMH with monthly contact lens wear (Lotrafilcon A) during six months,[27] or with daily disposable contact lens during eight hours in healthy patients (Stenfilcon A and Delefilcon A) [9] or presbyopic patients (Nesofilcon A).[28] This result agrees with previous studies, which found a tear meniscus decrease after contact lens insertion, especially with high water content contact lenses such as the Somofilcon A lens studied here.[29] Contrary, no differences in TMH were found in another two analyses where eight hours of Nesofilcon A was used on the healthy patient,[9, 28] while previous studies also found differences or no differences in TMH parameter in the same session depending on the materials that were compared.[9] Differences among lens properties or surface wettability may explain the different results obtained since the authors of those studies assume that this result is due that the silicone-hydrogel lens behaving more like a traditional hydrogel lens at the surface, with much higher water content than that silicone-hydrogel lens.[9] When a contact lens is inserted the tear film becomes separated into pre- and post-lens tear film, therefore, the volume of the aqueous layer at the pre-lens tear film is decreased.[30] The wettability of the contact lens surface is not as high as that of the corneal surface due to the lack of a hydrophilic mucin layer.[30] All contact lens seems to have some impact on the total tear film aqueous phase volume cause to an increase in water loss from the lenses and the wettability of the lens surface.

For Interferometric evaluation of the lipid layer to be performed is necessary to use devices mounted on a slit lamp, such as the Tearscope (Keeler Tearscope, not currently commercially available) or the EASYTEARview+.[17] To the author`s knowledge, there are no studies that have analysed the qualitative LLT right before a lens extraction with this device. The pre-lens tear film is usually measured by Non-Invasive Break-Up Time in the different studies,[9] but the status of the tear lipid layer during or after fitting needs to be still addressed. The lipid layer

stabilizes the tear film by preventing the evaporation of the aqueous component and lowering the surface tension of the tear film; such an unstable pre-lens tear film may be easily breakable within a short period after blinking.[30] The present results support this hypothesis, with a decrease in LLT right before contact lenses just since the beginning of the fitting process. The present results showed a statistically significant decrease of the LLT from an average thickness (Wave category) to a thin thickness (Closed meshwork) which could represent clinical implications;[31] a thinner lipid layer could be a trigger for the apparition of evaporative dry eye or enhance a meibomian gland dysfunction initial status.[13]

Ocular Surface redness is a non-specific sign usually associated with an inflammation processed on the ocular surface, or a hypoxia situation during contact lens wear.[3] The Brien Holden Vision Institute scale grading system is one of the most used scales in the assessment of this parameter.[24] In concordance with present results, Lorente-Velázquez et al. found no difference in the bulbar redness during eight hours of daily disposable contact lens wear, neither in presbyopia or non-presbioc patients;[28] in contrast, previous studies have found an increase in the bulbar hyperaemia during monthly contact lens use during six months[27] or with a monthly (Lotrafilcon B, Comfilcon A or Balafilcon A) and daily (Delefilcon A, Stenfilcon A or Nesofilcon A) lenses combination during the two months.[3] As previously stated in the present discussion, those differences might be explained by the different impacts that materials could have on the ocular surface inflammation response caused by water content, lens modulus, etc.

Corneal and bulbar staining is one of the widest tests used in the tear and problem diagnostic conjunctiva,[32-35] even though the interpretations and significations are still not clear.[36] The Oxford Grade is one of the staining scales more widely used in the clinic for corneal staining classification.[37-39] Although conjunctival staining < 2 in the Efron grading was suggested to be not considered clinically significant it may affect the level of comfort in contact lens wearers.[3, 40] In concordance with present results, previous studies have found an increase in the corneal and conjunctival staining during monthly contact lens use during six months[27] or with a monthly and daily lenses combination during two months.[3] An alteration on film functions as a lubricant

and the tear film volume decrease right before insertion may enhance the friction between the eyelid and the corneal/conjunctival surface at the site of the tear film,[30] which could be clinically represented by the staining findings assessed here. A possible explanation for the differences in ocular surface integrity area alteration found here between materials may be explained by their inherent characteristics of them: Omafilcon A is a low-Dk and low-modulus material that might increase the corneal hypoxia chances but reduce conjunctival friction process during blinking, while Somofilcon A has opposite in characteristics, with high-DK and modulus, that could reduce the hypoxia chances and increase the conjunctival friction during blinking. Additionally, silicone-hydrogel materials such as Somofilcon A have a higher hydrophobicity than Omafilcon A, leading to different wettability causes on the water contact angle on the lenses that could generate desiccation on the ocular surface.[41]

One strength of the present study was the use of daily contact lenses, which avoids the use of such the physical properties of those products that could affect the tear film characteristics.[42] Nevertheless, even though daily disposable contact lenses avoid ocular surface chronic exposure to lens care solutions,[5, 7] contact lens wearers are still exposed to lens packaging solutions.[43] It should be noted in contrast with other analyses,[9] the present study utilized a randomized double-blind design to have no affected on the results. On the other hand, is important to note that the present study results were limited by the size of the sample used (despite the sample size calculation analysis) or the brief time analysed; this issue should be addressed in future studies. In addition, it should be noted the intrasession comparison of some parameters such as the symptomatic score or the tear meniscus status was limited by the sympathetic response between the two eyes of the participants, which implies that the sensation due to lens wear in one eye may influence the sensation or the indirect reflex reactions in the other eye.[44] Finally, further analysis should use additional materials in the study protocol and compare the values obtained in each session between lenses to a deep understanding of how contact lens-wear impacts the tear film dynamics.

The present study showed that contact lenses had an impact on the symptomatology, tear film dynamics and ocular surface integrity. Nevertheless, this influence seems to be different

depending on the material on which the contact lens was manufactured: both studied materials generated an alteration in the contact lens associated symptomatology (analysed here by CLDEQ-8), lipid layer stability/distribution or thickening or the aqueous phase of the tear film (analysed here by TMH) before wear; but Somofilcon A seems to have a higher impact on the integrity of the conjunctiva near to the corneal area while Omafilcon A material showed a higher influence on the integrity of the cornea itself.

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## REFERENCES

1. Efron N, Morgan PB, Woods CA, et al. International survey of rigid contact lens fitting. *Optometry and vision science : official publication of the American Academy of Optometry* 2013; 90: 113-118. 2012/12/25. DOI: 10.1097/OPX.0b013e31827cd8be.

2. Efron N, Morgan PB, Woods CA, et al. An international survey of daily disposable contact lens prescribing. *Clinical & experimental optometry : journal of the Australian Optometrical Association* 2013; 96: 58-64. 2012/08/03. DOI: 10.1111/j.1444-0938.2012.00773.x.

3. Sapkota K, Franco S and Lira M. Daily versus monthly disposable contact lens: Which is better for ocular surface physiology and comfort? *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2018; 41: 252-257. 2017/12/10. DOI: 10.1016/j.clae.2017.12.005.

4. Downie LE and Craig JP. Tear film evaluation and management in soft contact lens wear: a systematic approach. *Clinical & experimental optometry : journal of the Australian Optometrical Association* 2017; 100: 438-458. 2017/09/25. DOI: 10.1111/cxo.12597.

5. Diec J, Papas E, Naduvilath T, et al. Combined effect of comfort and adverse events on contact lens performance. *Optometry and vision science : official publication of the American Academy of Optometry* 2013; 90: 674-681. 2013/06/26. DOI: 10.1097/OPX.0000000000000008.

6. Nichols KK, Redfern RL, Jacob JT, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the definition and classification subcommittee. *Investigative ophthalmology & visual science* 2013; 54: TFOS14-19. DOI: 10.1167/iovs.13-13074.

7. Stapleton F, Marfurt C, Golebiowski B, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the subcommittee on neurobiology. *Investigative ophthalmology & visual science* 2013; 54: TFOS71-97. DOI: 10.1167/iovs.13-13226.

8. Dumbleton K, Caffery B, Dogru M, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the subcommittee on epidemiology. *Investigative ophthalmology & visual science* 2013; 54: TFOS20-36. DOI: 10.1167/iovs.13-13125.

9. Montani G and Martino M. Tear Film Characteristics During Wear of Daily Disposable Contact Lenses. *Clin Ophthalmol* 2020; 14: 1521-1531. 2020/06/26. DOI: 10.2147/OPTH.S242422.

10. Chalmers RL, Begley CG, Moody K, et al. Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and opinion of contact lens performance. *Optometry and vision science : official publication of the American Academy of Optometry* 2012; 89: 1435-1442. 2012/09/11. DOI: 10.1097/OPX.0b013e318269c90d.

11. Chalmers RL, Keay L, Hickson-Curran SB, et al. Cutoff score and responsiveness of the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) in a Large daily disposable contact lens registry. *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2016; 39: 342-352. 2016/05/02. DOI: 10.1016/j.clae.2016.04.005.

12. Berntsen DA, Hickson-Curran SB, Jones LW, et al. Subjective Comfort and Physiology with Modern Contact Lens Care Products. *Optometry and vision science : official publication of the American Academy of Optometry* 2016; 93: 809-819. 2016/06/17. DOI: 10.1097/OPX.0000000000000901.

13. Wolffsohn JS, Arita R, Chalmers R, et al. TFOS DEWS II Diagnostic Methodology report. *The ocular surface* 2017; 15: 539-574. DOI: 10.1016/j.jtos.2017.05.001.

14. Garcia-Resua C, Santodomingo-Rubido J, Lira M, et al. Clinical assessment of the lower tear meniscus height. *Ophthalmic Physiol Opt* 2009; 29: 487-496. 2009/07/03. DOI: 10.1111/j.1475-1313.2009.00634.x.

15. Pena-Verdeal H, Garcia-Resua C, Barreira N, et al. Interobserver variability of an open-source software for tear meniscus height measurement. *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2016. DOI: 10.1016/j.clae.2016.02.009.

16. Bandlitz S, Purslow C, Murphy PJ, et al. The relationship between tear meniscus regularity and conjunctival folds. *Optometry and vision science : official publication of the American Academy of Optometry* 2014; 91: 1037-1044. 2014/07/26. DOI: 10.1097/OPX.0000000000000358.

17. Zhou N, Edwards K, Colorado LH, et al. Development of Feasible Methods to Image the Eyelid Margin Using In Vivo Confocal Microscopy. *Cornea* 2020; 39: 1325-1333. 2020/05/02. DOI: 10.1097/ICO.0000000000002347.

18. Johnson ME and Murphy PJ. The Effect of instilled fluorescein solution volume on the values and repeatability of TBUT measurements. *Cornea* 2005; 24: 811-817.

19. Abelson MB, Ousler GW, 3rd, Nally LA, et al. Alternative reference values for tear film break up time in normal and dry eye populations. *Advances in experimental medicine and biology* 2002; 506: 1121-1125.

20. Bron AJ, Evans VE and Smith JA. Grading of corneal and conjunctival staining in the context of other dry eye tests. *Cornea* 2003; 22: 640-650. Review 2003/09/26.

21. Bandlitz S, Purslow C, Murphy PJ, et al. Comparison of a new portable digital meniscometer and optical coherence tomography in tear meniscus radius measurement. *Acta*

448 *ophthalmologica* 2014; 92: e112-118. Comparative Study 2013/10/15. DOI:
449 10.1111/aos.12275.
450 22. Bron AJ, Tomlinson A, Foulks GN, et al. Rethinking dry eye disease: a perspective on
451 clinical implications. *The ocular surface* 2014; 12: S1-31. Research Support, Non-U.S. Gov't
452 Review 2014/04/15. DOI: 10.1016/j.jtos.2014.02.002.
453 23. Guillon JP. Non-invasive Tearscope Plus routine for contact lens fitting. *Cont Lens*
454 *Anterior Eye* 1998; 21 Suppl 1: S31-S40.
455 24. Terry RL, Schnider CM, Holden BA, et al. CCLRU standards for success of daily and
456 extended wear contact lenses. *Optometry and vision science: official publication of the*
457 *American Academy of Optometry* 1993; 70: 234-243.
458 25. Armstrong RA, Davies LN, Dunne MC, et al. Statistical guidelines for clinical studies of
459 human vision. *Ophthalmic Physiol Opt* 2011; 31: 123-136. Review 2011/02/12. DOI:
460 10.1111/j.1475-1313.2010.00815.x.
461 26. Jones L, Brennan NA, Gonzalez-Meijome J, et al. The TFOS International Workshop
462 on Contact Lens Discomfort: report of the contact lens materials, design, and care
463 subcommittee. *Investigative ophthalmology & visual science* 2013; 54: TFOS37-70.
464 2013/09/24. DOI: 10.1167/iovs.13-13215.
465 27. Best N, Drury L and Wolffsohn JS. Predicting success with silicone-hydrogel contact
466 lenses in new wearers. *Contact lens & anterior eye : the journal of the British Contact Lens*
467 *Association* 2013; 36: 232-237. 2013/03/26. DOI: 10.1016/j.clae.2013.02.013.
468 28. Lorente-Velazquez A, Garcia-Montero M, Gomez-Sanz FJ, et al. Comparison of the
469 impact of nesofilcon A hydrogel contact lens on the ocular surface and the comfort of
470 presbyopic and non-presbyopic wearers. *Int J Ophthalmol* 2019; 12: 640-646. 2019/04/27.
471 DOI: 10.18240/ijo.2019.04.19.
472 29. Nagahara Y, Koh S, Maeda N, et al. Prominent Decrease of Tear Meniscus Height
473 With Contact Lens Wear and Efficacy of Eye Drop Instillation. *Eye & contact lens* 2015; 41:
474 318-322. 2015/04/04. DOI: 10.1097/ICL.0000000000000134.

30. Kojima T. Contact Lens-Associated Dry Eye Disease: Recent Advances Worldwide and in Japan. *Investigative ophthalmology & visual science* 2018; 59: 102-107.

31. Garcia-Resua C, Pena-Verdeal H, Minones M, et al. Interobserver and intraobserver repeatability of lipid layer pattern evaluation by two experienced observers. *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2014; 37: 431-437. DOI: 10.1016/j.clae.2014.07.006.

32. Korb DR. Survey of preferred tests for diagnosis of the tear film and dry eye. *Cornea* 2000; 19: 483-486. 2000/08/06.

33. Benelli U, Nardi M, Posarelli C, et al. Tear osmolarity measurement using the TearLab Osmolarity System in the assessment of dry eye treatment effectiveness. *Cont Lens Anterior Eye* 2010; 33: 61-67. 2010/02/16. DOI: S1367-0484(10)00004-4 [pii] 10.1016/j.clae.2010.01.003.

34. Sullivan BD, Whitmer D, Nichols KK, et al. An objective approach to dry eye disease severity. *Invest Ophthalmol Vis Sci* 2010; 51: 6125-6130. 2010/07/16. DOI: iovs.10-5390 [pii] 10.1167/iovs.10-5390.

35. Turner AW, Layton CJ and Bron AJ. Survey of eye practitioners' attitudes towards diagnostic tests and therapies for dry eye disease. *Clinical & experimental ophthalmology* 2005; 33: 351-355. 2005/07/22. DOI: 10.1111/j.1442-9071.2005.01026.x.

36. Fonn D, Peterson R and Woods C. Corneal staining as a response to contact lens wear. *Eye & contact lens* 2010; 36: 318-321. 2010/09/09. DOI: 10.1097/ICL.0b013e3181f35d54.

37. Gumus K, Yurci A, Mirza E, et al. Evaluation of ocular surface damage and dry eye status in chronic hepatitis C at different stages of hepatic fibrosis. *Cornea* 2009; 28: 997-1002. Clinical Trial 2009/09/03. DOI: 10.1097/ICO.0b013e3181a0a3c5.

38. Baudouin C, Aragona P, Van Setten G, et al. Diagnosing the severity of dry eye: a clear and practical algorithm. *The British journal of ophthalmology* 2014 2014/03/15. DOI: 10.1136/bjophthalmol-2013-304619.

39. Labbe A, Liang Q, Wang Z, et al. Corneal nerve structure and function in patients with non-sjogren dry eye: clinical correlations. *Investigative ophthalmology & visual science* 2013; 54: 5144-5150. Comparative Study
Research Support, Non-U.S. Gov't 2013/07/09. DOI: 10.1167/iovs.13-12370.
40. Guillon M and Maissa C. Bulbar conjunctival staining in contact lens wearers and non lens wearers and its association with symptomatology. *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2005; 28: 67-73. 2005/12/02. DOI: 10.1016/j.clae.2005.02.002.
41. Giraldez MJ, Resua CG, Lira M, et al. Contact lens hydrophobicity and roughness effects on bacterial adhesion. *Optometry and vision science : official publication of the American Academy of Optometry* 2010; 87: E426-431. 2010/04/09. DOI: 10.1097/OPX.0b013e3181da8656.
42. Pena-Verdeal H, Garcia-Queiruga J, Garcia-Resua C, et al. Osmolality and pH of commercially available contact lens care solutions and eye drops. *Contact lens & anterior eye : the journal of the British Contact Lens Association* 2020 2020/11/15. DOI: 10.1016/j.clae.2020.10.009.
43. Menzies KL and Jones L. In vitro analysis of the physical properties of contact lens blister pack solutions. *Optometry and vision science : official publication of the American Academy of Optometry* 2011; 88: 493-501. DOI: 10.1097/OPX.0b013e3181ff9d39.
44. Fonn D, du Toit R, Simpson TL, et al. Sympathetic swelling response of the control eye to soft lenses in the other eye. *Investigative ophthalmology & visual science* 1999; 40: 3116-3121. 1999/12/10.

## FIGURE LEGENDS

Figure 1. Graphical representation of the values found for CLDEQ-8 scores on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens. CLDEQ-8: Contact Lens Dry Eye Questionnaire-8. *p < 0.05 versus baseline (Wilcoxon test).

Figure 2. Graphical representation of the values found for TMH values on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens. TMH: tear meniscus height. ‡p < 0.05 general differences (Greenhouse-Geisser correction), *p < 0.05 versus baseline (Sidak test), **p < 0.05 versus day 1 with CL (Sidak test), ***p < 0.05 versus day 7 with CL (Sidak test).

Figure 3. Graphical representation of the values found for LLT values on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens. LLT: lipid layer thickness. ‡p < 0.001 general differences (Friedman test), *p < 0.05 versus baseline (Wilcoxon test).

Figure 4. Graphical representation of the values found for conjunctival hyperemia on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens.

Figure 5. Graphical representation of the values found for corneal staining on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens. ‡p < 0.05 general differences (Friedman test).

Figure 6. Graphical representation of the values found for conjunctival staining on each session/material. Error bars show the 95% confidence interval of each parameter. CL: Contact Lens. ‡p < 0.05 general differences (Friedman test), *p < 0.05 versus baseline (Wilcoxon test), †p < 0.05 between the two groups (Mann-Whitney U test).