Association Between Ocular Surface Temperature and Tear Film Stability in Soft Contact Lens Wearers

Takashi Itokawa,[1,2] Yukinobu Okajima,[2] Takashi Suzuki,[2,3] Koji Kakisu,[2] Hiroko Iwashita,[1] Yoshitaka Murakami,[4] and Yuichi Hori[1,2]

[1]Department of Ophthalmology, Toho University Graduate School of Medicine, Tokyo, Japan
[2]Department of Ophthalmology, School of Medicine, Toho University, Tokyo, Japan
[3]Ishizuchi Eye Clinic, Ehime, Japan
[4]Department of Medical Statistics, School of Medicine, Toho University, Tokyo, Japan

PURPOSE. To investigate the correlation between the changes in the ocular surface temperature (OST) and tear film stability over soft contact lenses (SCLs).

METHODS. We enrolled 20 eyes of 20 normal SCL wearers (20 men; 24.4 ± 4.1 years). We used four different daily disposable SCLs: one silicone hydrogel lens (delefilcon A) and three hydrogel lenses (etafilcon A with polyvinylpyrrolidone [PVP], etafilcon A, and polymacon). OST was measured every second during 10 seconds without blinking. We defined the difference in the OST from 0 to 10 seconds as ΔOST. To evaluate tear film stability, we measured noninvasive tear break-up time (NIBUT) and tear interference patterns on the contact lenses (TIPCL) using tear film interferometry. The parameters were measured before and 15 minutes after wearing each SCL.

RESULTS. ΔOST was correlated significantly with NIBUT without ($r = 0.411$, $P < 0.01$) and with SCL ($r = 0.642$, $P < 0.01$). TIPCL grade was correlated significantly with ΔOST over SCLs ($r = -0.636$, $P < 0.01$). ΔOST was significantly smaller with silicone hydrogel delefilcon A than hydrogel etafilcon A and polymacon lenses ($P < 0.05$ and $P < 0.01$, respectively). Delefilcon A and etafilcon A with PVP lenses had significantly smaller NIBUT than etafilcon A ($P < 0.05$ for both comparisons). TIPCL grade of delefilcon A lens was significantly smaller than those of etafilcon A and polymacon ($P < 0.01$ for both comparisons).

CONCLUSIONS. The changes in OST over SCLs are related to tear film stability. Measurements of OST can be used to evaluate tear film stability for SCL wearers.

Keywords: ocular surface temperature, tear interferometry, contact lenses, BUT, silicone hydrogel

More than 50% of contact lens wearers have dry eye symptoms such as ocular dryness and discomfort,[1] and approximately 15% of contact lens wearers stop wearing the lenses due to discomfort.[2] The presence of the contact lens on the ocular surface disrupts the tear film by dividing it into the pre- and postlens tear film. Nichols and King-Smith[3] reported that contact lenses reduce the tear film thickness to 2.31 μm in the prelens tear film and 2.34 μm in the postlens tear film. A thin prelens tear film leads to an increased evaporation rate of the tear film[4] and shortens the tear film break-up time (BUT)[5] over soft contact lenses (SCLs), which can cause tear film instability and ocular surface discomfort in the wearers.

The body surface temperature represents the fundamental feature of tissue metabolism. Therefore, the temperature on the ocular surface is a possible parameter of ocular surface physiology. In 1968, Mapstone[6] measured the ocular surface temperature (OST) in humans for the first time. In 1995, Morgan et al.[7,8] used infrared thermography to measure OST in patients with dry eye and reported that the decreased OST during sustained eye opening in dry eye occurred significantly faster than in normal eyes. The decrease of OST is associated with evaporation of the tear fluid, convective heat transfer, emission of infrared radiation, and heat conduction.[9–11] Several studies have shown that the tear evaporation rate and BUT were correlated significantly with the degree of the decrease in OST.[12–14] These findings indicated that OST is related to tear film stability.

Hill and Leighton[15] measured OST over contact lenses for the first time in 1965 using a contact type probe. In 2005, Purslow et al.[16] measured OST over disposable contact lenses using a noninvasive infrared camera. However, to the best of our knowledge, no study has evaluated the relationship between OST and tear film stability over SCLs. The aim of the current study was to investigate the relationship between OST and tear film stability in contact lens wearers using ocular surface thermography and tear film interferometry.

METHODS

Subjects

Twenty eyes of 20 normal SCL wearers (20 men; mean $\pm$ SD, 34.4 ± 4.1 years; range: 20–35 years) were enrolled in this study. The Toho University Institutional Review Board (#27068) approved the study, which adhered to the tenets of the Declaration of Helsinki. All patients provided informed consent

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TABLE 1. Characteristics of the Study Subjects

Age, y	24.4 ± 4.1
Sex ratio, male:female	20:0
SCL wearing history, y	7.0 ± 5.6
SCL wear frequency, d/wk	6.1 ± 1.2
Schirmer test, mm	23.1 ± 8.2
TBUT, s	8.8 ± 1.6
Dry Eye-Related Quality-of-Life Score Subjective score	8.8 ± 8.7

after they received an explanation of the possible consequences of the study. SCL wearers were included who wore the lenses more than 4 days a week. The exclusion criteria were subjects who had a history of allergic keratoconjunctivitis, dry eye, ocular injuries, infectious keratitis, and ocular surgery. An experienced ophthalmologist (YO) conducted all screening examinations. The diagnosis of dry eye was established based on a fluorescein tear film BUT of less than 5 seconds, Schirmer I test of less than 5 mm, positive fluorescein corneal and conjunctival staining, and the results obtained using the Dry Eye-Related Quality-of-Life Score questionnaire with a cutoff score of 33 for dry eye.[17] Based on these examinations, if at least two of four categories were positive, we diagnosed the subject with dry eye. Table 1 shows the characteristics of the study subjects.

As this was not an intervention study, we did not calculate sample size before conducting the study. The sample size was set as 20 patients, which was the available number in our university hospital during the study period.

SCL Types

We used one silicone hydrogel and three hydrogel daily disposable contact lenses. Table 2 shows the four commercially available daily disposable contact lenses used in this study: a water gradient silicone hydrogel lens, delefilcon A (Dailies Total 1; Alcon, Fort Worth, TX, USA); a hydrogel lens including moisture-rich ingredient, etafilcon A with polyvinylpyrrolidone (PVP), (1-Day Acuvue Moist; Johnson & Johnson, New Brunswick, NJ, USA); a hydrogel lens, etafilcon A (1-Day Acuvue; Johnson & Johnson); and a colored cosmetic contact lens (hydrogel lens), polymacon (Ever Color 1 Day Decolog; Aisei Co. Ltd., Osaka, Japan). In this study, we confirmed that these SCLs fit each subject properly.

OST Measurement

OST was measured using a noninvasive ocular surface thermographer (TG-1000; Tomey Corporation, Nagoya, Japan).[12,18] Subjects were asked to close their eyes for 5 seconds and then to keep their eyes open for 10 seconds.[19] During the examination, the subjects were asked to look straight ahead. OST was analyzed quantitatively in the central 4-mm diameter of the cornea (Fig. 1). OST was measured every second during 10 seconds without blinking. We defined the difference in OST from 0 to 10 seconds as ΔOST. We measured ΔOST before (baseline) and 15 minutes after wearing each contact lens. To compare OST between SCLs, we calculated the difference of the ΔOST between baseline (no contact lens) and with SCL (equals ΔΔOST).

Measurement of Tear Film Stability

A tear film interferometer (DR-1a; Kowa Co. Ltd., Tokyo, Japan) was used to assess the tear film stability, including the noninvasive tear BUTs (NIBUTs) and tear interference patterns on the contact lens (TIPCLs).[20] During the measurements, the subjects were asked to blink naturally and then keep their eyes open for 10 seconds. The NIBUT was measured in subjects before and 15 minutes after wearing each SCL using a tear film interferometer with low magnification (7.2 × 8.0 mm).[20] In subjects with no BUT during the 10-second observation period, the NIBUT was recorded as 10 seconds. The TIPCL indicates the thickness of the lipid and aqueous layer on the contact lenses and can represent the tear film stability on contact lenses.[20] The TIPCL was measured by a tear film interferometer with high magnification (2.5 × 3.4 mm) and classified from grade 1 to 5 according to a previous report by Maruyama et al.[20] (i.e., 1, gray interference fringes due to a normal lipid and aqueous layer; 2, colorful interference fringes due to a thin aqueous layer under gray interference fringes; 3, clear colorful interference fringes due to no lipid layer; 4, clear colorful interference fringes and part of SCL surface exposed; and 5, the entire exposed SCL surface).

Study Protocol

Subjects were required to remove their SCLs the day before the examinations. The study was conducted between 9:00 and 11:30 AM in winter (December–February). The temperature (25.8 ± 0.8°C) and humidity (34.8% ± 2.8%) in the measurement room were maintained at constant levels.

One examiner (TI) measured the OST and tear stability to eliminate interexaminer variations. The examiner and subjects were blinded to the SCL type worn. Subjects wore contact lenses in both eyes, but measurements were obtained only from the right eyes in this study.

The examinations were conducted in each subject over a period of 2 days. Subjects wore two types of SCL during 1 day. At first, we measured OST and performed the tear film stability tests (NIBUT and TIPCL) without SCL 15 minutes after the subjects entered the examination room. After the first SCL was worn for 15 minutes, we measured them over SCL. Fifteen minutes after removing the first SCL, we again measured OST and performed the tear film stability tests without SCL; and after the second SCL was worn for 15 minutes, we measured them over the second SCL. To reduce any bias from the order in which SCLs were worn, we divided the subjects into groups A and B. Group A wore SCLs in the following order: delefilcon A and etafilcon A with PVP on day 1 and etafilcon A and polymacon on day 2. Group B wore SCLs in the following order: polymacon and etafilcon A on day 1 and etafilcon A with PVP and delefilcon A on day 2.

TABLE 2. Generic Data of SCL Used in This Study

Type	Material	Products	DIA/BC, mm	H2O, %	Charge	Dk
Silicone hydrogel	Delefilcon A	Dailies Total 1	14.1/8.8	33–80	Ionic	140
Hydrogel with PVP (FDA Group IV)	Etafilcon A with PVP	1-Day Acuvue Moist	14.2/9.0	58	Ionic	28
Hydrogel (FDA Group IV)	Etafilcon A	1-Day Acuvue	14.2/9.0	58	Ionic	28
Hydrogel (FDA Group I)	Polymacon	Ever Color 1-Day Decolog	14.5/8.7	38	Nonionic	9.5

BC, base curve; DIA, diameter; Dk, diffusionskonstante (i.e., oxygen permeability of contact lens); PVP, polyvinylpyrrolidone.
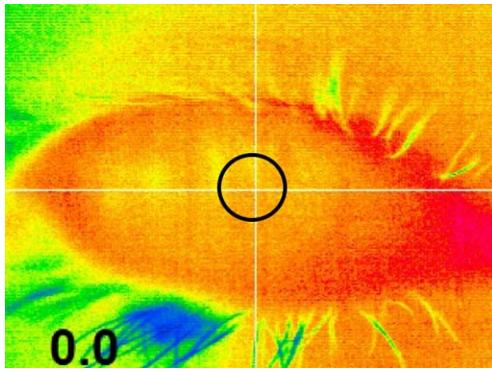
FIGURE 1. The 4-mm central area of the cornea is measured. The margin in the cornea is aligned automatically.

Statistical Analysis

Spearman nonparametric correlations were used to assess the correlations among the ΔOST, NIBUT, and TIPCL. Among the four SCL types, 1-way ANOVA was used to compare the differences between the baseline ΔOST or NIBUT (no contact lens) and with SCL. Multiple comparisons were performed using the Tukey significant difference (HSD) test when significant differences were identified across SCLs. $P \leqq 0.05$ was considered significant. All analyses were conducted with statistical analysis software (JMP version 11; SAS Institute, Inc., Cary, NC, USA).

RESULTS

Relationship Between ΔOST and Tear Film Stability

We found a positive correlation between the ΔOST and NIBUT at baseline (no SCL; Spearman $r = 0.411$, $P < 0.01$; Fig. 2A). We also found that the two parameters were positively correlated over SCLs (Spearman $r = 0.642$, $P < 0.01$; Fig. 2B). In each SCL group ($n = 20$), the correlation coefficients of the delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon lenses were 0.747 ($P < 0.01$); 0.618 ($P < 0.01$); 0.428 ($P = 0.05$); and 0.510 ($P < 0.05$), respectively, indicating the same tendency as the overall results. Regarding the interferometry pattern, the ΔOSTs for all SCLs were significantly (Spearman $r = -0.636$, $P < 0.01$) correlated negatively with the TIPCL (Fig. 3).

Differences in ΔOST or NIBUT With and Without SCLs

The differences in the ΔOST with and without delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon lenses were $0.15 \pm 0.33°C$, $0.22 \pm 0.33°C$, $0.46 \pm 0.33°C$, and $0.50 \pm 0.35°C$, respectively. The value of the delefilcon A lens was significantly smaller ($P < 0.05$ and $P < 0.01$, respectively, Tukey HSD test) than those of the etafilcon A and polymacon lenses (Fig. 4A).

The differences in the NIBUT between with and without the delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon lenses were 2.6 ± 2.6, 2.3 ± 3.6, 5.3 ± 3.2, and 4.8 ± 2.8 seconds, respectively. The values with the delefilcon A and etafilcon A with PVP lenses were significantly smaller ($P < 0.05$ for both comparisons, Tukey HSD test) than with the etafilcon A lens (Fig. 4B).

TIPCL with delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon lenses were 1.7 ± 0.9, 2.1 ± 1.0, 2.7 ± 0.9, and 2.8 ± 1.0, respectively. The value of the delefilcon A lens was significantly smaller ($P < 0.01$ for both comparisons, Tukey HSD test) than those of etafilcon A and polymacon (Fig. 4C).

DISCUSSION

The changes in OST correlated positively with the NIBUT and correlated negatively with the TIPCL over the contact lenses in tolerant SCL wearers. These data indicated that the ΔOST is associated with the tear film stability over the SCLs.

Many researchers have tried to measure OST and concluded that the destruction of the tear film on the ocular surface decreased OST.[6-16,18,19,21,22] Destruction of the tear film is associated with tear evaporation and loss of wettability of the ocular surface.[23] Craig et al.[13,21] reported that the tear film evaporation rate was correlated significantly with ocular surface cooling in patients with dry eye. Kamao et al.[12] reported that the BUT and the ΔOST were correlated significantly in normal eyes and patients with dry eye. Furthermore, two recent studies have confirmed that the locations of the fluorescein tear break-up areas and low temperature areas on the ocular surface were correlated significantly using a dual real-time imaging system with a thermographic and fluorescent camera.[14,22] These reports suggested that the changes in OST represent the stability of the tear film on the ocular surface.

Wearing contact lens has a great effect on the ocular surface resulting from continuous disruption of the tear film. Guillon
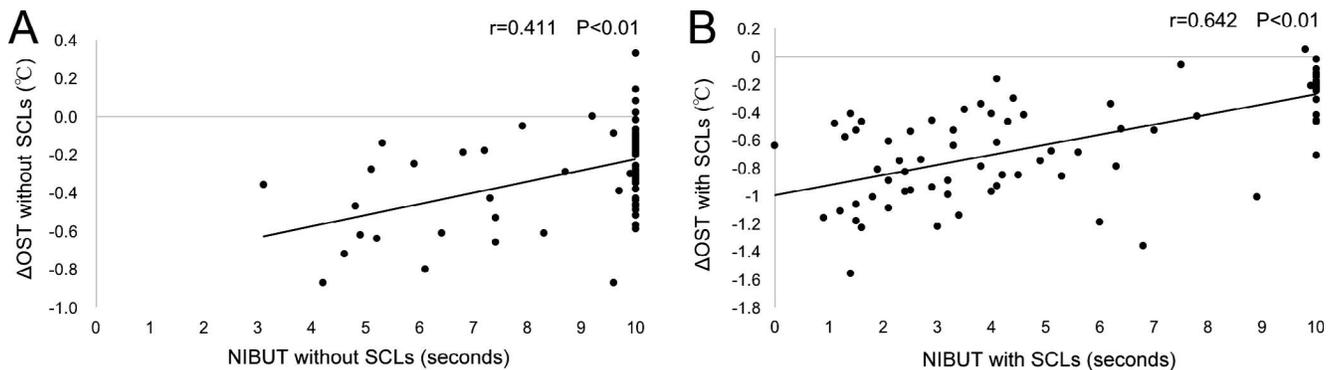

FIGURE 2. Correlation between the ΔOST and NIBUT (A) without SCLs and (B) with SCLs. Positive correlations are seen between the ΔOST and NIBUT (A) at baseline (without SCL; Spearman $r = 0.411$, $P < 0.01$) and (B) during SCL wear (Spearman $r = 0.642$, $P < 0.01$). ΔOST, the difference in OST from 0 to 10 seconds without blinking.
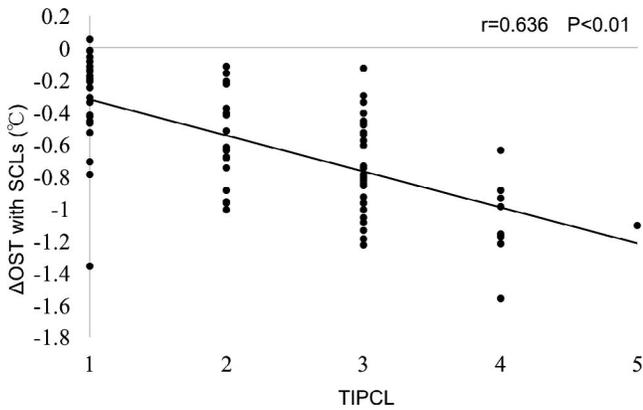
FIGURE 3. Correlation between the ΔOST with SCLs and TIPCL. The ΔOSTs with all SCLs are significantly (Spearman $r = -0.636$, $P < 0.01$) negatively correlated with the TIPCLs.

and Maissa[4] reported that wearing contact lenses significantly induced evaporation of the tear film. Glasson et al.[5] reported that the NIBUT decreased significantly even in subjects who were tolerant of contact lens wear. Regarding OST, Purslow et al.[16] measured OST over SCLs in 2005 and reported that OST decreased dramatically with contact lens wear. However, the relationship between OST and tear film stability over SCLs remains unknown. In the current study, we measured OST and

NIBUT in subjects who tolerated SCL and found that the ΔOST over the SCLs was correlated significantly with the tear film stability, NIBUT, in addition to the correlation between ΔOST and NIBUT without SCLs.

A tear interferometer observes the tear film dynamics in real time noninvasively.[24,25] Yokoi et al.[24] reported that tear interference patterns were highly correlated with dry eye severity. Maruyama et al.[20] classified the TIPCLs for the first time in 2004. Because this classification represents the thickness of the tear film,[20] we can evaluate the tear film stability over SCLs qualitatively in vivo. The current results showed that the ΔOST in all SCLs was associated significantly with the TIPCL. Therefore, we found that the changes in OST over SCLs were correlated highly with the tear film stability both quantitatively (NIBUT) and qualitatively (TIPCL).

We also found that the ΔOST with a water-gradient silicone hydrogel delefilcon A lens was significantly smaller than with the hydrogel lenses, etafilcon A and polymacon. Delefilcon A contains a low (33%) water content core and a higher (80%) water content surface. The aim of this design was to provide high oxygen transmissibility while retaining a wettable surface.[26] Szczesna-Iskander et al.[26,27] used lateral shearing interferometry to measure a tear film surface quality (TFSQ) noninvasively, and reported that silicone hydrogel delefilcon A lens maintained better TFSQ compared with hydrogel nelfilcon A lens. Wolffsohn et al.[28] reported that no significant changes of the surface temperature were found among the three silicon hydrogel lenses, delefilcon A, narafilcon A, and filcon II-3.
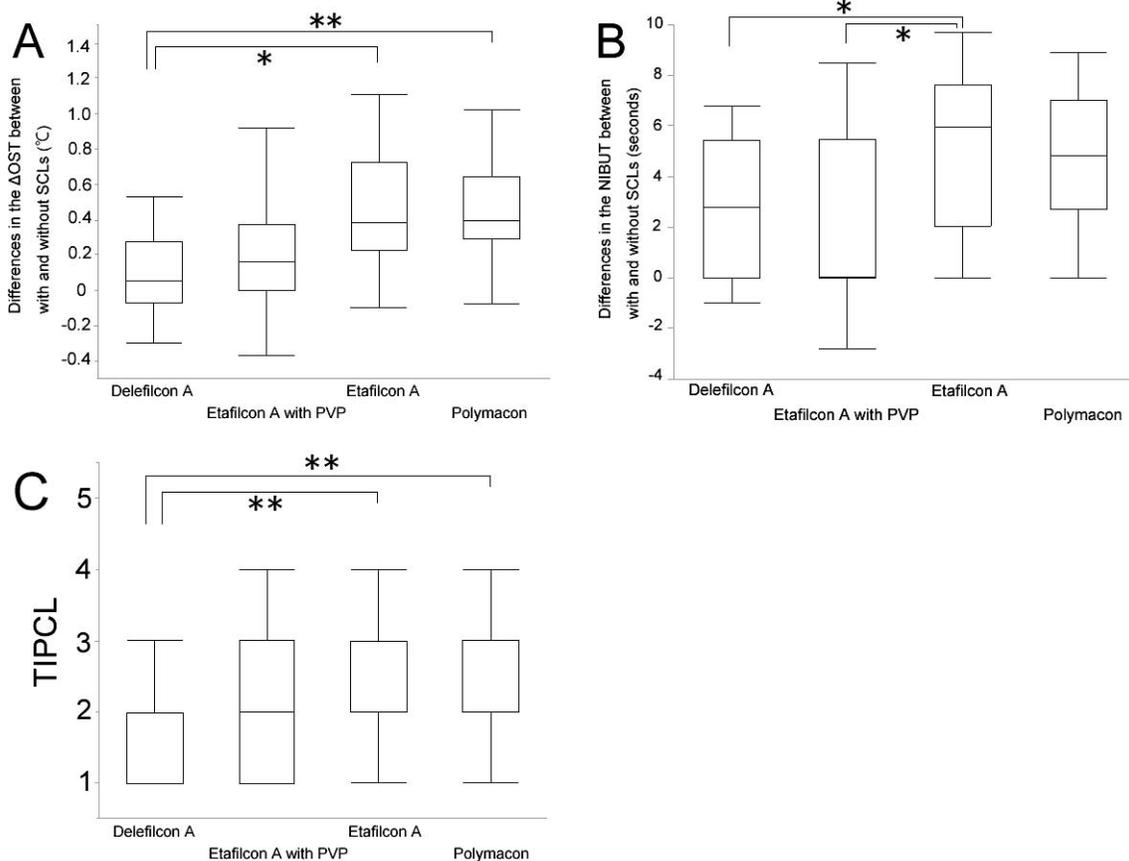

FIGURE 4. Comparison of the differences in the ΔOST and NIBUT between SCL wear and no SCL wear. (**A**) The differences in the ΔOSTs between with and without the delefilcon A lens is significantly smaller than with the etafilcon A and polymacon lenses (*$P < 0.05$ and **$P < 0.01$, respectively, Tukey HSD test). (**B**) The differences in the NIBUTs with the delefilcon A and etafilcon A with PVP lenses are significantly smaller than with the etafilcon A lens (*$P < 0.05$ for both comparisons, Tukey HSD test). (**C**) TIPCL grade of the delefilcon A lens was significantly smaller than those of etafilcon A and polymacon (**$P < 0.01$ for both comparisons, Tukey HSD test).

These data and our findings suggested that silicone hydrogel delefilcon A could maintain OST better than conventional hydrogel lenses as well as tear film stability.

The study had several limitations. First, the number of subjects in this study was small. Second, in this study we used only one type of silicone hydrogel lens. We should have included other silicone hydrogel lenses to compare with hydrogel lenses. Third, we measured the NIBUT up to 10 seconds to avoid reflective secretion of tear fluid. Therefore, in the subjects with no break-up of the tear film for 10 seconds, the NIBUT was recorded as 10 seconds. This "10 seconds" did not represent the true tear break-up time for the subjects. Because the thermography we used can measure OST continuously for 10 seconds, we measured NIBUT up to 10 seconds in this study. If we could measure for longer period, the correlation coefficient or *P* value may be changed. Finally, we measured OST or NIBUT after 15 minutes of wearing each SCL. We think the longer wearing SCLs before the measurement, the more adjusting the SCLs to the subjects' ocular surface. Because of time limitations, we measured OST or NIBUT after 15 minutes of wearing each SCL. A longer wearing period might have affected the value of OST or NIBUT.

In conclusion, we found that the changes in OST over SCLs were correlated with the tear film stability. OST measurements can be used to evaluate the tear film stability in contact lens wearers.

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